Childhood Cancer Survivor Study

Coordinating Center

Standard Operating Procedures Manual

Reviewed 10/1/2020

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Childhood Cancer Survivors Study Coordinating Center

Standard Operating Procedures Manual

Introduction

Overview

The Standard Operating Procedures (SOPs) Manual documents and describes regularly recurring work processes associated with the Childhood Cancer Survivors Study (CCSS). The procedures were written to cover standard and routine processes. Undoubtedly there will be occasions where case-by-case decisions need to be made to address specific situations or emergent questions. If questions arise or if a written procedure does not seem to adequately address a task, seek guidance from a supervisor.

Procedure Structure

In general, each procedure begins with background or contextual information, if applicable, to help frame the task. The procedure that follows is written in a step-by-step manner. Document control information, such as version and revision date, can be found in the header of the procedure. Additionally, a revision record documenting who wrote/edited the procedure and the date on which the procedure was revised can be found on the last page of each procedure.

Procedures Revisions

This manual is intended to be a dynamic resource where procedures are added, updated, and inactivated as needed. Submit suggestions for adding new procedures or revising existing procedures to a supervisor.

All procedures in the manual are available in the CCSS SOP Library database which is accessible through SharePoint at http://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx. The CCSS SOP Library provides electronic access to the most recent version of each procedure and includes reports listing new procedures as well as those which may have been recently updated.

About the Childhood Cancer Survivors Study

The Childhood Cancer Survivor Study (CCSS) is a collaborative, multi-institutional study of individuals who survived five or more years after a qualifying diagnosis of childhood cancer, leukemia, tumor, or similar illness. The project is funded as a resource by the National Cancer Institute.

CCSS Quick Facts

What are some of the main goals of the study?

1. Examine the long-term effects of childhood cancer, leukemia, tumor, or similar illness
2. Determine which groups of survivors are at higher risk for future problems
3. Provide information about long-term outcomes to help inform current treatment of cancer and to develop interventions and screening recommendations for survivors

How many people are in the study?

The CCSS is a multi-institutional, collaborative cohort study initiated in 1994, which has successfully established and followed a cohort of 24,368 five-year survivors of childhood cancer diagnosed between 1970 and 1999 and a population of sibling controls. The cohort, derived through 31 original participating clinical centers, has collected detailed information on cancer diagnosis, therapy received along with health-related long-term outcomes. Additionally, over 5,000 siblings have been recruited to the study as a comparison group.

What diagnoses are included are included in the study?

> Qualifying diagnoses include childhood leukemia, central nervous system tumor, Hodgkin's disease, non-Hodgkin's lymphoma, kidney tumor, neuroblastoma, soft tissue sarcoma, and bone tumor.

Which institutions participate in this study?

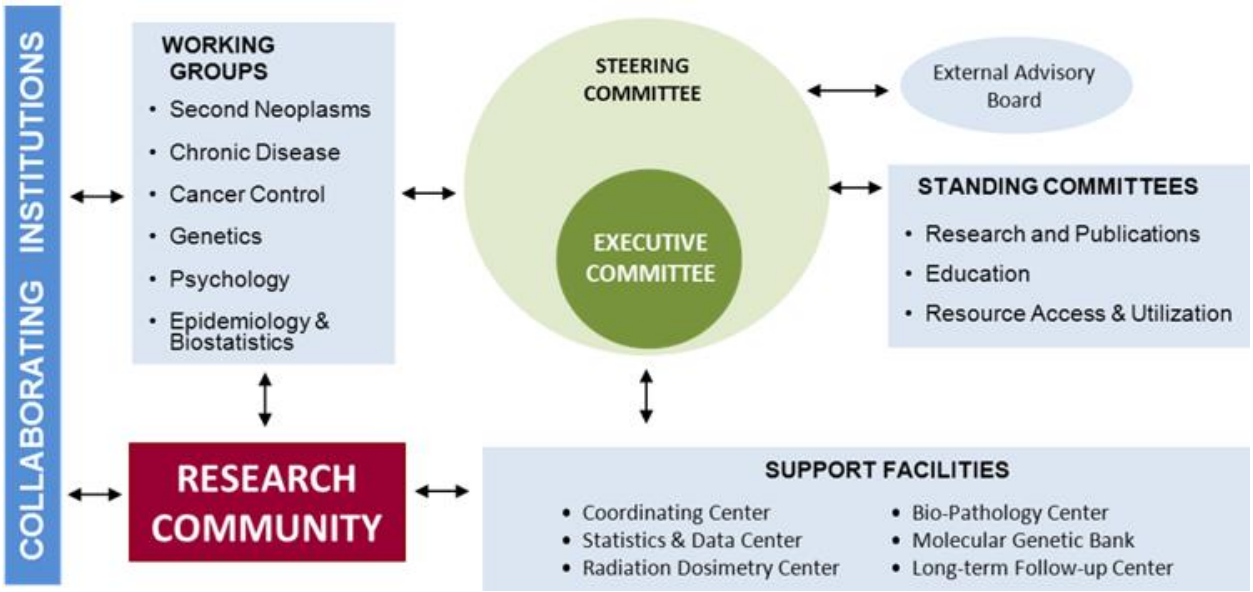
University Of Minnesota	Seattle Children's Hospital	Riley Hospital – Indiana Univ.
Children's Hospital of Colorado	Toronto Hospital for Sick Children	Univ. of Alabama (UAB)/ Children's Hospital of Alabama
Children's Hospital of Pittsburgh	St. Jude Children's Research Hospital	Mott Children's Hospital – University Of Michigan
Children's Hospital at Stanford	Nationwide Children's Hospital	UT Southwestern Medical Center
Dana-Farber Cancer Inst./Children's Hospital of Boston	Roswell Park Cancer Institute	Texas Children's Hospital
Emory University	Mayo Clinic	City of Hope
Children's National Medical Center DC	Children's Hospital and Clinics of Minnesota	Children's Hospital Orange County
UTMD Anderson Cancer Center	Children's Hospital of Philadelphia	University of Chicago Comer Children's Hospital
Memorial Sloan Kettering	St. Louis Children's Hospital	Lurie Children's Hospital of Chicago
Univ. California at San Francisco	Children's Hospital of Los Angeles	Cook Children's Hospital
UCLA Med Center/ Miller's Children's		

What is the difference between the Childhood Cancer Survivors Study and the Long Term Follow-Up (LTFU) Study?

Just the names. The research community knows the study as CCSS, and the survivor/participant community knows it as the LTFU Study.

What is the organizational structure of the study?

The diagram below shows the overall structure.



Who manages the day-to-day activities of the study?

The CCSS Coordinating Center – See the next section for details.

CCSS Coordinating Center

The CCSS Coordinating Center is housed within the Department of Epidemiology and Cancer Control at St. Jude Children's Research Hospital. Some of the key responsibilities addressed by the Coordinating Center are as follows:

Cohort Maintenance
- Maintain current addresses and participant information
- Trace subjects lost to follow-up; track refusals and deaths
- Manage subjects' participation in ancillary studies

Questionnaire Production and Processing
- Design and layout questionnaires; configure online versions and data exports
- Batch, print, and send questionnaires
- Receive questionnaires; edit for completeness and record refusals
- Assign subjects for tracing and/or to interviewers for completion by telephone
- Code drugs, medical procedures, and occupations from questionnaires
- Scan and verify questionnaires; export data to MS Access, images to Alchemy
- Create SAS datasets from exported data and run error-checking routines
- Forward datasets to Statistical Center for further error checks and analyses

Participant Contact and Education
- Staff the study toll-free line and answer email – provide information, referrals, patient education
- Maintain the LTFU Study web page, external links
- Produce the LTFU newsletter (two or more times yearly)

Biologic Samples Tracking
- Select eligible subjects
- Send contact letters and consents
- Coordinate efforts of blood collection subcontractors
- Mail, track, and receive Oragene kits

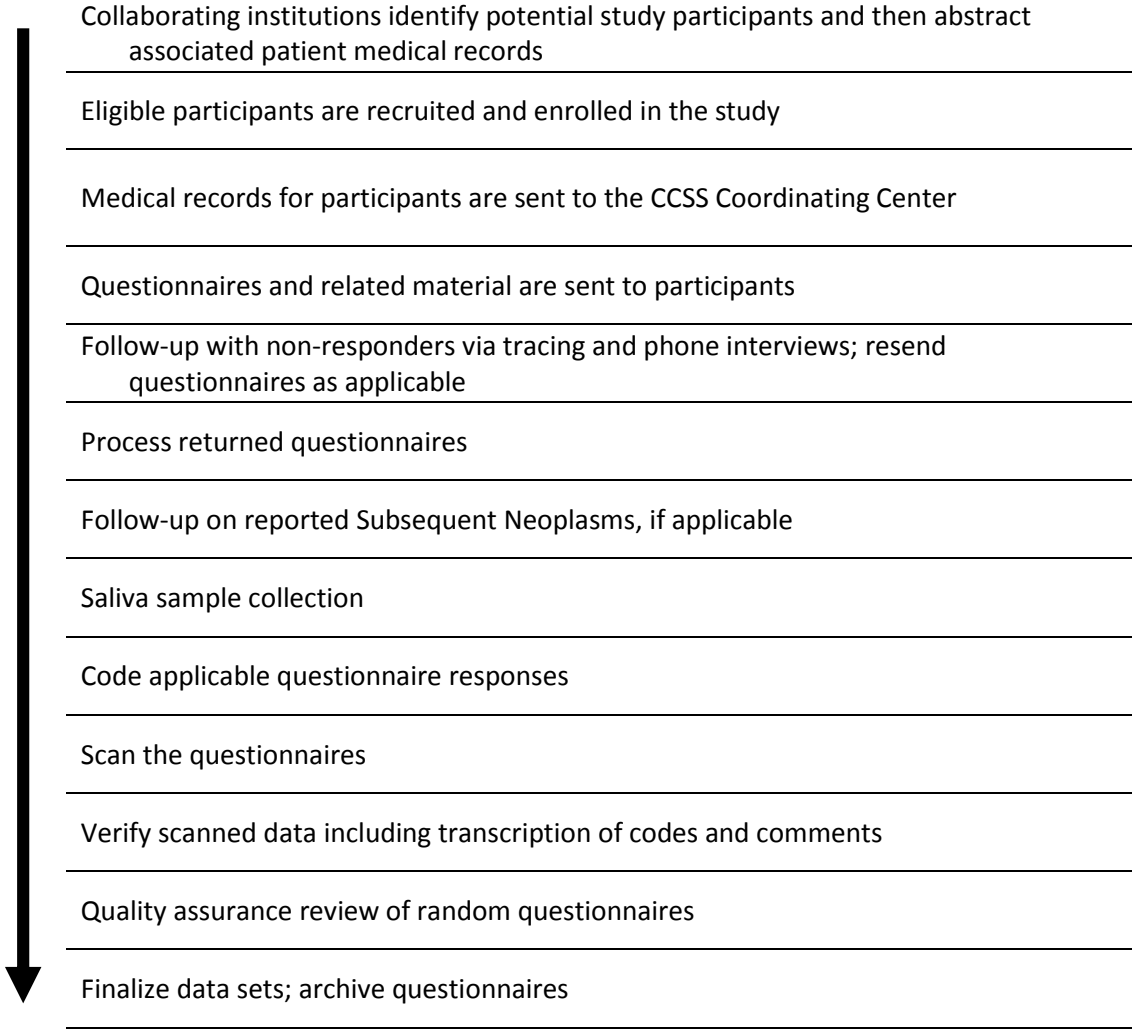
Subsequent Neoplasm Tracking
- Record SN/recurrence data
- Obtain pathology reports from treating hospitals
- Forward pathology reports to CCSS Biopathology lab
- Enter verified SN/recurrence information in MS Access database

Investigator/Collaborating Institution Services
- Maintain CCSS web page
- Plan and schedule meetings; create meeting books
- Maintain file for each collaborating institution for IRB approvals/renewals, site-specific letters and consents

CCSS Data Collection Process

An overview of the CCSS process is provided below. There are two important items of note:

1. There are many details excluded from this "big picture" overview.
2. Some of the categories are not as distinct as they appear. There is overlap between several categories.



Revision Record

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Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development
2.0	5/21/12	J. Bates	Exported to stand-along document
2.1	7/20/12	J. Bates	Update location of manual to SharePoint
2.2	11/30/15	R. Massey, J. Ford	Title update, formatting l
2.3	12/8/15	A. McDonald	Content update

Accessing Records in Alchemy

Background

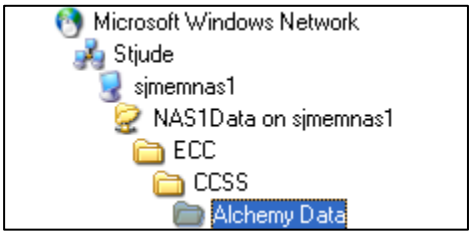
As questionnaires and prior MRAF records are scanned, a file with an image of the questionnaire is created. These files are stored in a program called Alchemy. If a questionnaire needs to be viewed, then the scanned image can be accessed instead of the filed hardcopy. This is useful for older questionnaires that have been archived.

Procedure

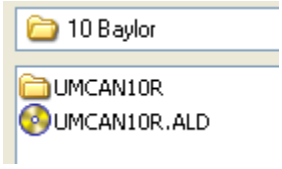
1. Open Alchemy
    a. Start/Programs/Alchemy/Search
2. Right click on "Databases" folder in upper left hand corner
3. Open Database
4. Click the Browse button. Choose File System
    a. Z:/Archive/ECC/CCSS/Alchemy Data/(MRAF or applicable Survey/data source)
5. Choose the file that looks like a disk (icon)
6. Data storage/organization varies by instrument/data source
    a. Ex: Case Baseline is housed by institution and then participant 5-digit unique
    b. Ex: FU2 is Sequence number, but can search for CCSSID in this one
    c. MRAF is stored by institution and then unique 5 digit ID for each participant (a portion of the CCSSID)

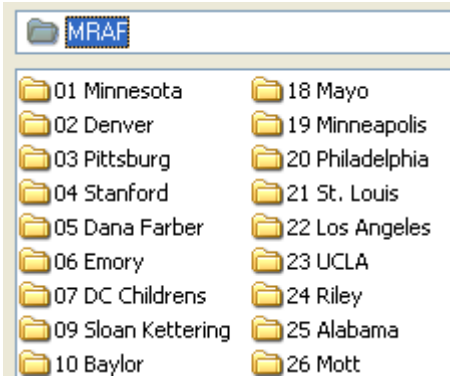
Special Function: Printing historical MRAF forms from Alchemy

1. Open Alchemy (software)
2. Open the appropriate database
    a. Right-click Databases folder in left menu panel.
    b. In the Open Database dialog box, click Browse….
    c. Then pick File System…
    d. Browse to ECC/CCSS/AlchemyData

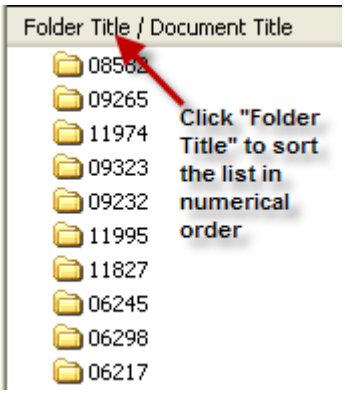


3. From Alchemy Data, double-click MRAF. This displays contents of the MRAF folder.
4. In MRAF, locate the folder for the appropriate institution. Double-click the institution folder to open it.
5. In the institution folder, double-click the disk icon (not the folder) to display a list of individual cases from that institution.

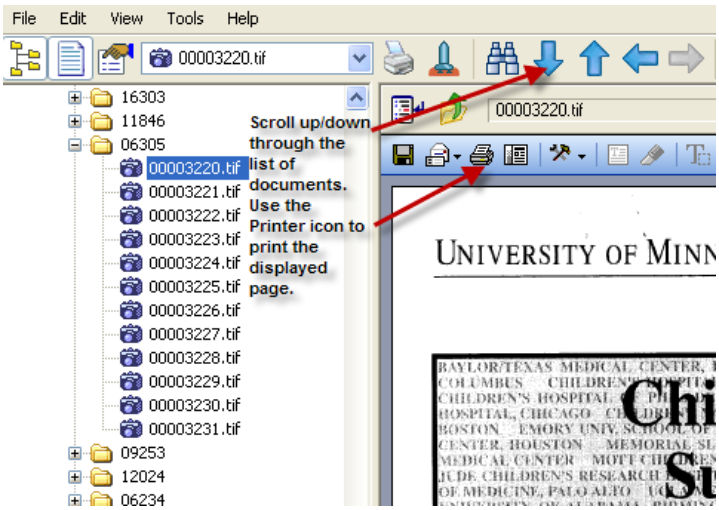




6. Cases are in folders listed by their 5-digit case number.
7. Sort the folder list of cases by case number.
8. Locate, then open the folder for the needed case number. The case number corresponds to digits 3-7 of the CCSSID.
9. The case folder will contain a list of Tif files (one or many).



10. Double-click the file name to open the tif file.
11. Print the document.
12. Continue through the list of tif files, opening and printing. (The blue down-arrow is helpful for moving through the list of tifs.)



Revision Record

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Revision No.	Date	Responsible Author	Change Description
1	6/2/09	A. McDonald	Initial Development for Manual
1.1	9/25/09	J. Bates	Add printing MRAF illustrated steps
1.3	1/24/10	J.Bates	Style formatting
1.4	9/27/12	J.Bates	Path to alchemy files

Addressing Print Quality for Copier 1 and 2

Background

When an issue arises on Copier 1 or 2 with the coloration of surveys, charts, etc., a test page can be printed in order to determine if the Cyan, Magenta, Yellow, or Black imaging unit(s) needs to be replaced. If a unit is depleted, then a service call must be placed (see *Color Copiers and Laser Printer and Supply and Service* procedure) as these units should not be replaced by St. Jude personnel. The following procedure applies to Copier 1 and 2.

Procedures

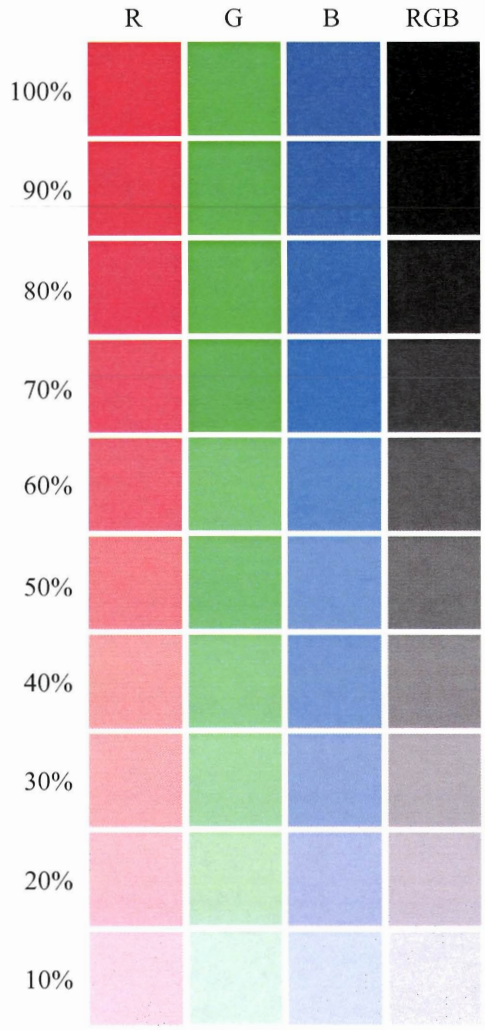
1. **Menu.**
2. **Utility.**
3. **User Settings**.
4. **Printer Setting**.
5. **Print Reports**.
6. **Demo Page** (the paper size should default to 8.5 x 11).
7. Press the start button (this should print the test page).
8. Push the reset button after the page has printed.
9. Visually inspect the printed Test Page to determine if any of the four circular, colored images are poor.
    a. See examples below of GOOD and POOR print quality (attachment).
10. Check supply room for imaging unit for the color of interest.
    b. If we do not have one in stock, then you will need to order the imaging unit when you schedule a service call.
    c. If we do have one, then just place the service call.
        i. Note - Both copiers use the same imaging units.
11. Schedule a service call.
    d. See *Color Copiers and Laser Printer and Supply and Service* procedure.
    e. If we do not have the imagining unit of interest in the storage room, then don't forget to order the imaging unit when you schedule a service call.

Revision Record Printed 1/21/2015 11:54 AM

270 Current Filename:		Addressing Print Quality for Copier 1 and 2 ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	5/27/2014	J. Ford	Initial Development
1.1	1/15/2015	J. Ford	Revised Sequence

Example of GOOD print quality

Test Page



CYAN

MAGENTA

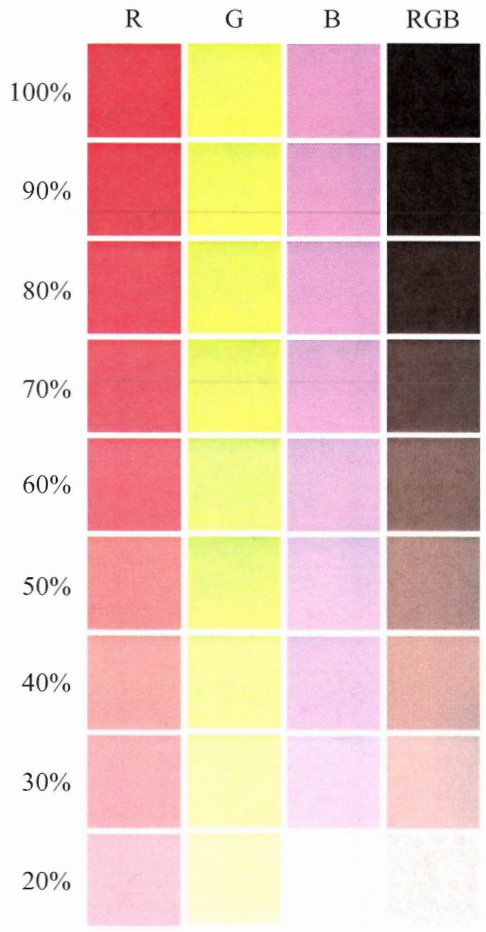
YELLOW

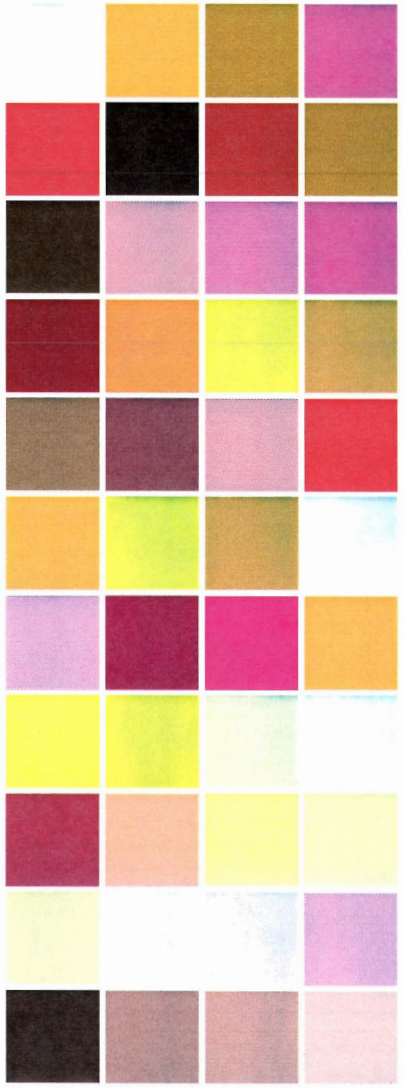
BLACK

The quick brown fox jumps over the lazy dog.
The quick brown fox jumps over the lazy dog .
The quick brown fox jumps over the lazy dog.
The quick brown fox jumps over the lazy dog.
The quick brown fox jumps over the lazy dog.
The quick brown fox jumps over the lazy dog
The quick brown fox jumps over the laz
The quick brown fox jumps over th
The quick brown fox jumps ove
The quick brown fox jump

Test Page

Example of POOR print quality





CYAN

MAGENTA

YELLOW

BLACK

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The quick brown fox jumps over the lazy dog.
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The quick brown fox jumps over the lazy dog
The quick brown fox jumps over the laz
The quick brown fox jumps over th
The quick brown fox jumps ove
The quick brown fox jump

Adjusting Spanish Status in Expansion Database

Background

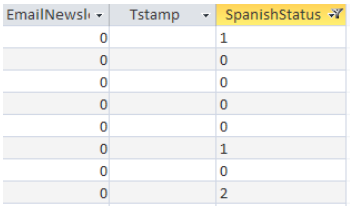
Spanish Status is a variable in the Expansion Tracking and Recruitment databases that indicates whether a case or sibling needs to have materials in Spanish. The Spanish Status codes are "0" for English only, "1" for participants requiring Spanish, "2" to indicate both English and Spanish languages are available, and "3" to indicate Spanish is not required but is preferred. When a record has a Spanish Status of 1, we will not mail the printed baseline survey which is only available in English. If we learn that a case or sibling we *thought* needed Spanish does, in fact, speak English (and thus does NOT NEED to have the survey facilitated by a Spanish-speaking interviewer), we must update the case/sibling's Spanish Status. Only the Lead CRA or Lead SI process Spanish Status updates for cases; Survey Interviewers update Spanish Status values for siblings. (For procedures to post the initial Spanish Status in the Recruitment database, see the SOPs **Data Entry Process for Verbal HIPAA Authorizations** and **Processing Returned Spanish Authorizations** in the SOP Library.)

Procedures

Updating Spanish Status for Cases (blue records)

IMPORTANT: Updates to the **Spanish Status** field for cases is done by the Lead SI or Lead CRA only.

1. Locate the blue case record in the Expansion Tracking database after choosing the Cases option on the main switchboard.
2. Document the change in the **Comments** field on the Quest tab:
    a. Add a dated note with your SI ID or initials explaining the change.
    b. Example: "9/25/2012: Changed Spanish Status from 1 to 0 based on SI information: case does NOT speak Spanish. [89]"
    c. Move to the next record in the database.
3. Open the table tblBaselineTrackingInfo.
    a. Locate the record for the case by CCSSID.
    b. To avoid losing your place, filter the table to show ONLY THAT RECORD.
    c. Tab or scroll to the column for **SpanishStatus** and enter the correct value. (**SpanishStatus** is currently the rightmost column in the table).



EmailNewsl	Tstamp	SpanishStatus
0		1
0		0
0		0
0		0
0		0
0		1
0		0
0		2

    d. The following are the valid codes for **SpanishStatus**:
        i. 0: English
        ii. 1: Spanish Only
        iii. 2: Both English and Spanish
        iv. 3: Spanish Preferred
    e. Release the filter on the table, and move to the PREVIOUS record.
    f. Close the table.
4. Return to the CCSS_ET Main Data Entry tab and search for the case.
5. Use the Refresh button (not Refresh All) to refresh the values being displayed. Your CORRECTED value for **Spanish Status** should now be displayed.

Survey Interviewer, Lead SI, Lead CRA

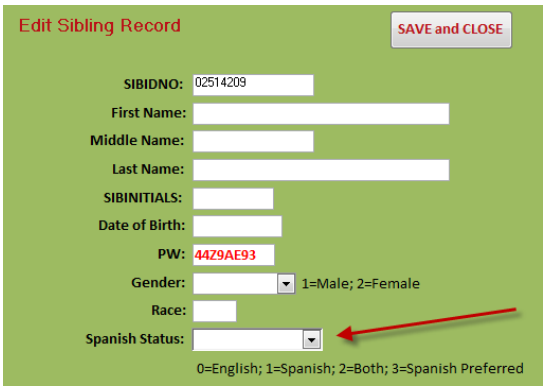
Updating Spanish Status for Siblings (green records)

NOTE: Survey Interviewers may update the Spanish Status field for sibling participants without assistance from the Lead SI or the Lead CRA.

1. Locate the green sibling record for the SIBIDNO in question:
   a. Open the Expansion Tracking database.
   b. Choose the Siblings option on the main switchboard.
   c. Use the Find feature of MS Access to search for the sibling record in question.
   d. Confirm in the Header fields that you have found the correct record.

2. Click the **Edit Header** button in the upper right-hand corner of the record.

3. In the Edit Sibling Record screen, use the drop-down menu in the Spanish Status field to select the appropriate Spanish Status for the participant. Note the available codes:
   a. **0** indicates English only
   b. **1** indicates Spanish only (meaning the participant MUST complete the sibling survey on the telephone with a Spanish-speaking interviewer)
   c. **2** indicates both English and Spanish are available
   d. **3** indicates that the participant speaks both English and Spanish but Spanish is preferred (meaning the participant should be contacted by a Spanish-speaking interviewer)



4. Click the **Save and Close** button.

5. Document the change in the **Comments** field on the Sib Info tab:
   a. Add a dated note with your SI ID or initials explaining the change.
   b. Example: "9/25/2012: Changed Spanish Status from 1 to 0 based on SI information: sibling does NOT speak Spanish. [89]"

6. Move to the next record in the database, then move back to the sibling record in question.

Revision Record Printed 10/17/2013 10:43 AM

Current Filename:		Adjusting Spanish Status in Expansion ver 2_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	10/11/12	J.Bates	Initial Development
2.0	10/9/13	R. Massey, L. Harrison, J. Ford	Add Spanish Status 3, modify audience, add sibling instructions.

Age of Majority-Identifying Re-consent Needed

Background

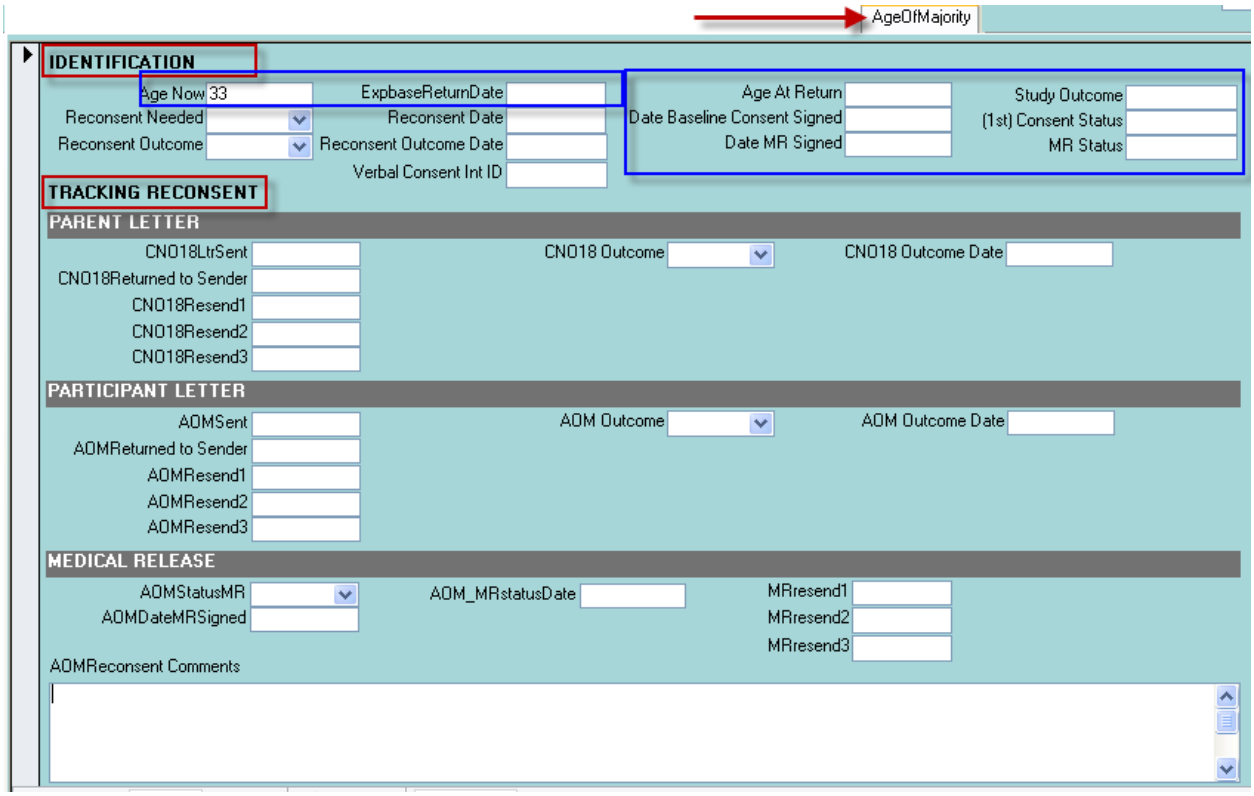
We need to re-consent cases consented to the study while a minor, once they attain the age of majority. We display whether or not a study participant may need to be re-consented to the study on the **AgeOfMajority** tab, in the top IDENTIFICATION section (in the **ReconsentNeeded** field). Each morning, the CRA2 checks all cases and updates ReconsentNeeded as needed. This accommodates newly in-processed surveys, people who just turned 18, and a few other unique situations. If the ReconsentNeeded field is not blank, it will display YES, NO, or NotYet. This document explains what those ReconsentNeeded values mean.

Procedures

The AgeOfMajority tab has two sections: **IDENTIFICATION** and **TRACKING RECONSENT.**

1. The **IDENTIFICATION** section displays whether reconsent is/was needed, reconsent outcome and date, reconsent date, and Interviewer ID for verbal reconsent. The IDENTIFICATION section also displays information from other tabs for quick reference [e.g., Age Now (calculated), ExpbaseReturnDate, Age At Return (calculated), Date Baseline Consent Signed, Date MR Signed, Study Outcome, 1st Consent Status, and MR status].

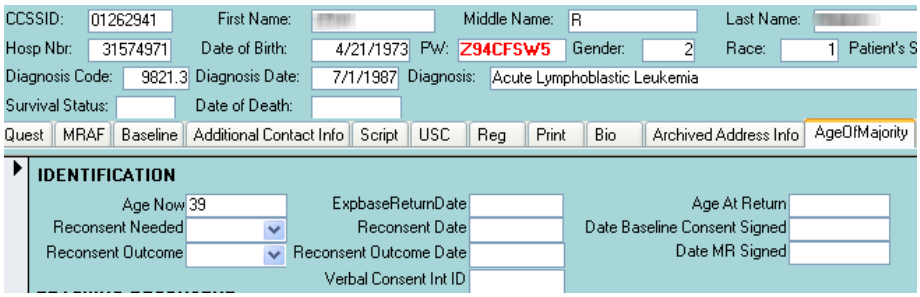
2. The second section, **TRACKING RECONSENT**, is where we log steps taken to obtain a reconsent (documented separately).



UNDERSTANDING "ReconsentNeeded" in the AgeOfMajority Identification Section

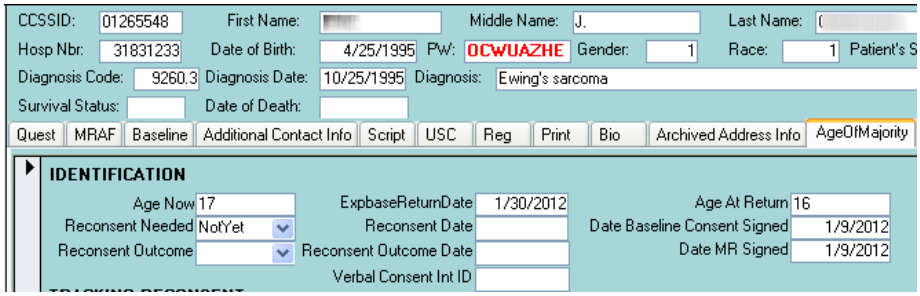
1. Cases where Reconsent Needed is blank:

When ReconsentNeeded is blank, it is because the baseline *survey has not been received.* The case has therefore not yet been consented to the study.



2. Cases where Reconsent Needed is NotYet:

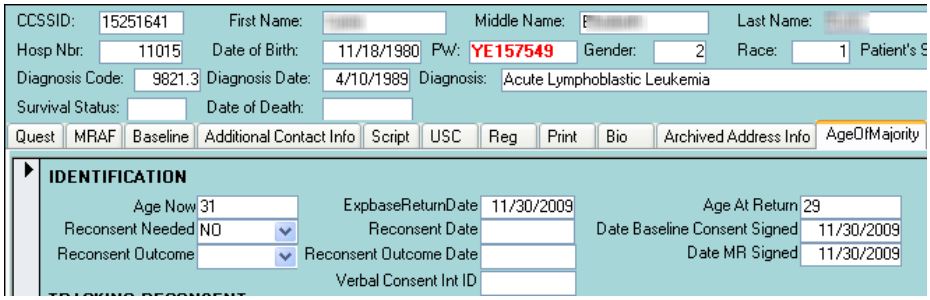
When ReconsentNeeded is NotYet, it is because the case was a minor when consented, and has not yet turned 18.



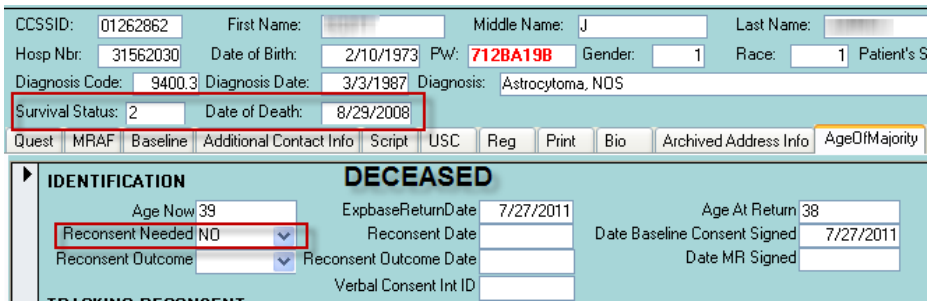
3. Cases where Reconsent Needed is NO:

When ReconsentNeeded is NO, it is for one of two reasons. Either the case was an adult when originally consented, or the case is deceased.

Example 1: Case was an *adult*



Example 2: Case is *DECEASED*.

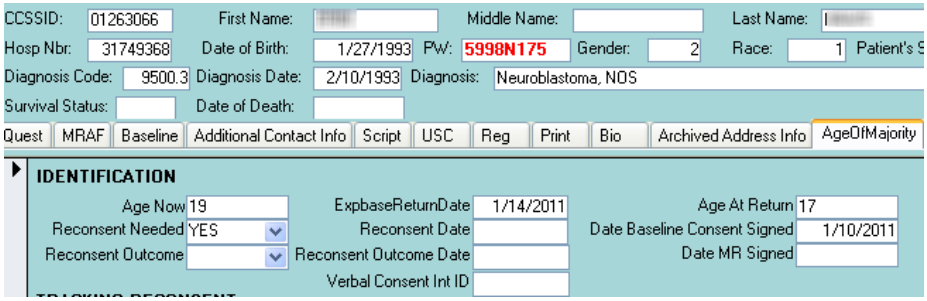


Everyone

4. Cases where Reconsent Needed is YES:

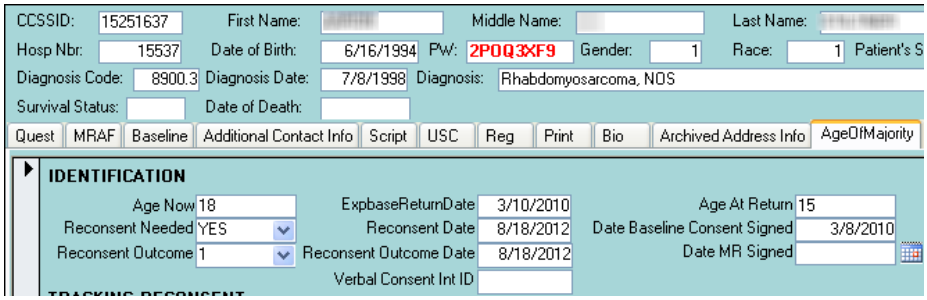
When ReconsentNeeded is "YES", it is because the case DOES (or DID) need to be reconsented because the minor case has become an adult. When we attempt to reconsent these cases, there can be several outcomes. When we have attempted to obtain the reconsent, we record the appropriate **Reconsent Outcome** (and outcome date). Cases where ReconsentNeeded is YES and ReconsentOutcome is blank still need to be reconsented. When there is a ReconsentOutcome on file, no further reconsent effort is needed.

Example 1: case needs to be reconsented (is now over 17). We do not have a ReconsentOutcome yet.



Example 2: case need(ed) to be reconsented (is now over 17), and **HAS been reconsented** (Reconsent Outcome=1).

NOTE: The TRACKING RECONSENT section of the Age Of Majority tab is where we track the actual reconsent actions.



5. **ReconsentOutcomes** are the following:
   - 1=Consented
   - 2=LAR Consented (used when the adult survivor has a guardian)
   - 7=Participant Refused (used when the participant refused to participate, even though her/his parents had consented to the study while s/he was a minor)
   - 10=Ineligible (used for those rare circumstances when we learn new information that indicates the survivor is/was not eligible and thus do NOT pursue the reconsent)
   - 11=ParentalPermissionDenied (used when we ask parents for permission to contact the now-adult survivor in order to obtain consent, but the parents refuse to let us contact the now-adult survivor. It is conceivable at some point that the parental denial may be overridden)
   - 38=Deceased (used when the now-adult survivor dies before we obtain her/his consent)

Revision Record Printed 11/26/2012 12:40 PM

Current Filename:		Age of Majority-Identifying Reconsent Needed ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	8/21/12	J.Bates	Initial Development
1.1	11/26/12	J.Bates	Fix typos

Age of Majority Reconsenting

Background

If a participant was under 18 at the time of recruitment for the Long-Term Follow-Up (LTFU) Study, a parent or a legally authorized representative (LAR) of the individual was invited to participate in the study on behalf of the minor. At the time of enrollment, the LTFU Informed Consent, and in many cases the HIPAA authorization, were provided by the parent or LAR. For living individuals who do not have a LAR (due to, for example, a cognitive or physical disability), those agreements expire when the individual turns 18. Before we collect any new information from these individuals (e.g. follow-up survey), they must be reconsented to the LTFU Study.

Participants eligible for reconsent will be approached for reconsent in preparation for each follow-up survey or applicable ancillary study (e.g. St. Jude Life (SJL) visit, pursuing a blood and/or tissue sample, saliva, etc.). The reconsent process typically begins with a courtesy contact with the parents or former guardian of the now-adult participant to obtain at least tacit permission to contact the individual. An exception to this may occur when the now-adult individual is seen during a SJL visit. If a parent or LAR does not refuse permission to contact the individual, then a special age of majority letter is mailed to the now-adult individual along with the applicable survey and/or study materials.

NOTE: Individuals in need of reconsenting can consent to the LTFU Study via either direct or implied consent. Examples of direct consent include a) verbal reconsent with an SI, b) signing and returning a HIPAA authorization, c) signing an ancillary study-specific consent. An example of implied consent would be completing a follow-up or ancillary study survey but not signing the consent form or HIPAA authorization.

Procedure

AOM Tracking

Currently, the FU5 TRACKING tab in the CCSS Follow-Up Survey Tracking database displays information related to Age of Majority (AOM) reconsenting. AOM reconsenting data in the Expansion Tracking database is static and, in general, should be ignored (see the Call Center Coordinator, Lead Survey Interviewers (LSIs), or project coordinators for more information).

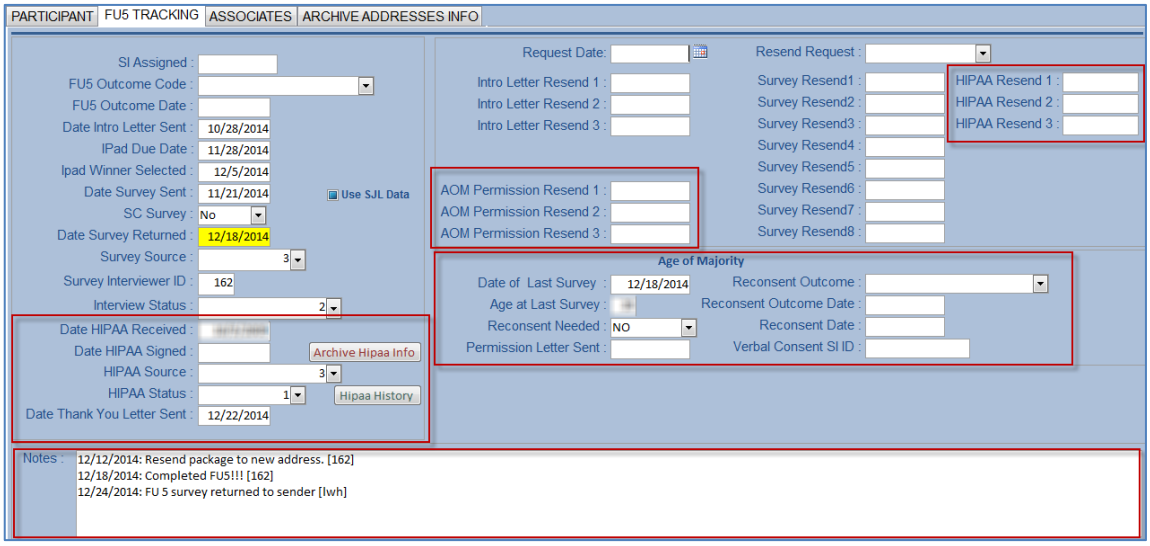
In the Age of Majority group:

1. **Date of Last Survey** – For reference only, displays the date of the last completed survey.
2. **Age at Last Survey** – For reference only, displays the participant's age at the time of the last completed survey.
3. **Reconsent Needed** – Indicates whether reconsent was ever needed. See the section of this document titled *Identifying Participants for Reconsenting* for details.
4. **Permission Letter Sent** – Indicates the date a letter was sent to the parents or LAR requesting permission to contact the participant regarding the LTFU Study.
5. **Reconsent Outcome** – Indicates that the reconsent process is resolved and displays the outcome of that process.
6. **Reconsent Outcome Date** – Indicates the date the reconsent outcome is recorded in the **Reconsent Outcome** field.

Everyone

7. **Reconsent Date** – For now-adult participants that have been successfully reconsented, indicates the date of the reconsenting.

   Verbal Consent SI ID – For now-adult participants that have been successfully reconsented via telephone, indicates the ID of the Survey Interviewer (SI) that completed the reconsent process.
8. **AOM Permission Resend #** - Indicates dates the parent/LAR permission letter was resent.
9. Notes – Contains notes related to the FU5 survey and AOM reconsenting.



Identifying Participants for Reconsenting

1. A process is run in the LTFU Participants database (mcrAOMReconsent) each weekday morning to identify individuals who need reconsenting. The procedure:
   A. Inspects survey return dates
   B. Returns individuals who recently reached the age of majority
   C. Screens for refusals, deceased, and ineligible cases
   D. Updates each identified individual's **Reconsent Needed** field as either *No*, *Yes*, or *NotYet*. (See coding table below).
      i. To determine the need to reconsent an individual, the process examines two ages: the current age (based on birthdate) and the consent age (in most cases, based on the date the baseline survey was received).
      ii. Consent Date – The **Date Survey Returned** value is used as the standard proxy for the consent date. There is always a **Date Survey Returned** value, whereas the date consent signed may be missing or obviously erroneous (e.g. participant wrote in a birth date or a future date).
      iii. 17-18 Exception – Individuals who were 18 by the time we received the survey but were only 17 when consent form was signed by a parent/legal guardian are identified, because those individuals need to be reconsented. In these instances, **Reconsent Needed** is manually changed from NO to YES, and the modification is documented in the notes. This is the one exception when **Reconsent Needed** automatically set to NO is manually changed to YES.
      iv. Refusal While a Minor – At this time, prior parental refusal for a minor to participate in the LTFU Study precludes the individual from being reconsented at age 18.

Everyone

What does Reconsent Needed mean and when does it change?

Reconsent Needed = blank when we have NOT received a baseline survey. When **Reconsent Needed** is blank, the morning reconsenting macro examines it to see whether it is time to change it. The decision to change the field is based on the following.

Reconsent Needed will be changed to ….. when……

NO	**Not Yet**	**YES**
• We receive baseline survey on behalf of a DECEASED case. *OR* • We receive baseline survey from a living case who was a MINOR at the time of consent, is now 18, but his/her parent/LAR refused all else prior to the participant turning 18. *OR* • We receive baseline survey from a living case who was an ADULT at the time of consent. *OR* • We HAVE NOT received baseline survey BUT case/LAR explicitly refused all else after having signed the initial institutional/recruitment HIPAA form. **NOTES:** When **Reconsent Needed** = NO, • It does NOT change again. (**See 17-18 Exception.) • **Reconsent Outcome** remains blank.	• We receive baseline survey for a living case who was a MINOR at the time of consent, who has not yet turned 18. **NOTES:** When **Reconsent Needed** = Not Yet, the reconsenting macro WILL re-evaluate **Reconsent Needed** when the case turns 18 (and change to YES or NO).	• Someone from whom we received a baseline survey/consent when they were a MINOR has now become an ADULT. *OR* • Although we received the baseline survey when the person was an ADULT, consent was dated before the person turned 18. (In this situation, we override the "NO" in **Reconsent Needed**, changing it to "YES.") **NOTES:** When **Reconsent Needed** =YES, it does NOT change again, even after reconsent is obtained. Always examine **Reconsent Outcome.** SEE BELOW.

2. When **Reconsent Needed** is YES, refer to **Reconsent Outcome** to determine the current status of the reconsent:
   A. **Reconsent Outcome** will remain blank until a reconsent outcome is obtained.
   B. When a reconsent outcome is obtained, the **Reconsent Outcome** code and **Reconsent Outcome Date** are manually posted. The **Reconsent Needed** field will remain YES to represent the fact that reconsent was needed. The code values for **Reconsent Outcome** are:
      i. 1-Consented
      ii. 2-LAR
      iii. 7-Participant Refused
      iv. 10-Ineligible
      v. 11-Parental Permission Denied
      vi. 38-Deceased

Parent Permission Letter Procedures

NOTE: The tblAgeOfMajority table and related queries refer to the parent permission letter as "CNO18" (Child Now Over 18) as this was the nomenclature used in the IRB document approval. In fact, the child is now over ***17*** (i.e. is now 18 or older). The acronym CNO18 is too deeply embedded in the database to change query/field names to CNO17. Forms, however, refer to these items as "CNO17."

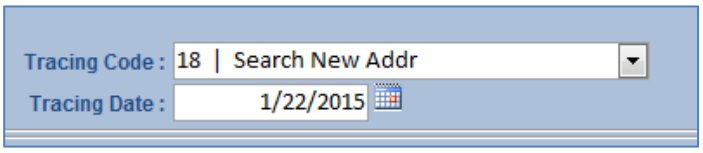
1. In preparation for recruitment for each follow-up survey or applicable ancillary study, project coordinators will identify participants eligible for reconsent. See the applicable project-level SOP for more information.

Everyone

2. If a parent permission letter was previously mailed (See the field **CNO18LtrSent** in tblAgeOfMajority.), proceed to the section of this document titled *Reconsenting Now-Adult Participant – Parent Permission Obtained, Implied, or Not Applicable*, below.
3. If a parent permission letter has never been mailed (See the field **CNO18LtrSent** in tblAgeOfMajority.), the project coordinator of the follow-up survey or applicable ancillary study sends a **parent permission letter to parents/LAR** of children who are now over 17 using the address on file. *NOTE: In general, we do not mail a parent permission letter to Original Cohort participants. This process was previously performed during applicable follow-up/ancillary study recruitment to participants from this cohort.*
   A. The letter a) alerts the parent/guardian to the planned contact with the now-adult, b) gives parents/guardians an opportunity to refuse permission to contact the now-adult, and c) requests an updated address for the now-adult.
   B. A current version of the IRB approved parent letters (**AOM Parent Permission Letter_Merged**) can be found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Follow-Up 5\AOM Parent Letter Mailing*.
4. The project coordinator posts the mailing date in the **Permission Letter Sent** or **AOM Permission Resend #** field, as appropriate, either manually or via an update query to the applicable fields in tblAgeOfMajority.

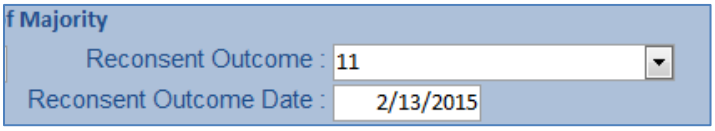
Parent/Guardian Response

1. When the permission letter has **not been returned to sender**:
   A. Parental permission to contact the now-adult participant will be assumed after 14 days of non-response, and we will begin pursuing reconsent of the now-adult.
   B. Proceed to the section of this document titled *Reconsenting Now-Adult Participant – Parent Permission Obtained, Implied, or Not Applicable*.
2. When a parent permission letter is **returned to sender**:
   A. **Tracing Code** (PARTICIPANTS tab in CCSS LTFU Participants database) – See SOPs titled **Notifications from Mail Carrier about Participant Correspondence** and **LTFU Participant Database Data Entry**.
   B. **Tracing Date** (PARTICIPANTS tab in CCSS LTFU Participants database) – Enter the date the returned letter was received.
   C. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Add a dated comment with initials indicating the circumstances.



3. When updated **participant contact information is received**:
   A. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Document receipt of contact information.
   B. Update the database with all confirmed contact information. See SOP titled **LTFU Participant Database Data Entry** for instructions.
   C. Note that parental permission to contact the now-adult (whether explicit or implied) is *not* coded in the **Reconsent Outcome**, **Reconsent Outcome Date**, or **Reconsent Date** fields.
4. When parental/LAR permission is **refused**:
   A. Update the LTFU Participant database with a "Refused All Else" outcome as instructed the SOP titled **LTFU Participant Database Data Entry** or **Processing Refusals: Participants, Proxies, and Associates**.
   B. **Reconsent Outcome** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with 11-Parental Permission Denied.

C. **Reconsent Outcome Date** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with the current date.



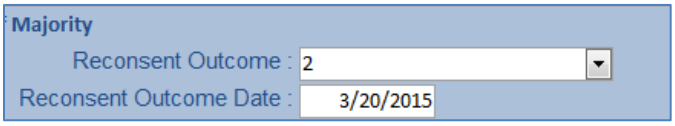
D. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Document refusal with a dated note and SI ID/initials.

E. NOTE: If a divorced or separated parent refuses permission, typically permission from the other parent will *not* be pursued. These should be handled on a case-by-case basis and discussed with the Call Center Coordinator, LSIs, project coordinator, and/or Research Scientist before updating the **Reconsent Outcome** and **Reconsent Outcome Date** fields.

5. When the **adult who originally provided consent advises s/he is the LAR of the now-adult** or when an **adult who did not provide the original consent advises s/he is the now-adult's LAR** (e.g. mother completed baseline survey but is now deceased and father is LAR):

A. Ensure the LTFU Participant database is updated with the LAR status information. See the SOP titled **LTFU Participant Database Data Entry** for instructions.

B. **Reconsent Outcome** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with 2-LAR.



C. **Reconsent Outcome Date** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with the current date.

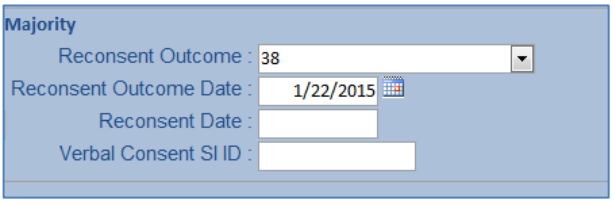
D. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Document the reconsent outcome with a dated note and SI ID/initials.

6. When it is discovered that the **participant is deceased**:

A. Take all appropriate action to update the participant's vital status in the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** or **Updating Databases with Post-Recruitment Death Notices**.

B. **Reconsent Outcome** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with 38-Deceased.

C. **Reconsent Outcome Date** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database – Populate with the current date.



D. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Record a dated note with SI ID or initials explaining the field changes. *Example: 11/22/16: Participant found to be deceased during AOM permission process. Updated Reconsent Outcome from <null> to 38 and Reconsent Outcome Date from <null> to 1/22/2015. [111]*

E. Discontinue pursuit of permission/reconsent as it is not applicable to deceased participants.

Tracing Parents

1. If the now-adult **participant is coincidentally contacted** during parent tracing calls, use the appropriate reconsent script to pursue the reconsent from the participant without having first spoken with or obtained permission from parents.
2. If a Tracer determines the **participant is deceased** while tracing for the parents, s/he should:

A. See instructions, above, for participants found to be deceased during the permission effort.

B. Discontinue tracing but leave the tracing code in place.

Everyone

3. If a Tracer determines that the participant's **parent(s) or LAR are/is deceased**:
    A. If *both* parents are deceased, the SI should:
        i. Take all appropriate action to update each associate's vital status. See the SOP titled **LTFU Participant Database Data Entry** for details.
        ii. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Make a dated note with SI ID documenting the findings. *Example: 4/9/16: Both parents discovered to be deceased during trace for AOM permission letter. [63]*
        iii. Email the findings to the Call Center Coordinator, the LSIs, and the project coordinator. Include the participant ID in both the subject line and body of the email.
        iv. Trace the now-adult participant since delivery to the parent address previously failed.
    B. If *only one* parent is deceased, the SI should:
        i. Take all appropriate action to update the associate's vital status. See the SOP titled **LTFU Participant Database Data Entry** for details.
        ii. Trace for the other parent. Permission *will* be sought from the surviving parent.
4. If all **parent tracing efforts fail**:
    A. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Make a dated note with SI ID documenting this outcome. *Example: 4/9/15: Unable to successfully trace either parent for AOM permission letter. [63]*
    B. Email the findings to the Call Center Coordinator, the LSIs, and the project coordinator requesting approval to proceed with tracing the now-adult participant. Include the participant ID in both the subject line and body of the email.
    C. If approval is provided, trace the now-adult participant.
    D. If approval is denied, update appropriate database fields.
    E. Data entry and next steps will depend on the requested course of action by the Call Center Coordinator, the LSIs, and/or the project coordinator.
5. When **parent/guardian tracing succeeds**, the SI will request verbal permission to contact now-adult participant.
    A. If a reconsent outcome (e.g. now-adult has an LAR) is determined during the call, follow the instructions in the section of this document titled *Parent/Guardian Response*, above.
    B. If permission to contact the now-adult participant is granted:
        i. Request contact information for the now-adult.
        ii. Follow the instructions for contact information gained in the section of this document titled *Parent/Guardian Response*, above.
    C. If parent/guardian requests a resend of the mailed information:
        i. Update the LTFU Participant database with the new contact information. See the SOP titled **LTFU Participant Database Data Entry**.
        ii. **Tracing Code** and **Tracing Date** fields (PARTICIPANTS tab in CCSS LTFU Participants database) – Update as instructed in the SOP titled **LTFU Participant Database Data Entry**.
        iii. **Resend Request** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with 3-AOM Permission.

        iv. **Request Date** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with the current date.

v. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Enter a dated note with SI ID indicating the field changes on the FU5 TRACKING tab. *Example: 4/4/2016: New parent address confirmed. Requested resend of AOM Permission letter. [63]*

Resending the Parent Permission Letter

1. Identify Resend Requests (**Resend Request** = 3-AOM Permission). See applicable project-level SOP for more information.
2. Resend the parent permission letter. See applicable project-level SOP for more information.
3. The project coordinator clears the resend request and date and posts the resend date in the **AOM Permission Resend #** field. See applicable project-level SOP for more information.
4. Proceed to **Parent/Guardian Response** section above.

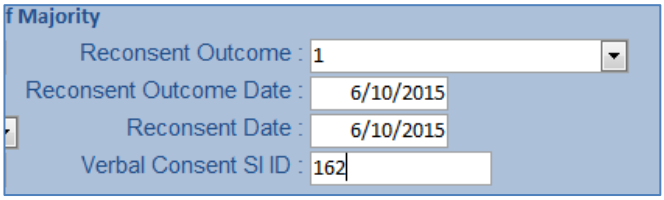
Reconsenting Now-Adult Participant – Parent Permission Obtained, Implied, or Not Applicable

When parental/LAR permission to contact the now-adult participant is obtained, implied (no response to permission letter after 14 days), or not applicable (e.g. when both parents are deceased), the next step in the reconsent process is to contact the now-adult participant.

1. **Identifying Individuals Eligible for AOM Participant Letters** – The project coordinator will identify alive individuals who need reconsent, were mailed a parent permission letter at least 14 days prior to the current date, do not currently have an address-related tracing code, and whose parent/guardian did not refuse permission. See the applicable project-level SOP for more information. *NOTE: In general, we do not mail a parent permission letter to Original Cohort participants. This process was previously performed during applicable follow-up/ancillary study recruitment to participants from this cohort.*
2. **Mailing AOM Participant Letters** – Using the appropriate AOM letter, the project coordinator sends applicable project-level materials to the AOM case and posts the date of the AOM mailing. See the applicable project-level SOP for more information.
   A. Post to tblAgeOfMajority in **AOMSent** or **AOMResend1** - **AOMResend3**. Seek guidance, if needed.
   B. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Enter a dated note indicating for which study the AOM letter was sent.
3. **Received Signed HIPAA, Survey, or Consent** – When a signed HIPAA, completed survey, or signed consent is received, navigate to the FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and:
   A. **Reconsent Outcome** – Enter 1-Consented (if completed by the participant) or 2-LAR (if completed by the LAR).
   B. **Reconsent Outcome Date** – Enter the date received.
   C. **Reconsent Date** – If reconsented, enter the date signed/completed. If the date is clearly out of range (e.g. DOB written instead of date signed), document this in the **Notes** field.
   D. **Notes** – Document the reconsent circumstances with a dated note with initials.
   E. For signed HIPAAs (completed by the participant or LAR):
      i. **Archive Hipaa Info** – If any of the **Date HIPAA Received**, **Date HIPAA Signed**, **HIPAA Source**, and/or **HIPAA Status** fields are populated, click the **Archive Hipaa Info** button.
      ii. **Date HIPAA Received** – Enter the date received.
      iii. **Date HIPAA Signed** – Enter the date signed.
      iv. **HIPAA Source** – Choose the source from the drop-down menu.
      v. **HIPAA Status** – Choose 1-Complete.

Everyone

4. **AOM Participant Letter Non-Responders** – If the participant does not respond to the mailing, the Call Center will pursue verbal reconsent with the participant using the existing call schedule based on days elapsed since the project-level mailing.
   A. If the participant's **parent or LAR denies permission** to speak to the participant, **indicates that the participant is deceased**, or we discover that the participant has a **LAR who wishes to participate** for the participant, see instructions in the section of this document titled *Parent/Guardian Response*, above.
   B. If the participant is reached, the SI will use the appropriate reconsent script to explain the LTFU Study, attempt to obtain verbal consent to the study, and (if reconsented) encourage the participant to participate in the follow-up survey or ancillary study. See the applicable project-level SOP for more information.
      i. **Verbal Reconsent –** If verbal reconsent is obtained, the SI will go to the FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and:
         a. **Reconsent Outcome –** Populate with 1-Consented.
         b. **Reconsent Outcome Date** – Populate with the current date.
         c. **Reconsent Date** – Populate with the current date.
         d. **Verbal Consent SI ID** – Populate with the SI ID.
         e. **Notes** – Document the verbal reconsent in a dated note with SI ID.

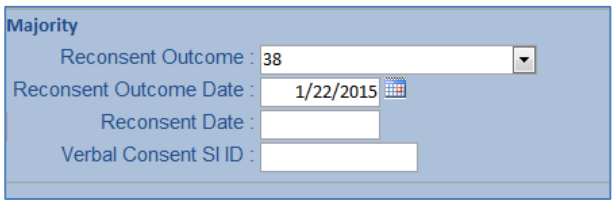


      ii. **Resend** – If the participant requests a resend of the AOM Letter and/or study-specific materials, the SI will go to the applicable study database and:
         a. **Notes** – Add a dated note with SI ID documenting the request.
         b. Proceed with requesting study-specific materials. See the applicable project-level SOP for more information.
      iii. For refusals, deceased, or ineligible outcomes, see below.
5. **Participant Refusal** – If the now-adult participant *actively* declines participation in the LTFU Study (Passive non-responders are still eligible for participation and are *not* recorded as refusals.):
   A. Document the "Refused All Else" outcome in the LTFU Participant database as instructed in the SOP titled **LTFU Participant Database Data Entry** or **Processing Refusals: Participants, Proxies, and Associates**.
   B. **Reconsent Outcome** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Enter 7-Participant Refused.
   C. **Reconsent Outcome Date** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Enter the current date.
   D. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Document the refusal in a dated note with SI ID or initials. *Example: 10/3/2016: Sibling participant refused LTFU Study participation in writing. Updated Reconsent Outcome from <null> to 7 and Reconsent Outcome Date from <null> to 10/3/2016. [kk]*
6. **Deceased Participants** – If it is discovered during the reconsent process that the participant is now deceased:
   A. Take all appropriate action to update the participant's vital status in the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** or **Updating Databases with Post-Recruitment Death Notices**.
   B. SIs should submit an **Expired Participant Information Sheet** with as much information as is available.

Everyone

C. **Reconsent Outcome** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with 38-Deceased.

D. **Reconsent Outcome Date** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Populate with the current date.



E. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Record a dated note with SI ID or initials explaining the field changes.

F. Discontinue pursuit of reconsent. Reconsent is not applicable to deceased participants.

7. **Ineligibles** – The **Reconsent Outcome** code 10-Ineligible should only be posted at the LSI level and above. If an SI believes a participant is ineligible, s/he should document this in the **DB Change** field of the contact or trace log for further review. For LSI/project coordinator:

   A. **Reconsent Outcome** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Enter 10-Ineligible.

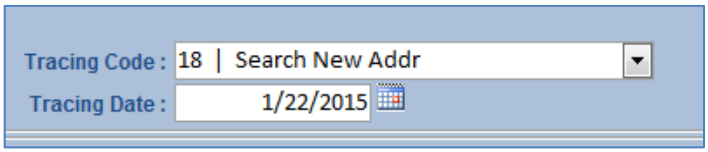
   B. **Reconsent Outcome Date** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Enter the current date.

   C. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database) – Enter a dated note with SI ID or initials documenting the ineligibility.

   D. Update the LTFU Participant database with the ineligibility as instructed in the SOP titled **Documenting Ineligibility**.

8. **Returned to Sender** – When the AOM mailing to the participant is returned to sender, the project coordinator will:

   A. **Tracing Status** (PARTICIPANTS tab in CCSS LTFU Participants database) – Update to appropriate tracing code. See SOPs titled **Notifications from Mail Carrier about Participant Correspondence** and **LTFU Participant Database Data Entry**.



   B. **Tracing Date** (PARTICIPANTS tab in CCSS LTFU Participants database) – Update to the current date.

   C. **Notes** (FU5 TRACKING tab in CCSS Follow-Up Survey Tracking database and PARTICIPANTS tab in CCSS LTFU Participants database) – Enter a dated note with initials documenting the return.

9. **Tracing the Now-Adult Participant**

   A. If a Tracer determines the **participant is deceased**, s/he should:

      i. See the "Deceased Participants" instructions in the section of this document titled *Reconsenting Now-Adult Participant – Parent Permission Obtained, Implied, or Not Applicable*, above.

      ii. Discontinue tracing but leave the tracing code in place. Reconsent is not applicable to deceased participants.

   B. When **participant tracing succeeds**:

      i. If the **participant is reached**, the SI will use the appropriate reconsent script to explain the LTFU Study and attempt to obtain verbal consent to the study.

         a. If the participant is reconsented, the SI will follow the instructions for "Verbal Reconsent" in section of this document titled *Reconsenting Now-Adult Participant – Parent Permission Obtained, Implied, or Not Applicable*, above.

         b. If the participant is NOT reconsented, the SI should confirm the participant's mailing address and either:

            1) Enter a resend request for study materials (See the applicable project-level SOP for more information.) OR

2) Follow the instructions for "Participant Refusal" in section of this document titled *Reconsenting Now-Adult Participant – Parent Permission Obtained, Implied, or Not Applicable*, above.

ii. If **someone other than the participant is reached** but the participant information is confirmed:

a. Update the LTFU Participant database with the new contact information. See the SOP titled **LTFU Participant Database Data Entry** for details.

b. Proceed with requesting a resend of study-specific materials. See the applicable project-level SOP for more information.

Revision Record Printed 8/19/2020 1:40 PM

	Current Filename:	Age of Majority Reconsenting ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/19/2020	R. Massey, J. Ford, L. Harrison, A. McDonald	Title change from "Age of Majority (AOM) Re-consenting Cases: Overview" and complete rework of process to reflect current databases and procedures (reworked over extended time period)

Age of Majority Status Updates

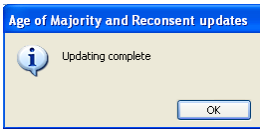
Background

The Expansion Tracking database maintains two tables for documenting the age of majority reconsent procedures. We use a dedicated macro each morning to update this table. We also use two separate queries to identify cases and siblings who were 17 when the consent was signed, but 18 by the time we received it.

Procedure

Step 1: Running the AOM update macro

After (a) the morning rollover from recruitment and (b) the DatStat import and (c) the DatStat complete update macro, run the macro **mcrJB_UpdtAOMReconsent**.



The AOMReconsent macro runs 8 separate queries (listed below) and displays 2 information messages, one before it begins and another when updating is complete. Click OK at each message. ***Note: Run the MACRO, NOT the queries!***

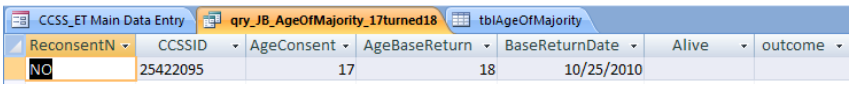
1. *Qapp_JB_AgeOfMajority.* This query adds new records to the AgeOfMajority table. These are records that have rolled over from the Recruitment database.
2. *Qry_JB_AOMreconsentNO_00_UPDATE*. This query identifies cases that do NOT need to be reconsented, and posts "NO" to the ReconsentNeeded field. Cases consented as adults as well as those deceased, refused, or ineligible do NOT need to be reconsented.
3. *Qry_JB_AOMreconsentYES_00_UPDATE*. This query identifies cases that DO need to be reconsented, and posts "YES" to the ReconsentNeeded field. Living eligible cases who were consented before they were 18 but who have now turned 18 DO need to be reconsented.
4. *Qry_JB_AOMreconsentNotYet_UPDATE*. This query identifies cases that WILL need to be reconsented, but NOT YET. Living eligible cases consented before the age of 18 who have not yet turned 18 are classified with "NOT YET."
5. *Qapp_JF_AgeOfMajority_Sib.* This query adds new sibling records to the AgeOfMajoritySib table.
6. *Qry_JF_AOMreconsentNo_00_Sib_UPDATE*. This query identifies siblings that do NOT need to be reconsented, and posts "NO" to the ReconsentNeeded field. Siblings consented as adults as well as those deceased, refused, or ineligible do NOT need to be reconsented.
7. *Qry_JF_AOMreconsentYes_00_Sib_UPDATE*. This query identifies siblings that DO need to be reconsented, and posts "YES" to the ReconsentNeeded field. Living eligible siblings who were consented before they were 18 but who have now turned 18 DO need to be reconsented.

8. *Qry_JF_AOMreconsentNotYet_Sib_UPDATE*. This query identifies siblings that WILL need to be reconsented, but NOT YET. Living eligible siblings consented before the age of 18 who have not yet turned 18 are classified with "NOT YET."

Step 2: Identifying 17-year olds who had turned 18 by the time the consent was received

1. Run **qry_JB_AgeOfMajority_17turned18** & **qry_JF_AgeOfMajority_17turned18_Sib** (be patient; it takes time)

2. Continue only if the query DOES display records. Print the query output (or export and save as excel)



Step 3: Manually adjusting ReconsentNeeded for cases listed in the 17turned18 query(ies)

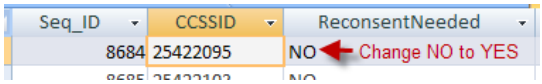
For EACH CCSS/SIBID listed in the query

1. Search for the record on the main data entry form.

2. On the **AgeOfMajority** tab, document the manual change to the field with a note in **AOM ReconsentComments**: *mm/dd/yyyy: pt was 17 when consent was signed but 18 when it was received. Manually changed ReconsentNeeded from NO to YES [inits]*

3. Move to the next record.

4. Open **tblAgeOfMajority** or **tblAgeOfMajoritySib**.



5. Search for the CCSS/SIBID. Change **ReconsentNeeded** from NO to YES. Then go to the next record.

Revision Record

Printed 1/31/2014 1:12 PM

Current Filename:		Age of Majority Status Updates ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	1/25/2012	J.Bates	Initial Development
2	1/31/2014	J. Ford	Development of Sibling procedure

ASK Study Calls

Background

Survivors of childhood cancer or similar illness that were treated with radiation are at an increased risk of skin cancer. The Long-Term Follow-Up (LTFU) Study partnered with Harvard School of Public Health (HSPH) to initiate the Advancing Survivors' Knowledge (ASK) about Skin Cancer Study; the Principal Investigator (PI) is Alan Geller at HSPH. The ASK Study seeks to enroll 801 adult LTFU Study participants from the original cohort who are survivors of childhood cancer (or a similar illness) and who were treated with radiation. The purpose of the study is to determine the best ways to improve skin self-examination and physician screening for skin cancer.

Participation in the study will last 18 months and will include a baseline survey at enrollment ($25 gift card upon completion), a survey at 12 months ($25 gift card upon completion), and a survey at 18 months ($50 gift card upon completion). Cases will be randomly assigned to one of 3 groups:

- Group A will receive print materials, text messages, and access to a website on early detection of skin cancer for 12 months.
- Group B will receive the same information as Group A **and** the case's medical provider will receive information about skin cancer detection that will help him/her carefully examine the case for skin cancer.
- Group C will receive the same information as Groups A and Group B **and** the case will also receive a special attachment for his/her cellphone to take high-quality pictures of suspicious moles and lesions on his/her skin. The case can upload these pictures to the study website to be reviewed by the study dermatologist who will send the findings to the case's regular health care provider.

Survey Interviewers (SIs) will make calls to non-responders approximately 2 weeks after ASK packet mailings to confirm receipt of the materials, answer questions, and encourage participants to complete the surveys (online, over the phone, or on paper) and to sign and return the HIPAA form. Special calls will also be made to obtain missing critical information from completed surveys.

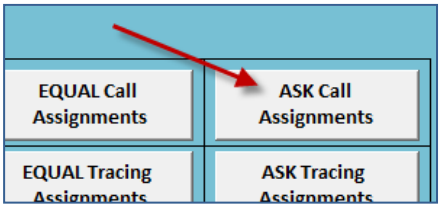
Procedures

Tools Needed

1. CCSS SI Assignments database, located at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
2. CCSS LTFU Participants Database, located at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
3. ASK .NET database, located at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx

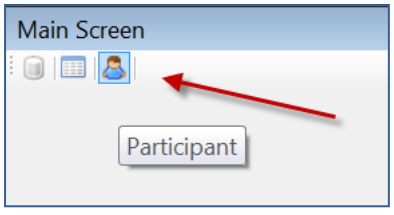
4. **ASK Study Calls**, located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
5. **Pre-Post Call Checklist – ASK Studyy Calls**, located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
6. **Phone Message Guidance_Rev 5-30-2014**, located at Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools
7. **ASK Study Follow-Up Recruitment Call Script ajm**, located at Z:\SJShare\SJCOMMON\ECC\Interviewers\ASK - Skin Cancer Study\Scripts
8. **CCSS Skin Cancer Consent Script rev 20 2 irb appr 10-13-14_dr-rev4-9-2015**, located at Z:\SJShare\SJCOMMON\ECC\Interviewers\ASK - Skin Cancer Study\Scripts
9. **ASK Study Ineligible Calls ajm**, located at Z:\SJShare\SJCOMMON\ECC\Interviewers\ASK - Skin Cancer Study\Scripts
10. Backup paper copies of surveys, located at Z:\SJShare\SJCOMMON\ECC\Interviewers\ASK - Skin Cancer Study\Survey
11. ASK email templates, located at Z:\SJShare\SJCOMMON\ECC\Interviewers\ASK - Skin Cancer Study\Email Templates
12. **LTFU Participant Database Data Entry**, located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx

Before the Call



1. Locate the first participant to be called.
   A. Open the CCSS SI Assignments database. Click the **ASK Call Assignments** button, enter the SI ID at the prompt, and click **OK**.
   B. Note the first participant in the assignment list.
      i. Determine the type of call needed: baseline survey, 12-month survey, 18-month survey, HIPAA, missing information, or a combination of these.
      ii. If s/he is in multiple studies, as indicated in the "# of Studies" column, prepare to address the ASK study and the other studies in the same call. Coordination with another SI may be necessary.

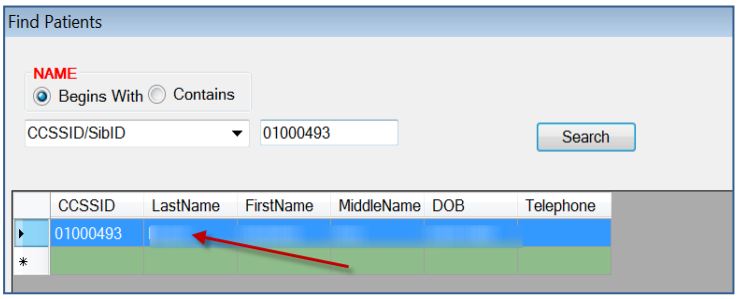
2. Open the CCSS LTFU Participants database, and open the participant's record. See the SOP titled **LTFU Participant Database Data Entry** for instructions on using the Search Information screen.



3. Open the ASK .NET database, and locate the participant ID from the assignments list, above.
   A. Click the Participant icon.
   B. Choose the filter radio button **Begins With** or **Contains**.

C. Choose the type of search from the drop-down list, enter the search criteria, and click the **Search** button. The search results will populate.

D. Double-click on the desired search result to open the participant's record.



4. Review the following data in the participant's record:
   A. CCSS LTFU Participants database – Review all fields indicated in the **Pre-Post Call Checklist – ASK Study Calls** to create a pre-call profile.
   B. ASK .NET database
      i. Case tab, Survey Data group – If the baseline survey has been completed, confirm all needed data is populated. Missing data may be needed from the participant.
      ii. Tracking tab –
         a. **Study Group ID** – Note the participant's assigned study group, if s/he has been assigned.
         b. **Skin Cancer Study Outcome** and date
         c. Baseline survey fields – Survey already returned?
         d. 12-Month and 18-Month survey fields – Survey already returned?
         e. **Preferred Contact Info/Time**
         f. **Notes**
         g. Resend data – Note date of most recent resend and what materials were sent.
      iii. HIPAA tab – Review the **Hipaa Status**, **Hipaa Date Received**, **Hipaa Source**, **Hipaa Date Signed**, **Hipaa Resend Date#**, and **Hipaa Notes** fields.

During the Call: Baseline/Enrollment Calls

1. Use the script **CCSS Skin Cancer Consent Script rev 20 2 irb appr 10-13-14** and **Phone Message Guidance_Rev 5-30-2014** to make calls to the assigned participants.
   A. Ask if the participant received the ASK materials.
   B. Ask if we may explain the study.
   C. Answer the participant's questions about the study.
   D. Ask if s/he is willing to participate.
      i. If yes:
         a. Participant Copy of Consent
            1) Case received packet – Advise that his/her copy of the informed consent is in the materials received and should be kept on file.
            2) Case did NOT receive packet – Advise that we will send a copy of the informed consent via email (preferred) or on hard copy. Determine which format the participant needs.

b. Determine how the case would like to complete the enrollment survey (telephone, online, or paper). If appropriate, begin the consent script and then the survey. See the section of this document titled *During the Call: Completing the ASK Survey*.
c. Remind the case to sign and return the LTFU HIPAA form or direct the participant to the online site.

ii. If no:
a. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
b. If it is unclear if the participant is refusing just the ASK Study or all further participation in the LTFU Study, clarify.

E. Confirm all contact information.
F. Thank the participant for taking our call.

1. If the participant reports s/he has **already returned** the baseline/enrollment survey:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. If a paper copy was returned more than one month ago, it may be lost. Offer to complete the survey over the telephone to avoid further losses.
      ii. If a paper copy was returned less than one month ago, it may still be in route. Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.
      iii. If an online survey was returned before today but the **Survey Returned** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday and Saturday will have the **Survey Returned** field populated the following Monday.
         a. Confirm the participant is referring to the LTFU Study's ASK (skin cancer) baseline survey. The participant could be thinking of another study in which s/he participates.
         b. Try logging in to the online survey to determine the survey status. It may be that the participant neglected to click the **Submit** button.
      iv. If an online survey was returned today, the **Survey Returned** field will be populated on the next business day (Monday through Friday). Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.

2. If the participant requires or prefers a **Spanish-speaking** SI:
   A. And a Spanish-speaking SI is available, tell the participant, "Un momento, por favor," and transfer the call to the Spanish-speaking SI.
   B. And a Spanish-speaking SI is not available but the participant can understand, ask the best time for a Spanish-speaking interviewer to call back.

3. If it is determined that the participant is **deceased**, offer condolences and, if possible, complete the **Expired Participant Information Sheet**. Do not pursue participation.

During the Call: 12-Month Survey Calls

1. Use the script and **Phone Message Guidance_Rev 5-30-2014** to make calls to the assigned participants.
   A. Ask if the participant received the ASK 12-month survey materials.
   B. Answer the participant's questions about the study.
   C. Ask if s/he is willing to complete the survey via telephone.
      i. If yes, begin the survey. See the section of this document titled *During the Call: Completing the ASK Survey*.
      ii. If no, determine if the participant prefers to complete the survey online or on paper.
      iii. When appropriate, remind the case to sign and return the LTFU HIPAA form or direct the participant to the online site.
   D. Confirm all contact information.
   E. Thank the participant for taking our call.

2. If the participant reports s/he has **already returned** the 12-month survey:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. If a paper copy was returned more than one month ago, it may be lost. Offer to complete the survey over the telephone to avoid further losses.
      ii. If a paper copy was returned less than one month ago, it may still be in route. Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.
      iii. If an online survey was returned before today but the **Survey Returned** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday and Saturday will have the **Survey Returned** field populated the following Monday.
         a. Confirm the participant is referring to the LTFU Study's ASK (skin cancer) 12-month survey. The participant could be thinking of another study in which s/he participates.
         b. Try logging in to the online survey to determine the survey status. It may be that the participant neglected to click the **Submit** button.
      iv. If an online survey was returned today, the **Survey Returned** field will be populated on the next business day (Monday through Friday). Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.

3. **Refusal**
   A. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.

B. If it is unclear if the participant is refusing just the ASK 12-month survey, the ASK Study, or all further participation in the LTFU Study, clarify and document this important distinction.

4. If the participant requires or prefers a **Spanish-speaking** SI:
   A. And a Spanish-speaking SI is available, tell the participant, "Un momento, por favor," and transfer the call to the Spanish-speaking SI.
   B. And a Spanish-speaking SI is not available but the participant can understand, ask the best time for a Spanish-speaking interviewer to call back.

5. If it is determined that the participant is **deceased**, offer condolences and, if possible, complete the **Expired Participant Information Sheet**. Do not pursue the survey.

During the Call: 18-Month Survey Calls

1. Use the script and **Phone Message Guidance_Rev 5-30-2014** to make calls to the assigned participants.
   A. Ask if the participant received the ASK 18-month survey materials.
   B. Answer the participant's questions about the study.
   C. Ask if s/he is willing to complete the survey via telephone.
      i. If yes, begin the survey. See the section of this document titled *During the Call: Completing the ASK Survey*.
      ii. If no, determine if the participant prefers to complete the survey online or on paper.
      iii. When appropriate, remind the case to sign and return the LTFU HIPAA form or direct the participant to the online site.
   D. Confirm all contact information.
   E. Thank the participant for taking our call.

2. If the participant reports s/he has **already returned** the 18-month survey:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. If a paper copy was returned more than one month ago, it may be lost. Offer to complete the survey over the telephone to avoid further losses.
      ii. If a paper copy was returned less than one month ago, it may still be in route. Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.
      iii. If an online survey was returned before today but the **Survey Returned** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday and Saturday will have the **Survey Returned** field populated the following Monday.
         a. Confirm the participant is referring to the LTFU Study's ASK (skin cancer) 18-month survey. The participant could be thinking of another study in which s/he participates.

b. Try logging in to the online survey to determine the survey status. It may be that the participant neglected to click the **Submit** button.

iv. If an online survey was returned today, the **Survey Returned** field will be populated on the next business day (Monday through Friday). Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.

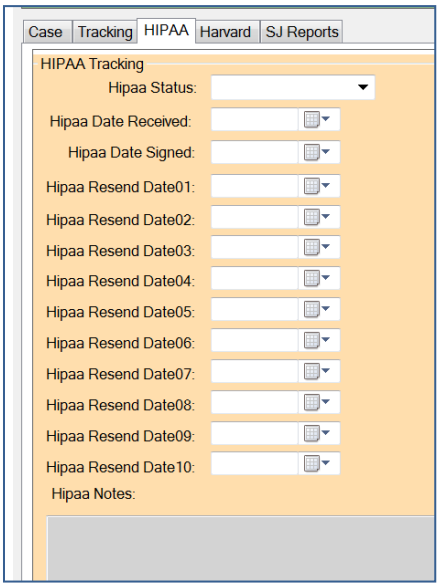
3. **Refusal**
   A. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
   B. If it is unclear if the participant is refusing just the ASK 18-month survey, ASK Study, or all further participation in the LTFU Study, clarify.

4. If the participant requires or prefers a **Spanish-speaking** SI:
   A. And a Spanish-speaking SI is available, tell the participant, "Un momento, por favor," and transfer the call to the Spanish-speaking SI.
   B. And a Spanish-speaking SI is not available but the participant can understand, ask the best time for a Spanish-speaking interviewer to call back.

5. If it is determined that the participant is **deceased**, offer condolences and, if possible, complete the **Expired Participant Information Sheet**. Do not pursue the survey.

During the Call: HIPAA Calls

A HIPAA authorization is required for the LTFU Study to release the participant's data to the HSPH team and for the ASK Study to request medical records from the participant's doctor. If the participant does not sign the HIPAA during one of the study surveys, SIs will contact him/her to request completion of the HIPAA form.



1. Use the script and **Phone Message Guidance_Rev 5-30-2014** to make calls to the assigned participants.
   A. Ask if the participant received the paper HIPAA form. If not, the participant may be able to complete the HIPAA authorization online in some situations. Consult with a member of the Lead Survey Interviewer (LSI) team for clarification.
   B. Answer the participant's questions about the form.
      i. The online HIPAA form authorizes the LTFU Study to release the participant's ASK Study information to HSPH.
         a. For the online HIPAA process, the participant must personally access the website and click the agreement. An SI should NOT do this process for the participant.

b. The online HIPAA can be accessed at www.stjude.org/ltfu-askhipaa.

ii. The paper HIPAA form both authorizes the LTFU Study to release the participant's ASK Study information to HSPH and allows the ASK Study to request medical records from the participant's doctor.

C. Ask the participant to complete and return the HIPAA authorization. When appropriate, the online link can be emailed.

D. Confirm all contact information.

E. Thank the participant for taking our call.

2. **Refusal**

A. Refusal to complete the HIPAA form constitutes refusal to participate in the ASK Study. Advise the participant, "No problem. Without your approval of the HIPAA medical release authorization, we will not be able to forward your information to our study partners at Harvard, and you will not be eligible for THIS study. However, we appreciate your continued participation in the LTFU Study."

B. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. Offer a hold if this is more appropriate.

C. If it is unclear if the participant is refusing just the ASK Study or all further participation in the LTFU Study, clarify.

3. If the participant requires or prefers a **Spanish-speaking** SI:

A. And a Spanish-speaking SI is available, tell the participant, "Un momento, por favor," and transfer the call to the Spanish-speaking SI.

B. And a Spanish-speaking SI is not available but the participant can understand, ask the best time for a Spanish-speaking interviewer to call back.

4. If it is determined that the participant is **deceased**, offer condolences and, if possible, complete the **Expired Participant Information Sheet**. Do not pursue the HIPAA form.

During the Call: Missing Information Calls

When a participant returns the baseline ASK survey without information necessary to study participation (e.g. cell phone number to receive text messages, smart phone model, primary care doctor's name/address, etc.), an SI will follow up with the participant to obtain the needed information. Please note that a person may need additional information as well as a HIPAA authorization.

1. Use the script and **Phone Message Guidance_Rev 5-30-2014** to make calls to the assigned participants.

A. Obtain the missing data.

B. Confirm all contact information.

C. Thank the participant for taking our call.

2. **Refusal**

A. In many situations, refusal to provide the missing information will constitute refusal to

participate in the ASK Study. Please consult with a member of the LSI team for assistance.

B. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. Offer a hold if this is more appropriate.

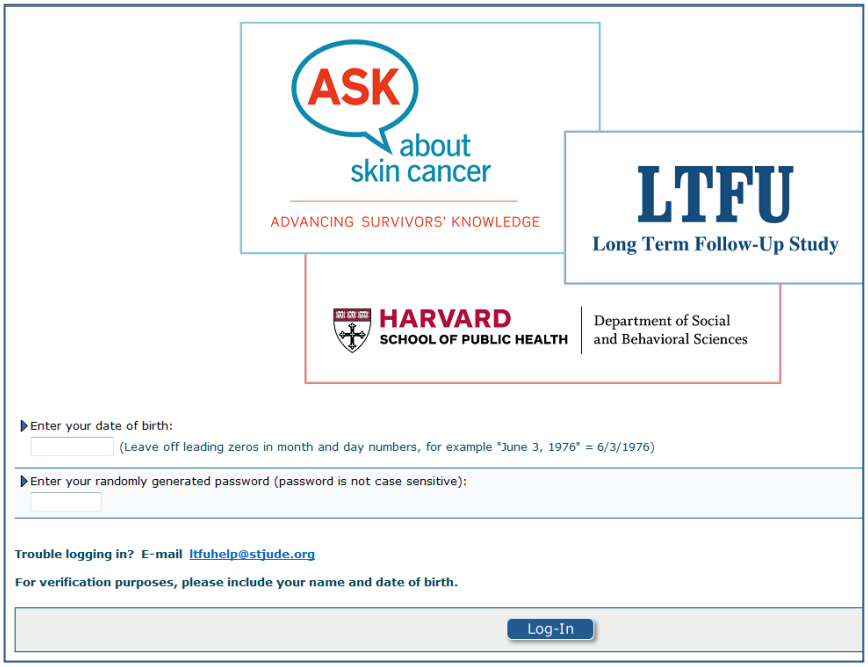
C. If it is unclear if the participant is refusing just the ASK Study or all further participation in the LTFU Study, clarify.

3. If the participant requires or prefers a **Spanish-speaking** SI:
   A. And a Spanish-speaking SI is available, tell the participant, "Un momento, por favor," and transfer the call to the Spanish-speaking SI.
   B. And a Spanish-speaking SI is not available but the participant can understand, ask the best time for a Spanish-speaking interviewer to call back.

4. If it is determined that the participant is **deceased**, offer condolences and, if possible, complete the **Expired Participant Information Sheet**. Do not pursue the missing information.

During the Call: Completing the ASK Survey

1. Click on the link to the appropriate survey. There are three types of ASK surveys:
   A. Baseline/Enrollment Survey: www.stjude.org/ltfu-ASK
   B. 12-Month Survey: link to be determined
   C. 18-Month Survey: link to be determined
2. On the survey login page, enter:
   A. The participant's date of birth omitting leading zeros (e.g. 6/3/1976 instead of 06/03/1976)
   B. The password from the LTFU Participant database

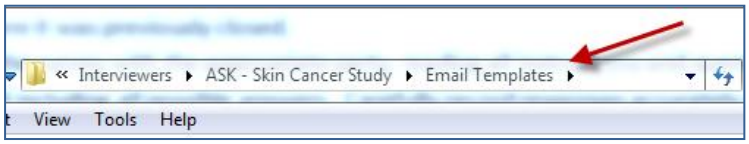


3. For the baseline survey:
   A. Follow the verbal consent script.
   B. HIPAA – Explain that we will need a HIPAA authorization to release their information to our partners at HSPH. Explain the paper and online options.
      i. If the participant AGREES, then "agree" to the HIPAA in the baseline survey to proceed to the survey questions.
      ii. If the participant DOES NOT AGREE, then stop the survey. See the section of this document titled *During the Call: HIPAA Calls* under the "Refusals" instructions.

4. If the survey was previously started, either by the participant or by an SI, DatStat will display the options to **Start Over** or **Restore** the survey. In general, click on the **Restore** button to start the survey where it was previously closed.
5. Complete the survey with the appropriate party, reading all instructions and questions as written and including all possible answers. Carefully record responses accurately in the online survey.
6. When a valid HIPAA has not yet been received from the participant, remind the participant to sign and return the paper HIPAA form or, when appropriate, to complete the HIPAA online. NOTE: If the participant began the ASK baseline survey without the assistance of an SI and agreed to the HIPAA in the online survey form, then finishes the survey with the assistance of an SI, the HIPAA is a valid online HIPAA agreement.

After the Call

1. **Emailing Survey or HIPAA Links** - If the participant requested to complete the ASK survey or HIPAA form online, send an email with the appropriate link.
   A. Open the appropriate email template, based on the participant's stage of participation:



      i. Enrollment/Baseline Survey – **ASK Enrollment Email Template**
      ii. 12-Month – TBD
      iii. 18-Month – TBD
      iv. HIPAA – **ASK Online HIPAA Email Template**
   B. Create a new email in Outlook.
      i. Copy the body of the template, and paste it into the body of the new email using the "Keep Source Formatting" paste option.
         a. Replace any automatic Outlook signature in the body of the email with the signature in the template.
         b. *Do NOT copy and paste the subject line* from the template to the body of the email.
      ii. Copy the subject line from the template (NOT the words "Subject Line:"), and paste it into the **Subject:** bar of the new email.
      iii. Close the template without saving changes.
   C. Personalize the new email.
      i. Replace the greeting in the body of the email with the correct salutation and name.
      ii. Replace "[from the LTFU Pt database]" in the body of the email with the correct password. Copy the value from the participant's LTFU Participant database record and paste it into the email using the "Match Destination Formatting" option.
      iii. Replace "[Survey Interviewer's Name]" in the email signature with the first and last name of the SI sending the email.
   D. Copy the participant's email address from the LTFU Participant database, and paste it into the **To:** bar of the email.

E. Proofread the email to ensure there are no mistakes.
F. Click the **Send** button to send the email.
G. LTFU Participant Database Contact Log – Document the email communication including which link was sent. See the SOP titled **LTFU Participant Database Data Entry** and the section of this document titled *Updating the LTFU Participant Database* for full instructions.
H. **Notes** field in the Tracking tab of the ASK .NET database – Add a dated note with SI ID documenting which link was sent.

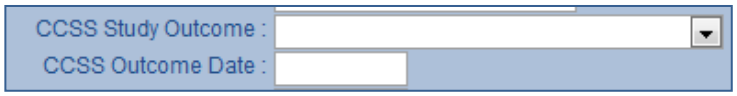
2. **Updating the LTFU Participant Database**
   A. **Contact/Trace Log** – Create a new contact or trace log record for each communication (call, email, etc.). See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
      i. **Project** – Populate with 14-ASK.
      ii. **Contact Reason** – Populate with:
         a. 4-Survey for baseline, 12-month, and 18-month survey calls
         b. 5-HIPAA for online and paper HIPAA calls, including calls requesting both the HIPAA and other missing information
         c. 3-Other for missing information calls
   B. Update the LTFU Participant database with all **confirmed contact information** for the participant and his/her associates. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
   C. **Ineligible** – All situations of suspected ineligibility (e.g. out of the country, previous skin cancer diagnosis, no text-capable phone, etc.) should be documented in the **DB Change** field of the contact or trace log. A member of the LSI team will review the possible ineligibility with the leadership team for a final determination.
   D. **Needs Tracing** – Update the **Tracing Code** and **Tracing Date** fields on the Participant tab. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.

3. **Deceased** – If it was discovered that the participant is now expired:
   A. LTFU Participant Database - The deceased outcome should be documented in the **DB Change** field of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
   B. **Expired Participant Information Sheet** – Submit the completed form in file cabinet A.
   C. ASK .NET Database, Tracking tab:
      i. **Notes** field – Add a dated note with SI ID documenting the deceased outcome.
      ii. **Skin Cancer Study Outcome** and date – Do NOT populate.
   D. Email the project coordinator to advise of the deceased outcome. Copy the Research Scientist, Call Center Coordinator, and LSI team.

4. **Refusal** – If the participant refused an ASK survey, the ASK or LTFU study, or refused to authorize the HIPAA (which is equivalent to refusing the study):
   A. LTFU Participant Database –
      i. **Outcome** field of the contact or trace log – Populate with 7-Refused.

ii. Refused ASK survey or study ***ONLY*** – Do NOT update the **CCSS Study Outcome** or **CCSS Outcome Date** fields.

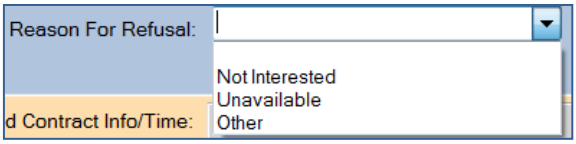
iii. Refused All Else (i.e. the case refused all further participation in the LTFU Study) – Update the **CCSS Study Outcome** and **CCSS Outcome Date** fields in the header.



See the SOP titled **LTFU Participant Database Data Entry** for full instructions.

B. ASK .NET Database –

i. If the participant **refused the 12-Month or 18-Month ASK Survey *only***, go to the Tracking tab:



a. **Reason for Refusal** – Use the drop-down menu in the appropriate survey group to choose the applicable reason.

b. **Notes** – Add a dated note with SI ID documenting the refusal and specifying the type of refusal (survey only). If "Other" was selected at the **Reason for Refusal** field, specify the reason.

ii. If the participant **refused all further participation in either the ASK Study or in the entire LTFU Study**, go to the Tracking tab:

a. **Notes** – Add a dated note with SI ID documenting the refusal outcome**.**

b. **Skin Cancer Study Outcome** – Do NOT populate.

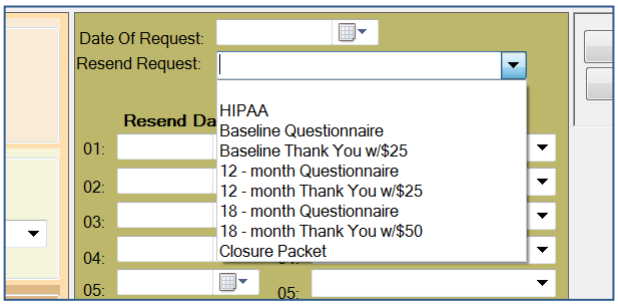
c. **Skin Cancer Study Outcome Date** – Do NOT populate.

iii. If the participant refuses participation by refusing to sign the HIPAA (paper or online), also add a dated note with SI ID documenting the HIPAA refusal in the **Hipaa Notes** field on the HIPAA tab.

C. Email the project coordinator to advise of the refusal. Copy the Research Scientist, Call Center Coordinator, and LSI team.

5. **Updating the ASK .NET Database**

A. **Resend Requests** – On the Tracking tab:



i. **Date of Request** – Populate with the current date.

ii. **Resend Request** – Use the drop-down menu to choose the hardcopy materials to be resent.

iii. **Notes** – Add a dated note with SI ID documenting the resend requested.

B. **Missing Information Obtained**

i. Populate the appropriate field(s) in the Survey Data group of the Case tab.

ii. Email the project coordinator to advise that the missing data has been obtained. Copy the Research Scientist, Call Center Coordinator, and LSI team.

6. Partially Completed Survey

A. Using the **Previous** and **Next** buttons on the online survey form, review every completed page of the online survey for accuracy. Complete any missing information or fields erroneously left blank before closing the survey.

B. LTFU Participant Database –
   i. Complete the contact or trace log for the call, specifying 8-Partially Complete in the **DB Change** field.
   ii. Update the database with any confirmed contact information using the SOP titled **LTFU Participant Database Data Entry**.

C. On the Tracking tab of the ASK .NET database:
   i. **Notes** – Add a dated comment with SI ID documenting the partially completed survey.
   ii. **Interviewer ID** – Do NOT populate.

D. For scheduled surveys, note the partially completed survey outcome on the Call Center appointment calendar according to the SOP titled **Call Center Appointment Calendar**.

E. For unscheduled surveys, email the participant ID to the closing monitor to include the partially completed survey in the closing report.

F. Update the Dry Erase Board (DEB) ASK Survey tally to indicate the partial survey by writing a "p" instead of a tally mark.

G. Log the time spent on the partial survey in your **Journal**. See the SOP titled **Survey Interviewer Journal Data Entry** for details.

7. Completed Survey

A. LTFU Participant Database –
   i. Complete the contact or trace log for the call.
   ii. Update with any confirmed contact information using the SOP titled **LTFU Participant Database Data Entry**.

B. Using the **Previous** and **Next** buttons on the online survey, review every page of the online survey for accuracy and check for missing information or fields erroneously left blank. Complete any missing information.

C. Click the **Submit** button on the last page of the survey. Click the **Close** button on the next page, and then choose **Yes** at the next prompt to close the browser instance.

D. On the Tracking tab of the ASK .NET database:
   i. **Interviewer ID** – Populate the field associated with the baseline, 12-month, or 18-month survey, as appropriate.

EXCEPTION: If the participant began the baseline ASK survey without the assistance of an SI and completed the HIPAA agreement, then later finishes the survey with the assistance of an SI, this field should NOT be populated. Instead, enter the dated note, as below, and email the project coordinator, copying the Research Scientist, Call Center Coordinator, and LSI team.

ii. **Notes –** Add a dated note with SI ID specifying which survey was completed.

iii. Do NOT populate any other field associated with the survey in question.

E. For completed scheduled surveys, place a check mark on the Call Center appointment calendar to indicate the kept appointment. See the SOP titled **Call Center Appointment Calendar** for full details.

F. For unscheduled surveys, email the participant ID to the closing monitor to include the completed survey in the closing report.

G. Note the completed ASK survey with a tally mark on the Dry Erase Board (DEB).

H. If the survey call plus post-call documentation took more than 30 minutes to complete, log the time beyond the first 30 minutes in your **Journal**. See the SOP titled **Survey Interviewer Journal Data Entry** for details.

8. **CCSS Skin Cancer Consent Script rev 20 2 irb appr 10-13-14** form

A. Submit the completed form, when applicable, in file cabinet A.

B. If a participant copy of the informed consent was needed, indicate this and the requested format on the form prior to submission.

Revision Record
Printed 4/20/2015 3:55 PM

[294] Current Filename:		ASK Study Calls ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	4/7/2015	R. Massey, D. Rinehart, A. Oyuela, A. McDonald	Initial Development

Assessing and Addressing Cognitively Impaired Potential CCSS Participants

Background

On rare occasions during the recruitment process and the completion of the expansion baseline questionnaire, a Survey Interviewer may encounter a cognitively impaired potential CCSS participant. In general, a legal guardian, parent or caregiver can serve as a proxy for the prospective recruit. These are dealt with on a case-by-case basis. When in doubt, you should always contact an LSI or coordinator for guidance.

Procedure

When the SI calls the participant:

- If the participant is impaired and has a legal guardian or legally authorized representative (LAR), most of the time the guardian will answer the phone. If you ask for the participant, and they say, "I am his legal guardian," or something similar, use the approved Expansion Recruitment scripts and proceed with the call.

- If the participant answers the phone, and during questions to confirm identity of the participant you detect any mental impairment (i.e., the participant is not understanding the questions being asked), repeat the questions slowly, and ask if they understand what you are asking of them. If it is apparent that the participant is confused, ask if there is a parent or guardian there with them.
  - If a parent or LAR *IS* available, verify you are speaking with the LAR of the participant.
    - If they say, "**yes**," then proceed with the purpose of the call.
    - If they say, "**No**," then ask if the participant *HAS* an LAR.
      - If they say, "**Yes**," ask when the LAR will be available, and call back at that time.
      - If they say, "**No**," then forward the case and information to the Coordinator of the Survey Interviewers.

- Note – when pursuing the baseline questionnaire, the cognitive impairment may have been documented during the institutional HIPAA process. Make sure you review all notes before making calls.

Revision Record Printed 7/9/2012 10:44 AM

Current Filename:		Addressing Cognitively Impaired CCSS Participants ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	5/16/12	D. Rinehart	Initial Development
1.1	5/23/12	Procedure Team	Content and format editing

Assigning Interviewers for Saliva Calls

Background

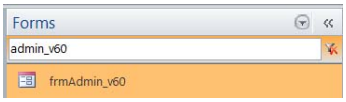
After the coordinating center sends a saliva kit, follow-up calls are made to those participants who have not responded to the mailing, in an attempt to recruit the individual into the Saliva Study. Before calls can begin, an interviewer must be assigned to the call each passive non-responder. The procedure below outlines how to do this.

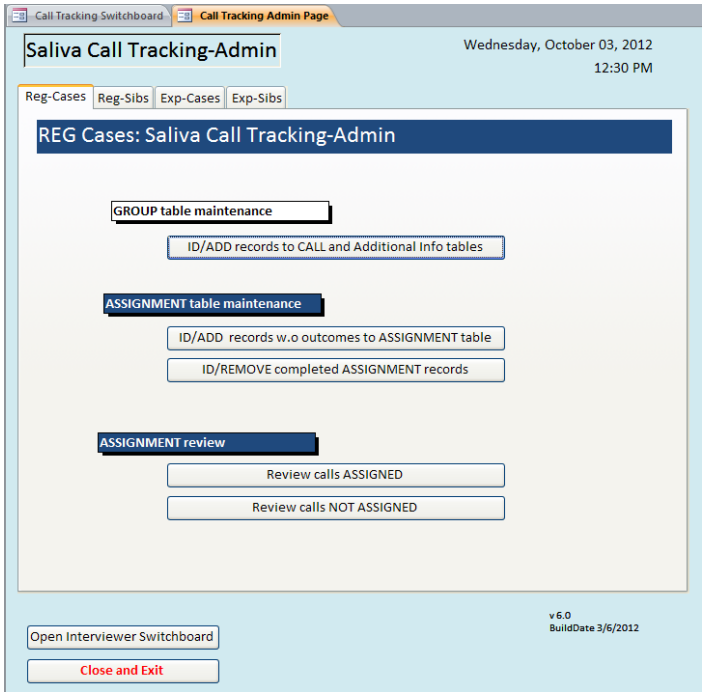
Procedure

1. Open *CCSS Saliva Call Tracking* database from the SharePoint Web-Link

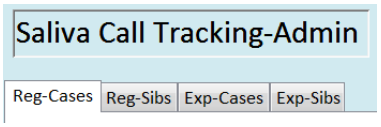
2. Follow *Managing Saliva Study Participant Status* procedures

3. Open the **Saliva Call Tracking ADMIN Page** (*frmAdmin_v60)*

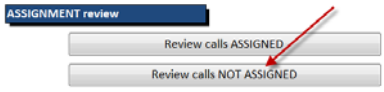




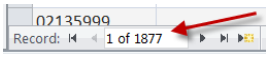
4. Choose the tab for the appropriate participant cohort (Reg-Cases, Reg-Sibs, Exp-Cases, Exp-Sibs). This opens the options for that cohort.



5. In the **ASSIGNMENT review** section, click ***Review calls NOT ASSIGNED***

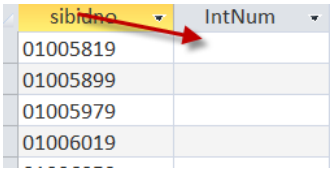


6. From the list of calls NOT assigned, determine the total number <u>not</u> assigned to an interviewer



7. Use this information to evenly distribute calls based upon # of interviewers and # of hours assigned to saliva calls
    a. For example, if 3 interviewers (with 8 hours per interviewer) are assigned to saliva study and there are 300 unassigned CCSSIDs, each interviewer should be assigned to 100 CCSSIDs

8. Then, key in the appropriate interviewer identification # in ***IntNum*** field



    a. Depending on the # of unassigned records, you may wish to either manually enter the interviewer ID # or to create an update query to assign cases.

Revision Record

Printed 10/3/2012 2:36 PM

Current Filename:		Assigning Interviewers for Saliva Calls ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/3/12	J.Ford	Initial Development

Assigning Tracing Cases

Background

The following outlines the steps involved in identifying and distributing tracing assignments for expansion recruitment, expansion baseline, and ancillary studies. This is the general format the Tracers will follow each week. Exceptions are as directed by the Research Scientist or Study Coordinator, based upon the immediate needs of a given study (i.e., the FedEx Resend Project).

Procedures

Expansion Recruitment

Each Tracer is assigned individual cases in separate workbooks. These workbooks are "refreshed" every four to six weeks. Before the workbooks are refreshed, they are converted into tables and imported into the Expansion Recruitment database. These tables are joined with tracing queries, to ensure that documentation and work done by the Tracers on cases still in tracing is not lost. The new query will include both new cases not yet assigned, and current cases with all Tracers notes attached.

For Expansion Recruitment and Baseline, the Tracer's assignments will include a column that indicates which SI the participant is assigned to in Call Rotation. This enables the Tracer to quickly determine which SI will need new contact information, as the Tracer finds the participant.

1. Create an **SI Call Assignment table**
    a. From the most recent Expansion Recruitment Call Assignment distribution, create and import into the Expansion Recruitment database, a new table that includes all the cases with Tracing codes and the SI's name currently assigned to the participant in Tracing.
2. Create a **Tracing History** table
    a. Combine all current Tracing assignments on to one table, with a column to indicate which Tracer is assigned to each group of CCSSID numbers, and import into the database.
3. Create a new query that combines the "Needs Tracing" query with the two new tables, to produce a Datasheet that includes:
    a. All cases which have active tracing codes
    b. All Tracer notes, for those cases that have already been traced, but not confirmed
    c. All SIs' currently assigned to those cases for Recruitment calls.
4. Export the datasheet as an Excel file.
5. Determine the total number of tracing cases to assign to each Tracer, using this table that includes distribution formulas:

Total Tracing Cases (n)	SI ID	Expansion Recruitment Tracing Case Weekly Hours Allocation	% of Total Hours Allocated	Total Tracing Cases* %
2,400	63	24	16%	389
	111	24	16%	389
	114	24	16%	389
	120	40	27%	649
	121	36	24%	584
	Total	148	100%	2400

6. Once the assignments are made, copy and paste them into the individual Expansion Recruitment Tracing Cases workbooks, located: Z…Interviewers/Tracing/Expansion Recruitment
7. After the individual workbooks have been updated, archive the previous workbook and notify the Tracing division via email, copying the LSI team, that their assignment workbooks have been updated and to please begin using the new version.

Expansion Tracking Baseline

Cycle: Every 4-6 weeks or as needed, in the "**All Others Tracing Workbook, mm-dd-yyyy**," located: Z…Interviewers/Tracing/All Others.

Before updating the Baseline Tracing assignments, check with the tracers on the status of the cases in the workbook, for any information that might affect the process of updating the cases. Also note, there are cases in the workbook that have not been confirmed and are still in tracing. As mentioned in the steps for distributing Expansion Recruitment cases, the tracing history and notes related to Baseline cases must remain in the workbook, when adding new assignments. This process is designed to retain tracing history on unconfirmed cases, omit cases that have been confirmed and no longer need to be in the workbook, and add those new cases that have been placed in tracing since the last cycle.

1. Before beginning any work in the "All Others…" tracing workbook, save and prepare the file as a table to be imported into the Expansion Tracking database.
2. Import and save as "**tbl_DR_ExpBasTracing_[mm-dd-yyyy]**."
3. Prepare a table of the current call assignments and import into the database.
4. Create a new query, using the call assignments table and the newly imported table, tbl_DR_ExpBasTracing_[mm-dd-yyyy]."
5. Link the tables by CCSSID, and set the link properties to "2" in the Link dialogue box
6. Use the column fields from call assignments table, CCSSID and SI, and the fields from the table, tbl_DR_ExpBasTracing_[mm-dd-yyyy], **Found**, **Phone**, **Confirmed**, **Tracer's Comments**, **Date1**, **TC1**, **SI1**, **Date2**, **TC2**, **SI2**, **Date3**, **TC3**, **SI3**.
7. Run the query. You should see a datasheet that includes new cases that have not been traced and the ones that have, but have not been confirmed.
8. Export the datasheet into a new Excel file, and save in your U drive, under U…Tracing/Baseline, and name the file, "qry_BaselineTracing,mm-dd-yyyy."
9. Highlight the data from the query, and copy and paste into the "All Others…" tracing workbook, on the Baseline worksheet.
10. Save the workbook. Select, "Save As," then change the date on the file name to the current date.
11. Send an email to the Tracing division team members that work this group, informing that the list has been updated, and Cc: the LSI team.

Ancillary Studies:

The priority and timing for tracing these cases will be directed either by the Research Scientist or the Coordinator for the individual study, or about every 4 to 6 weeks, unless on hold. The SI Coordinator will check with the study Coordinator quarterly for updates for cases or studies on hold.

1. The process is similar to Recruitment and Baseline: current work done by the tracers must be converted into a table that can be imported into the various project databases
2. After you have imported the applicable tables into the appropriate database, export the query Datasheet as an Excel file.
3. Open the "All Others…" Tracing workbook
    a. Update the date in the file name to the current date.
    b. Save and archive the previous workbook
4. Add new cases to the workbook
    a. Copy and paste the new list into the Tracing workbook.
    b. Save and close the workbook.
    c. Send an email to the Tracing team that the workbook has been updated.

Revision Record Printed 5/20/2013 1:17 PM

[239] Current Filename:		Assigning Tracing Cases ver 1_4.docx	
Revision No.	Date	Responsible Author	Change Description
1	6/8/12	D. Rinehart	Initial Development
2	8/2/2012	D. Rinehart	Additional content added
3	8/20/12	D. Rinehart	Content revision
4	5/20/2013	D. Rinehart	Content revision

Baseline Batch Mailing Fact Sheet

WHAT TO INCLUDE

- Letter
  - printed on St Jude Letterhead
  - LETTERS Approved letters (with merge fields) are filed in Z:\SjShare\SJCOMMON\ECC\CCSS\Expansion Baseline\IRB approved Letters .
  - NOTE: use SPECIAL LETTERS for 05-DanaFarber cases.
  - Different letter for adults (GT18) and minors (LT18)
  - *Date* the letter as indicated in the assignment email
  - *Use INTRO letter (unless instructed otherwise)*
- Participant copy
  - Stock in supply closet.
  - If need more, original is Consent and HIPAA Baseline Expansion_1-4-12-ParticipantCopy located in **Z:\SjShare\SJCOMMON \ECC\CCSS\Expansion Baseline.**
  - NOTE: use Special participant copy for University of Minnesota cases (inst 01) from Recruitment folder
  - NOTE: use Special participant copy for Dana Farber (inst 05) deceased
- LTFU (blue) BRE
  - Addressed to Survey Data Center/ ATTN Robison
  - If mailing to Canada, use *without indicia* and add 3 Canadian stamps. These envelopes do NOT have the "Stop labels"

WHAT NOT TO INCLUDE

- Brochure
- Pen
- $2 bill

MAILING LABEL/ENVELOPE

- Use White **first-class** mailer (Return requested) with LTFU/Robison return address (**not** bulk-mail unless otherwise instructed). Do NOT use the institution-specific white mailing envelopes.
- Mailing labels: include CCSSID and SeqNo in a LEGIBLY sized font!

MAILING

- At least 10% of each mailing needs to be thoroughly QC'd by another person before the envelopes are sealed and put out to mail. If n is less than 10, then fully QC at least ONE of the group.
- When the batch is put out to mail, email the CRA2 who will update the date sent in the database.

Revision Record Printed 7/6/2012 11:22 AM

Current Filename:		Baseline Batch Mailing FactSheet v2_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	7/10/2010	J.Bates	Initial Development
2	7/6/2011	J.Bates	Rename (no longer "USC" batch); exceptions
2.1	5/12/12	J.Bates	Participant copy filename change

Blood and Tissue Collection Process Original Cohort

Background

These procedures pertain to original cohort participants. If a CCSS participant has confirmed subsequent neoplasm (other than non-melanoma skin cancer), then blood and tissue collection process may begin. We contract with Examination Management Services, Inc (EMSI) to collect a blood sample for selected participants. Dr. Sue Hammond at the CCSS lab in Columbus collects the tissue samples.

General Eligibility criteria

- Confirmed subsequent cancer/tumor/etc (non-melanoma skin CA not included)
- 18 or over
- Alive (only for blood collection)
- Has not refused further participation in the study

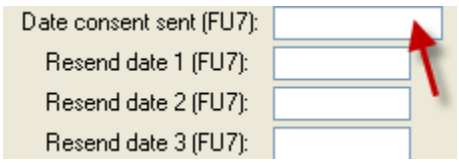
Phlebotomy specimen collection overview

- Examination Management Services, Inc (US residents) and Hooper Holmes Canada (Canadian residents) will perform mobile blood draws
- Orders will be submitted by fax or email
- Company representative will make contact with participants to set appointment for blood draw
- CCSS coordinating center will ship blood kits to the appropriate company
- Examiner completes appointment , prepares specimen in shipping container, ships specimen to the LTFU Molecular Genetics Lab in Cincinnati
  (See: Examination Management Services, INC – Clinical Services Client Protocol)

Procedure

1. *Checking for new eligible participants*
   - Open the frmSMNTrack form in CCSS Reg database
   - Click the "Check For Eligible Bloods" button
   - Run an update query (if needed) to add new participants in the table.

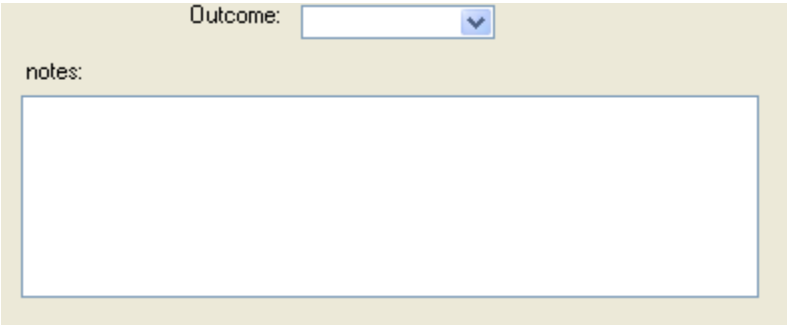
2. *Mailing out letters and consents:*
   a. Run an appropriate query that will generate participants who:
      i. Has never returned previously mailed informed consent, or
      ii. We received signed informed consent but we don't have blood sample
      iii. Meet other criteria listed in the opening section of the procedure
   b. Prepare appropriate cover letter and mail it together with informed consent document, participant's copy, and postage paid return envelope (consents and letters are located in Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue)
   c. Mail the packets
   d. Update the "Date consent sent (FU7)"



e. After 2 weeks, a CCSS interviewer will follow up with the participant if we haven't received signed consent (see separate procedure for interviewer phone calls)

3. *Receiving signed consents, participant's refusal or deceased participants*
   a. Receiving signed consents
      i. When you receive properly signed and dated consent:
         1. Update the "Date consent returned (FU7)"
         2. Update the "Consent granted (FU7)" (see page 5 of the consent document) and the options they agreed to.

   b. Participant's refusals
      i. If someone refuses to participate /sign the consent form, update "Outcome" field with "7. Refused" and enter a comment in "notes "field

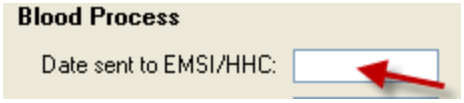


      ii. When participant refuses further participation in the entire CCSS, inform your supervisor about it and update the appropriate fields in Reg database
   c. Deceased participants
      i. When you receive signed consent by next of kin, update the Blood and Tissue form as it states in paragraph 5.a., additionally update the "Outcome" field with "38. Deceased" and make a note in "notes" field.
      ii. Inform your supervisor about this and update the appropriate fields in Reg. database
      iii. If the next of kin does not want to sign the B/T form, then you can still update the outcome fields to "deceased"

4. *Pursuing blood samples*
   a. Scheduling process with EMSI
      i. Generate a query that will populate participants that agreed to any of the blood options (and meet the other eligibility criteria). Make sure that the query contains the following information:
         1. CCSSID
         2. DOB
         3. First name and last name
         4. Full address
         5. Most current phone number

ii. Export this information into an Excel spreadsheet and then save in "csv" format.

iii. Send this spreadsheet to Mandy Burns from EMSI using St. Jude File Transfer Application (cc your supervisor). Her email address is maburns@emsinet.com.



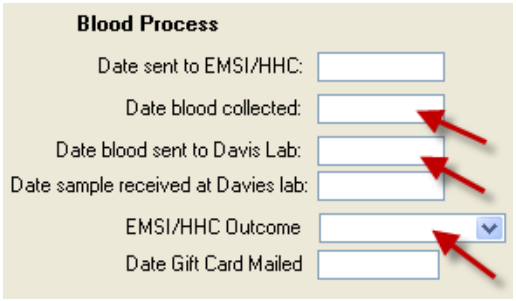
iv. Go to frmSMNTrack and update the "Date sent to EMSI/HHC" with the date when you sent email.

v. EMSI will send you daily schedule updates and bi-weekly you will receive status on every participant that was sent to EMSI to be scheduled

vi. ***Important –*** EMSI can only schedule the blood draw appointment from Monday through Thursday and the sample should be sent the same day to the LTFU Lab in Cincinnati

vii. You should receive the Site Contact Report Form from the EMSI examiner after blood has been drawn. Based on that information, update the following information in frmSMNTrack

1. "Date blood collected" - the date when blood was collected
2. "Date blood sent to Davis Lab" – the date when sample was send to Lab
3. "EMSI/HHC Outcome" – select "1. Collected"

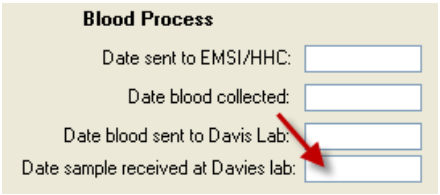


b. Blood sample received at LTFU Lab in Cincinnati.

i. After blood was collected and you updated the information in frmSMNTrack, the next step is to send an email to the LTFU lab (gretchen.radloff@cchmc.org) with the following information:

1. Participant CCSSID
2. The date when sample was shipped to the lab

ii. When lab receives sample, you will get email from them with a date sample received. Update then the "Date sample received at Davies lab" in frmSMNTrack



c. Participant refuses to give blood after signing the informed consent

i. It may happen that after signing the informed consent form the participant may refuse to give a blood sample when EMSI tries to schedule an appointment. In this case, you will need to update the following:

1. "EMSI/HHC Outcome" – select "2. Refused"
2. "Notes" – make a note that participant refused to give a blood while EMSI was trying to schedule an appointment. Enter date and your initials

d. EMSI unable to schedule blood draw appointment with participant
    i. EMSI may be unable schedule a blood draw appointment because:
        1. Participant is difficult to reach
        2. The phone numbers that we have are not correct
    ii. If three attempts go unacknowledged by the participant, EMSI will return the case to St. Jude Children Hospital via email notification.
        1. Create an Excel spreadsheet with these participants. See for example the spreadsheet called Follow_Up EMSI Calls located on the z:drive Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue. Send email to CCSS interviewer to notify them that cases have been added to the spreadsheet who need to be called (see procedure called Interviewer Follow-up with B/T Participants)
        2. CCSS interviewer will do follow up calls to participant to check what is the best time to call and schedule an appt
        3. If necessary, CCSS interviewer will schedule an blood draw appointment with the participant
        4. CRA will check the spreadsheet weekly and will send the updated information to EMSI
        5. If CCSS coordinating center is unable to schedule participant for the blood draw, select "3. Unable to contact" from the "EMSI/HHC Outcome" field and inform you supervisor about it
e. Unable to get blood
    i. It may happen that participant's vein conditions are bad and the phlebotomist is unable to draw blood. EMSI will notify us via email if this occurs.
    ii. Update the "EMSI/HHC Outcome" with "5. Unable to obtain blood". Inform supervisor too.

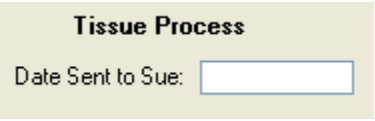
5. *Pursuing tissue samples*

Dr. Sue Hammond from Nationwide Hospital in Columbus will pursue the tissue samples. CCSS Coordinating Center at St. Jude will provide her with the necessary documents and information to start the process.

a. Generate a query that will populate participants that agreed to any of the tissue options. Make sure that the query contains the following information:
    i. CCSSID
    ii. First name and last name
    iii. Confirmed subsequent neoplasm along with the date of the diagnoses
    iv. Diagnosis and site codes
    v. Comments
b. Export this information into an Excel spreadsheet.
c. Create a batch of information that you will upload on St Jude Webshare. The batch needs to contain the following:
    i. Cover page with participant's CCSSID (hand written CCSSID is fine)

ii. Signed and dated informed consent form
iii. Any medical/pathology records that we have on the participant in the SMN folder (hard copy folders)

d. Open the frmSMNTrack and update the "Date Sent to Sue" field.



6. *Mailing the gift cards*

If participant agreed to provide a tissue specimen and/or blood specimen, he/she will receive a $50 gift card.

a. Mailing gift cards to the participants that agreed to blood and tissue or blood only options.
   i. Gift card will be mailed to these participants after the LFTU lab in Cincinattie receives the blood sample
   ii. Generate weekly appropriate query that will populate eligible participants
   iii. Prepare a cover letter that you can find here: Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue
   iv. Log gift card on "SMN Gift Card Tracking" spreadsheet placed : Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue
   v. Update the date "Date Gift Card Mailed" in frmSMNTrack

b. Mailing gift cards to the participants that agreed to tissue only options
   i. Gift card will be mailed to these participants that agreed to at least one of the tissue options (whether or not Sue is able to get a sample)
   ii. Generate weekly appropriate query that will populate eligible participants
   iii. Prepare a cover letter that you can find here: Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue
   iv. Log gift card on "SMN Gift Card Tracking" spreadsheet placed : Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue
   v. Update the date "Date Gift Card Mailed" in frmSMNTrack

Revision Record Printed 7/2/2015 7:01 AM

Current Filename:		SMN Blood and Tissue Process v2_0.doc	
Revision No.	Date	Responsible Author	Change Description
2.0	12/3/10	J.Dowdy	Initial Updated Development

Blood and Tissue Study Adding Expanded Cohort Cases

Background

CCSS participants that have a confirmed additional cancer are invited to participate in the Blood and Tissue study. Participants whose additional cancer is non-melanoma skin cancer are excluded from this study. Also, participants with a confirmed benign condition are excluded from the study, with the exception of the diagnosis of meningioma. Participants with a confirmed meningioma are asked to participate in the study.

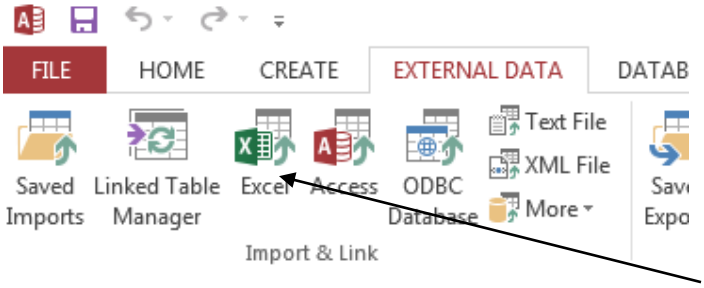
General Eligibility criteria

- Confirmed subsequent cancer/tumor/etc (non-melanoma skin CA not included) or meningioma
- 18 or over
- Alive
- Has not refused further participation in the study

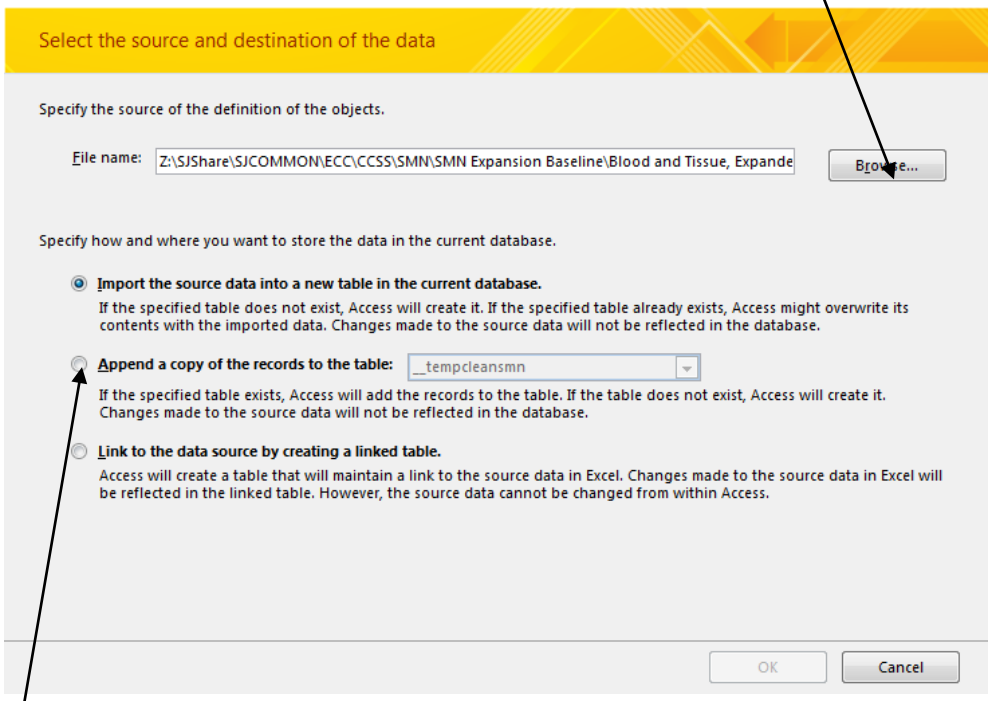
Procedure

1. *Checking for new eligible participants*
   a. In the Expansion Tracking database, run the query: Qry_bloodtissueeligible
   b. If there are any participants, save the file and export to: Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SMN Expansion Baseline\Blood and Tissue, Expanded Cohort\Blood and Tissue, new participants
   c. Remove any duplicate records from your list
   d. If a re-consent is needed (Reconsent Needed field is "YES") then check the Reconsent Outcome field to make sure the re-consent has been obtained
   e. Save the file adding a date extension.
   f. Once duplicates are removed and re-consent status has been checked, you are ready to append any new records into your Blood and Tissue table

2. *Appending New Records to Blood and Tissue:*
   a. On the Z drive, go to Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SMN Expansion Baseline\Blood and Tissue, Expanded Cohort\Blood and Tissue, new participants
   b. Open the template: appendtemplate New Blood and Tissue participants.xlsx
   c. Open the Qry_bloodtissueeligible that you just generated.
   d. Copy the information from the query spreadsheet to the append template, copying the fields: CCSSid, First Name, Last Name, DOB and Alive
   e. Save the append file using the extension with the current date
   f. In the Expansion Tracking database, under the tab External Data double click on the option Import Excel



g. You will see the following box: Click on the browse button and navigate to the folder where the append file you created in step d is saved; double click on the file



h. Click on the buton “Append a copy of the records to the table” and use the drop down menu to the right to select the table: TblBloodEligibleCases

i. Click Ok and continue until the records have been added.

j. You may wish to run the query Qry_bloodtissueeligible; if your new participants were added correctly, there should be no new names produced by the query

3. *Preparing the Blood and Tissue consent invitations:*

a. Go to Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SMN Expansion Baseline\Blood and Tissue, Expanded Cohort and open the word document: merge fields INTRO BLOOD-TISSUE LTR rev 6.17.14FINAL.

b. Enter today’s date. Load your printer so the letter will print on SJ Letterhead

c. You will do a mail merge to print individualized consent letters; the participants that you select will be those generated in the query created in Step 1 (make sure you have removed duplicates). Print the letters.

d. Next you will print the consent, merge fieldsCCSS Blood-Tissue Consent rev 20.1 found Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SMN Expansion Baseline\Blood and Tissue, Expanded Cohort. Use the mail merge to print individualized consents. Print front and back.
e. Staple the pages of the consent together, and include a "sign here" on the last page. You may also want to flag page 6 so the participants don't overlook where they are to check if they agree to the study. Print envelopes and assemble the packets:
   - Cover letter
   - Consent
   - Participant copy of the consent
   - Return envelope (include a label with your name and MS 735)
f. Mail the packets

4. *Document in the Database and Notify 4th floor*
   a. In Expansion Tracking, open the form frmSMNTracking
   b. Search for the participant using CCSSid
   c. In the Date Consent Sent field enter the day you mailed the consent
   d. Email the CCSSid's of the participants to Dayton's team on the 4th floor so they can follow up in several weeks with a phone call

Revision Record Printed 7/2/2015 7:06 AM

Current Filename:		Blood and Tissue Study Expanded Cohort v3_0.doc	
Revision No.	Date	Responsible Author	Change Description
2.0	12/3/10	J.Dowdy	Initial Updated Development
3.0	6/15/15	L.Harrison	Revised to SMN Blood and Tissue Process to limit to Expanded Cohort

Blood and Tissue Study: Blood Collection

Background

CCSS participants with a confirmed additional cancer, or meningioma, are asked to participate in the Blood and Tissue study. Participants whose only additional cancer is non-melanoma skin cancer are excluded from this study. Participants are asked to sign a consent and are given options to:

- Provide tissue for cancer research only
- Provide tissue for research concerning other health problems (non-cancerous)
- Provide a blood sample for cancer research
- Provide a blood sample for research concerning other health problems (non-cancerous)

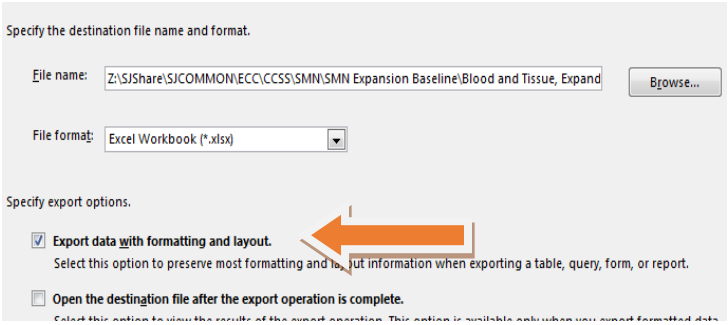
Participants may agree to any or all of the options (or decline all). The procedure to determine eligibility and invite participants is covered in **Blood and Tissue Study: Adding Expanded Cohort Cases**

1. *Receiving signed consents, participant's refusal or deceased participants*
    a. In the Expansion Tracking database, open the form: frmSMNTracking
    b. Review the form that has been mailed in:
    - Review page 6 to see which (if any) boxes the participant checked
    - Review the last page to see if the participant signed the form
    - Review the form for any handwritten notes (i.e. note from family that participant is deceased; a note indicating refusal)

Scenario	Date Resent Returned	Consent Granted	Outcome	Additional Action
Consent is returned, signed, with some or all boxes checked	Enter Date	Use drop down options to select what the participant selected	Blank	
Consent is returned, signed, with NO boxes checked	Enter Date	Leave blank		Notify 4th floor team and have them contact participant to verify what part(s) of the study they want to participate in
Consent is returned with boxes checked but no signature	Leave blank	Leave blank		Notify 4th floor team to contact participant and advise that we will be resending form for signature
Consent is returned with note of refusal	Leave blank	Declined All	7	If participant is refusing CCSS, also update LTFU database

Scenario	Date Resent Returned	Consent Granted	Outcome	Additional Action
Consent is returned with note from family that participant is deceased	Leave blank	If parents signed, we may be able to use form for tissue sample	38	If parent signed on behalf of participant, pursue tissue. If parent did not sign, consult with project manager concerning next course of action; update LTFU database with death information

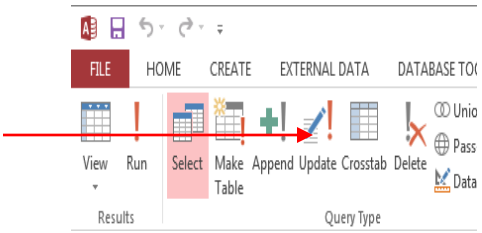
2. *Sending the thank you/gift card*
   - **a.** All participants who agree to participate in the study are sent a $50.00 gift card. Run the query qry_ThankYou_B&Tparticipant; save and export to Excel.
   - **b.** b. For this export you will need to check the option **Export data with formatting and layout.**



   - c. Save the query here: Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SMN Expansion Baseline\Blood and Tissue, Expanded Cohort\Thank you gift card
   - d. Use the Newmerged fields Blood Tissue Thank You Letter.docx to print your letters and the Envelope_Merged.docx for the envelopes; both found here: Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SMN Expansion Baseline\Blood and Tissue, Expanded Cohort\Thank you gift card
   - e. Follow Clin card procedures to assign cards
   - f. Mail cards and document the date you mailed them in the database

3. *Pursuing blood samples*
   - a. In the Expanded Tracking database, run the query: qry_For_EMSI. The query generates the list participants that agreed to any of the blood options (and meet the other eligibility criteria) and whose information has not already been sent to EMSI. Export this information into an Excel spreadsheet and save here: Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SMN Expansion Baseline\Blood and Tissue, Expanded Cohort\Information for EMSI.
   - b. Open the spreadsheet and delete the columns: I through P.

c. Add columns for phone numbers, phone type, and any pertinent notes EMSI might need for scheduling purposes.
d. Open the LTFU database, look up each participant and add their phone numbers (do not include phone numbers with a ranking of 9 or 37).
e. Go to the St. Jude Intranet and double click on the File Transfer Application; log in and click the Send File tab. You will send the file to the EMSI team
f. Update the field "Date sent to EMSI/HHC" with the date you sent email:
   - You may do this manually by opening each record or,
   - You may run an update query: select: qry_For_EMSI; right click your mouse and select design view; change the query to an update query;

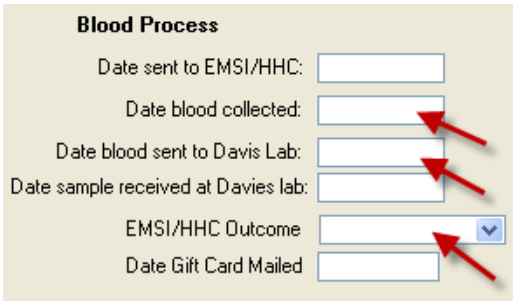


In the query, for DateToEMSI_HHC field, where the criteria "Is Null" enter the date you emailed to EMSI; run the query, don't save it.

DateConsentSent	DateResentReturned	ConsentGranted	DateToEMSI_HHC
tblBloodEligibleCases	tblBloodEligibleCases	tblBloodEligibleCases	tblBloodEligibleCases
Is Not Null	Is Not Null	<>"declined all" And	Is Null

Enter date

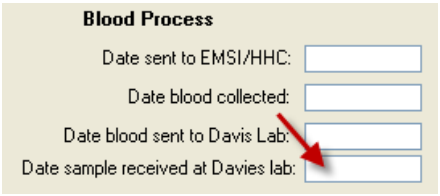
g. EMSI will send you daily schedule updates and bi-weekly you will receive status on every participant that was sent to EMSI to be scheduled
h. ***Important*** **–** EMSI can only schedule the blood draw appointment from Monday through Thursday and the sample should be sent the same day to the LTFU Lab in Cincinnati
i. You should receive the Site Contact Report Form from the EMSI examiner after blood has been drawn. Based on that information, update the following information in frmSMNTrack
   - "Date blood collected" - the date when blood was collected
   - "Date blood sent to Davis Lab" – the date when sample was send to Lab
   - "EMSI/HHC Outcome" – select "1. Collected"



b. Blood sample received at LTFU Lab in Cincinnati.
   a. After blood was collected and you updated the information in frmSMNTrack, the next step is to send an email to the LTFU lab (leslie.payton@cchmc.org) with the following information:

- Participant CCSSID
- The date when sample was shipped to the lab

b. When lab receives sample, you will get email from them with a date sample received. Update then the "Date sample received at Davies lab" in frmSMNTrack



c. Participant refuses to give blood after signing the informed consent
   a. It may happen that after signing the informed consent form the participant may refuse to give a blood sample when EMSI tries to schedule an appointment. In this case, you will need to update the following:
      - "EMSI/HHC Outcome" – select "2. Refused"
      - "Notes" – make a note that participant refused to give a blood while EMSI was trying to schedule an appointment. Enter date and your initials
d. EMSI unable to schedule blood draw appointment with participant
   a. EMSI may be unable schedule a blood draw appointment because:
      - Participant is difficult to reach
      - The phone numbers that we have are not correct
   b. If three attempts go unacknowledged by the participant, EMSI will return the case to St. Jude Children Hospital via email notification.
      - Create an Excel spreadsheet with these participants. See for example the spreadsheet called Follow_Up EMSI Calls located on the z:drive Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue. Send email to CCSS interviewer to notify them that cases have been added to the spreadsheet who need to be called (see procedure called Interviewer Follow-up with B/T Participants)
      - CCSS interviewer will do follow up calls to participant to check what is the best time to call and schedule an appt
      - If necessary, CCSS interviewer will schedule an blood draw appointment with the participant
      - CRA will check the spreadsheet weekly and will send the updated information to EMSI
      - If CCSS coordinating center is unable to schedule participant for the blood draw, select "3. Unable to contact" from the "EMSI/HHC Outcome" field and inform you supervisor about it
e. Unable to get blood
   a. It may happen that participant's vein conditions are bad and the phlebotomist is unable to draw blood. EMSI will notify us via email if this occurs.
   b. Update the "EMSI/HHC Outcome" with "5. Unable to obtain blood". Inform supervisor too.

Revision Record Printed 7/2/2015 6:48 AM

Current Filename:		Blood and Tissue Study: Blood Collecttion v3_0.doc	
Revision No.	Date	Responsible Author	Change Description
2.0	12/3/10	J.Dowdy	Initial Updated Development
3.0	6/16/15	L.Harrison	Major revision to SMN Blood and Tissue; revised queries and processes; excluded tissue pursuit

Breast Cancer Study: Database Queries

Background

The purpose of the Breast Cancer study is to learn more about the health history of females who were treated with chest radiation as a child. Research has shown that radiation to the chest area can increase a woman's risk of developing breast cancer. Specifically, we are studying factors that may influence the risk of breast cancer.

In this study there are four unique groups. These groups include females who received chest radiation and are alive or deceased and were or were not diagnosed with breast cancer. These groups are titled Alive Breast Cancer (BCAlive), Deceased Breast Cancer (BCDeceased), Alive No Breast Cancer (NoBCAlive), and Deceased No Breast Cancer (NoBCDeceased).

Using standard CCSS recruiting processes, we will mail each participant who is alive a group specific survey (BCAlive or NoBCAlive). For deceased participants, we will identify viable proxies to complete the group specific surveys (BCDeceased or NoBCDeceased). Potential proxies can be spouses, parents, or siblings (not necessarily a sibling LTFU participant)

While recruiting participants and proxies, it is highly likely that a participant's group status will change. For example, alive participants may now be deceased and/or participants identified as not having breast cancer may currently have or previously had breast cancer. This shift in status will not exclude a participant from the study. We will simply adjust the participants study group and recruit accordingly.

Database Design

The CCSS Breast Cancer database can be accessed via the **ECC Databases Switchboard**. The structure and design of the database is listed below.

- **CASE Tab**: Houses the contact information for Alive participants. The contact info here is connected directly to the Registration database. Any changes to this info (name, address, phone, email, etc) will be pushed to Reg and vice versa. *Note: If a participant is deceased, you will not be able to access this tab*.
- **PROXY Tab**: Contains the proxy contact information for Deceased participants. The proxy displayed on this tab has been identified as the proxy of choice for recruitment efforts (i.e. we are asking this proxy to complete the group specific survey). *Note: If a participant is alive, you will not be able to access this tab*.
- **PROXY IDENTIFICATION Tab**: Holds the tracing teams' efforts to identify viable proxies. Tracers are asked to find proxy contact information for each deceased participant and enter it here. Once proxies are identified, the study coordinator determines, on a case-by-case basis, which proxy is the most appropriate to contact.
- **TRACKING Tab**: Used to track the sending and receiving of surveys, study status, and responses to certain survey questions.
- **HIPAA-PATH-MR Tab**: Allows us to track a participant's HIPAA status and our medical record pursuit efforts.
- **ARCHIVE ADDRESSES Tab**: Contains participant addresses that have been archived (Alive participants and proxies).
- **PARENTS Tab**: Houses the contact information for a participant's parent that was entered into the Reg database. Any changes to this info (name, address, phone, etc) will be pushed to Reg and vice versa.
- **SPOUSE Tab**: Comprised of a participant's spouse contact information that was entered into the Reg database. Any changes to this info (name, address, phone, etc) will be pushed to Reg and vice versa.
- **ADDITIONAL CONTACT INFO Tab**: Holds additional contact information that was entered into the Reg database. Any changes to the *first record* (name, address, phone, etc) will be pushed to Reg and vice versa. Any subsequent records (2 of 4, 3 of 4, etc) will only be local to this database and will not be pushed to Reg.

Initial Mailing Queries

Qry_JF_MailingList_Alive

This query is used to identify alive participants who have not refused participation in the study/are not on hold, do not have an address tracing code (13 or 18), and have never been mailed a survey. (A variation of this query was used at the beginning of the study for the initial study mailing, which was based on Batch order as requested by the PI).

1. Run query
2. Export file to: Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings
3. Save as "qry_JF_MailingList_Alive n[#] m/d/yy"
4. Follow **Printing Breast Cancer Survey, Producing Mailing Materials, Assembling/QAing Mailing Materials** procedures
5. Search database by CCSSID and go to **TRACKING** tab
    a. Ideal when there are only a few CCSSIDs involved in mailing
6. Enter date of mailing in Current Group box **G[#] Date Sent**"
    a. Match the survey type and Group #

Qry_JF_MailingList_Proxies

This query is used to identify deceased participants who have a valid potential proxy who has not refused participation in the study/are not on hold, does not have an address tracing code (13 or 18), and has never been mailed a survey. (A variation of this query was used at the beginning of the study for the initial study mailing, which was based on Batch order as requested by the PI).

1. Run query
2. Export file to: Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings
3. Save as "qry_JF_MailingList_Proxies n[#] m/d/yy"
4. Follow **Printing Breast Cancer Survey, Producing Mailing Materials, Assembling/QAing Mailing Materials** procedures
5. Search database by CCSSID and go to **TRACKING** tab
    a. Ideal when there are only a few CCSSIDs involved in mailing
6. Enter date of mailing in Current Group box **G[#] Date Sent**
    a. Match the survey type and Group #

Resend Request Queries

Qry_JF_ResendRequest_Alive

This query is used to identify alive participants who have not changed group status and require a resend of a group specific survey.

1. Run query
2. Export file to Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\Resends
3. Save as "qry_JF_ResendRequest_Alive n[#] m/d/yy"
4. Follow **Printing Breast Cancer Survey, Producing Mailing Materials, Assembling/QAing Mailing Materials** procedures
5. Search database by CCSSID, go to **TRACKING** tab, and manually delete **Resend Request Date**
    a. Ideal when there are only a few CCSSIDs involved in resend
6. Enter date of mailing in next available Current Group box **G[#]Resend[#]**
    a. Match the survey type and Group #

Qry_JF_ResendRequest_Proxies

This query is used to identify deceased participants who have not changed group status and the proxy requires a resend of a group specific survey.

1. Run query
2. Export file to Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\Resends
3. Save as "qry_JF_ResendRequest_Proxies n[#] m/d/yy"
4. Follow **Printing Breast Cancer Survey, Producing Mailing Materials, Assembling/QAing Mailing Materials** procedures
5. Search database by CCSSID, go to **TRACKING** tab, and manually delete **Resend Request Date**
    a. Ideal when there are only a few CCSSIDs involved in resend
6. Enter date of mailing in next available Current Group box **G[#]Resend[#]**
    a. Match the survey type and Group #

Qry_JF_NoBCAlivetoBCAlive_Mailing Info

This query is used to identify alive participants who were in the No Breast Cancer group but we learned that the participant has been diagnosed with breast cancer via a No Breast Cancer paper survey or through communication with the participant (e.g. email, phone call, etc.)and requires an Alive with Breast Cancer survey.

1. Run query
2. Export file to Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\Group Status Change Mailings\Sent
3. Save as "qry_JF_NoBCAlivetoBCAlive_Mailing Info n[#] m/d/yy"
4. Open "Alive No BC to BC Letter 3-7-12 MERGED" located here: Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\Group Status Change Mailings
    a. Mailmerge with "qry_JF_NoBCAlivetoBCAlive_Mailing Info n[#] m/d/yy", update "Date" field, and print
5. Follow **Printing Breast Cancer Survey, Producing Mailing Materials, Assembling/QAing Mailing Materials** procedures
6. Insert printed "Alive No BC to BC Letter 3-7-12 MERGED" in white LTFU envelope on top of survey
7. Search database by CCSSID and go to **TRACKING** tab
    a. Ideal when there are only a few CCSSIDs involved in mailing
8. Enter date of mailing in Current Group box **G[#] Date Sent**
    a. Match the survey type and Group #

Qry_JF_NoBCDeceasedtoBCDeceased_Mailing Info

This query is used to identify deceased participants who were in the No Breast Cancer group but we learned via a No Breast Cancer paper survey or through communication with a proxy that the participant was diagnosed with breast cancer and the proxy requires a Deceased with Breast Cancer survey.

1. Run query
2. Export file to Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\Group Status Change Mailings\Sent
3. Save as "qry_JF_NoBCDeceasedtoBCDeceased_Mailing Info n[#] m/d/yy"
4. Open **Deceased No BC to BC Letter 3-7-12 MERGED** located here: Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\Group Status Change Mailings
    a. Mailmerge with "qry_JF_NoBCDeceasedtoBCDeceased_Mailing Info n[#] m/d/yy", update "Date" field, and print
5. Follow **Printing Breast Cancer Survey, Producing Mailing Materials, Assembling/QAing Mailing Materials** procedures
6. Insert printed "Deceased No BC to BC Letter 3-7-12 MERGED" in white LTFU envelope on top of survey
7. Search database by CCSSID and go to **TRACKING** tab
    a. Ideal when there are only a few CCSSIDs involved in mailing
8. Enter date of mailing in Current Group box **G[#] Date Sent**
    a. Match the survey type and Group #

Qry_JF_AlivetoDeceased_Mailing Info

This query is used to identify participants who were thought to be alive but we learned via communication with a proxy (e.g. note on paper survey, phone call, etc.) that the participant is now deceased and a viable proxy has been identified to complete a survey.

1. Run query
2. Export file to Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\Group Status Change Mailings\Sent
3. Save as "qry_JF_AlivetoDeceased_Mailing Info n[#] m/d/yy"
4. Open **Alive to Deceased Letter 3-7-12 MERGED** located here: Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\Group Status Change Mailings
    a. Mailmerge with "qry_JF_AlivetoDeceased_Mailing Info n[#] m/d/yy", update "Date" field, and print
5. Follow **Printing Breast Cancer Survey, Producing Mailing Materials, Assembling/QAing Mailing Materials** procedures
6. Insert printed "Alive to Deceased Letter 3-7-12 MERGED" in white LTFU envelope on top of survey
7. Search database by CCSSID and go to **TRACKING** tab
    a. Ideal when there are only a few CCSSIDs involved in mailing
8. Enter date of mailing in Current Group box **G[#] Date Sent**
    a. Match the survey type and Group #

Managing HIPAA Status Queries

Qry_JF_CompletedSurvey_NeedHIPAA

This query is used to identify alive participants who have completed all study surveys, either reported a breast biopsy or reported a diagnosis of breast cancer (prior to or during the current study), and have yet to sign/refuse to sign a LTFU HIPAA.

1. Run query
2. Determine which CCSSIDs require a HIPAA resend (compare current date to **HIPAAResend[#] date**)
    a. If current date is > 60 days of last **HIPAAResend[#]** date:
        i. Search database by CCSSID
        ii. Go to **HIPAA-PATH-MR** tab
        iii. Enter current date in **HIPAA Resend Request** field

Qry_JF_HIPAARequests

This query is used to identify alive participants who have completed a survey, either reported a breast biopsy or reported a diagnosis of breast cancer (prior to or during the current study), have yet to sign/refuse to sign a LTFU HIPAA, and a "HIPAA Resend Request" has been entered.

1. Run query
2. Export file to Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\HIPAA Requests
3. Save as "qry_JF_HIPAARequests n[#] m/d/yy"
4. Open **LTFU HIPAA_MERGED 4-3-12** located here: Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\HIPAA Requests
    a. Mailmerge with "qry_JF_HIPAARequests n[#] m/d/yy" and print

5. Open **BC Study HIPAA Request Cover Letter_MERGED 1-19-12** located here: Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\!Mailings\HIPAA Requests
    a. Mailmerge with "qry_JF_HIPAARequests n[#] m/d/yy", update "Date" field, and print

6. Print **BC HIPAA-WithWatermark**
    a. Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)
    b. Pre-printed copies may be in the storage room

7. Combine cover letter, HIPAA, and participant copy with #9 return address envelope and insert into #10 St. Jude mailing envelope
    a. Envelope type (1st Class or International) depends upon the participant's mailing address
        i. Remember to use Canadian postage as needed

8. Search database by CCSSID and go to **HIPAA-PATH-MR** tab
    a. Ideal when there are only a few CCSSIDs involved in mailing

9. Enter date of mailing in next available **HIPAA Resend[#]** field

Revision Record Printed 7/13/2012 11:07 AM

Current Filename:		Breast Cancer Study-Database Queries ver2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	2-7-12	J.Ford	Initial Development
2	5-16-12	J.Ford	Updates

Breast Cancer Study: Distribution and Processing Surveys

Background

The purpose of the Breast Cancer study is to learn more about the health history of females who were treated with chest radiation as a child. Research has shown that radiation to the chest area can increase a woman's risk of developing breast cancer. Specifically, we are studying factors that may influence the risk of breast cancer.

In this study there are four unique groups. These groups include females who received chest radiation and are alive or deceased and were or were not diagnosed with breast cancer. These groups are titled Alive Breast Cancer (BCAlive), Deceased Breast Cancer (BCDeceased), Alive No Breast Cancer (NoBCAlive), and Deceased No Breast Cancer (NoBCDeceased).

Using standard CCSS recruiting processes, we will mail each participant who is alive a group specific survey (BCAlive or NoBCAlive). For deceased participants, we will identify viable proxies to complete the group specific surveys (BCDeceased or NoBCDeceased). Potential proxies can be spouses, parents, or siblings (not necessarily a sibling LTFU participant)

While recruiting participants and proxies, it is highly likely that a participant's group status will change. For example, alive participants may now be deceased and/or participants identified as not having breast cancer may currently have or previously had breast cancer. This shift in status will not exclude a participant from the study. We will simply adjust the participants study group and recruit accordingly.

Procedures

Printing Breast Cancer Survey

Note: There are four print tables in the database. All participants are located in all four print tables. ***Check, double check, and triple check*** *your production file to make sure you are using the appropriate print table.*

1. Open the CCSS Breast Cancer database (Use the **ECC Databases Switchboard**).
2. Based upon your production file **CurrentGroup** status, open **AutoMerge Publisher** and "enable" the appropriate survey:
    a. 

= "CurrentGroup 1" (Alive NO Breast Cancer)
        i. Print in standard Booklet style
    b. 

= "CurrentGroup 2" (Alive Breast Cancer)
        i. Print in standard Booklet style
    c. 

= "CurrentGroup 3" (Deceased No Breast Cancer)
        i. Print Two-Sided
    d. 

= "CurrentGroup 4" (Deceased Breast Cancer)
        i. Print in standard Booklet style
3. Based upon your production file group status, open the appropriate print table:
    a. tblPrintNoBCAlive
    b. tblPrintBCAlive
    c. tblPrintNoBCProxy
    d. tblPrintBCProxy
4. Using production file, locate participant in print table by "SEQ_NUM" or "CCSSID"
5. Enter a "23" in the **Record_Sta** field
6. Verify that surveys printed correctly (i.e. participant/proxy name, password, CCSSID are visible; questions and responses are not missing, etc)

Producing Mailing Materials

Breast Cancer and No Breast Cancer ALIVE Groups	Breast Cancer and No Breast Cancer DECEASED Groups
1. Print BC HIPAA-WithWatermark a. Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin) b. Pre-printed copies may be in the storage room 2. Mailmerge production file with Mailing Labels Alive 5163 MERGE a. Place labels on White LTFU 1st Class mailer 3. Print STOP 5163 labels-ALIVE a. Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin) b. Pre-printed copies may be in the storage room 4. Affix STOP labels on back of LTFU blue return address envelope a. Blue BRE for US addresses b. Blue Non-BRE for international addresses i. See Jerry Bates for Canadian postage	1. Mailmerge production file with Mailing Labels Proxies 5163 MERGE a. Place labels on White LTFU 1st Class mailer 2. Print STOP 5163 labels-DECEASED a. Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin) b. Pre-printed copies may be in the storage room 3. Affix STOP labels on back of LTFU blue return address envelope a. Blue BRE for US addresses b. Blue Non-BRE for international addresses i. See Jerry Bates for Canadian postage

Assembling/QAing Mailing Materials

1. Insert documents into the White LTFU 1st Class mailer in the following order and facing the rear of the envelope:
    a. Survey
    b. Participant copy of HIPAA
        i. Alive participants only
    c. Return address envelope

2. QAing involves a full inspection of materials for at least 10% of the participants; ensure all materials are present for the remaining 90%
    a. Go back to the database and compare the address on the envelope to the address on file for a handful of participants.

Processing Returned Surveys

1. Open the CCSS Breast Cancer database
2. Remove survey from envelope and data stamp cover page using date on the return envelope
    a. If any contact info is listed on the return envelope or on the survey, update the contact info date, source, etc. on appropriate tab (CASE/PROXY) using standard CCSS data entry procedures
3. Search for CCSSID
4. Go to "TRACKING" tab
5. Update appropriate "G[#] Date Received" and "G[#] Source" fields, based upon survey type
6. Subsequent data entry is based upon survey type (see below)

PROCESSING RETURNED SURVEYS: Group 1: Alive NO Breast Cancer survey

1. Go to **TRACKING** tab
2. Update **Early Biopsy** field (**survey page 6 question 11**)
   a. If the participant answered "Unsure," inform the CRA overseeing the study
3. Update **Breast Cancer** field (**survey page 10 question 31**)
   a. If the participant answered "Yes" or "Unsure" to a relapse of breast cancer, inform the CRA overseeing the study
4. Go to **HIPAA-PATH-MR** tab
5. Open survey to **page** 2 and see if participant signed HIPAA
   a. If yes: (If the following fields contain a date prior to the date associated with the current survey, do not replace the older dates; add a note to the **HIPAA Notes** field "m/d/yy: HIPAA signed m/d/yy on BC survey [initials]")
      i. Update **HIPAA Status** to 3 Received
      ii. Update **HIPAA Date Received** and **HIPAA Date Signed** fields
   b. If no: (AND the **HIPAA Date Received** AND **HIPAA Date Signed** fields are blank)
      i. Enter the current date in "**HIPAA Resend Request**" field
6. If the participant answered "**Yes" to an early breast biopsy (question 11),** go to **MEDICAL RECORD Tracking** section: *If multiple institutions are listed, repeat the following steps for EACH institution*
   a. Select Biopsy Letter in the **MR Letter Type:** field
   b. Enter all "Institution" information from survey in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Institution" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
      i. If blank on survey, enter note in **MRNotes**: section "m/d/yy: institution information for early breast biopsy diagnosis not provided [initials]"
   c. Enter any additional notes from the survey in the **MRNotes**: section (e.g. "I had 3 biopsies from St. Jude and 1 at MSK; my biopsy showed a malignant lump; etc.)

7. If the participant answered "**Yes" to a relapse of breast cancer (question 31),** go to the **PATH Tracking** section and enter a note "m/d/yy: participant reported relapse of breast cancer in m/d/yy [initials]"
   a. If any "Institution" (diagnosis, treatment, etc.) information is provided, go to **MEDICAL RECORD Tracking** section: *If multiple institutions are listed, repeat the following steps for EACH institution*
      i. Select MR Letter"in the **MR Letter Type**: field
      ii. Update **Month** and **Year** of diagnosis from question 31
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: month [and/or] year of breast cancer relapse not provided [initials]"
      iii. Enter any "Institution" information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s)
      iv. Enter a note in the **MR Notes** section "m/d/yy: participant reported relapse of breast cancer [initials]"
8. Go to **page 12 question "Where was your breast cancer diagnosed?"**
   a. Go to **MEDICAL RECORD Tracking** section and enter **Hospital/Doctors' Name** (If blank, inform CRA overseeing the study): *If multiple hospitals are listed, repeat the following steps for EACH hospital*
      i. Select MR Letter in the **MR Letter Type**: field
      ii. Update **Month** and **Year** of diagnosis from question 18 (page 8)
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: month [and/or] year of breast cancer diagnosis not provided [initials]"
      iii. Enter all "Hospital" information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Hospital" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: hospital information for breast cancer diagnosis not provided [initials]"
      iv. Enter any additional notes from the survey in the **MRNotes**: section (e.g. First diagnosis of breast cancer at XX hospital and second at XX hospital; diagnosed by Dr. John Doe; etc.)
9. Go to **page 12 question "Where was your breast cancer treated?"**
   a. Go to **MEDICAL RECORD Tracking** section and enter **Hospital/Doctors' Name** (If blank, inform CRA overseeing the study): *If multiple hospitals are listed, repeat the following steps for EACH hospital*
      i. Select MR Letter in the **MR Letter Type:** field
      ii. Enter all "Hospital" information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Hospital" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: hospital information for breast cancer diagnosis not provided [initials]"
   b. Enter any additional notes from the survey in the **MRNotes**: section (e.g. First diagnosis of breast cancer at XX hospital and second at XX hospital; diagnosed by Dr. John Doe; etc.)
10. Initial and date front of survey
11. Place in Orange cabinet according to survey type and in CCSSID order for further processing or if previously noted, give survey to CRA overseeing study

PROCESSING RETURNED SURVEYS Group 2: Alive Breast Cancer

1. Go to **TRACKING** tab
2. Update **Early Biopsy** field (**survey page 6 question 11**)
   a. If the participant answered "Unsure," inform the CRA overseeing the study
3. Update **Breast Cancer** field (**survey page 10 question 31**)
   a. If the participant answered "Yes" or "Unsure" to a relapse of breast cancer, inform the CRA overseeing the study
4. Go to **HIPAA-PATH-MR** tab
5. Open survey to **page** 2 and see if participant signed HIPAA
   a. If yes: (If the following fields contain a date prior to the date associated with the current survey, do not replace the older dates; add a note to the **HIPAA Notes** field "m/d/yy: HIPAA signed m/d/yy on BC survey [initials]")
      i. Update **HIPAA Status** to 3 Received
      ii. Update **HIPAA Date Received** and **HIPAA Date Signed** fields
   b. If no: (AND the **HIPAA Date Received** AND **HIPAA Date Signed** fields are blank)
      i. Enter the current date in "**HIPAA Resend Request**" field
6. If the participant answered "**Yes" to an early breast biopsy (question 11),** go to **MEDICAL RECORD Tracking** section: *If multiple institutions are listed, repeat the following steps for EACH institution*
   a. Select Biopsy Letter in the **MR Letter Type:** field
   b. Enter all "Institution" information from survey in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Institution" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
      i. If blank on survey, enter note in **MRNotes**: section "m/d/yy: institution information for early breast biopsy diagnosis not provided [initials]"
   c. Enter any additional notes from the survey in the **MRNotes**: section (e.g. "I had 3 biopsies from St. Jude and 1 at MSK; my biopsy showed a malignant lump; etc.)
7. If the participant answered "**Yes" to a relapse of breast cancer (question 31),** go to the **PATH Tracking** section and enter a note "m/d/yy: participant reported relapse of breast cancer in m/d/yy [initials]"
   a. If any "Institution" (diagnosis, treatment, etc.) information is provided, go to **MEDICAL RECORD Tracking** section: *If multiple institutions are listed, repeat the following steps for EACH institution*
      i. Select MR Letter"in the **MR Letter Type**: field
      ii. Update **Month** and **Year** of diagnosis from question 31
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: month [and/or] year of breast cancer relapse not provided [initials]"
      iii. Enter any "Institution" information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s)
      iv. Enter a note in the **MR Notes** section "m/d/yy: participant reported relapse of breast cancer [initials]"
8. Go to **page 12 question "Where was your breast cancer diagnosed?"**
   a. Go to **MEDICAL RECORD Tracking** section and enter **Hospital/Doctors' Name** (If blank, inform CRA overseeing the study): *If multiple hospitals are listed, repeat the following steps for EACH hospital*
      i. Select MR Letter in the **MR Letter Type**: field
      ii. Update **Month** and **Year** of diagnosis from question 18 (page 8)
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: month [and/or] year of breast cancer diagnosis not provided [initials]"
      iii. Enter all "Hospital" information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Hospital" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: hospital information for breast cancer diagnosis not provided [initials]"
      iv. Enter any additional notes from the survey in the **MRNotes**: section (e.g. First diagnosis of breast cancer at XX hospital and second at XX hospital; diagnosed by Dr. John Doe; etc.)
9. Go to **page 12 question "Where was your breast cancer treated?"**
   a. Go to **MEDICAL RECORD Tracking** section and enter **Hospital/Doctors' Name** (If blank, inform CRA overseeing the study): *If multiple hospitals are listed, repeat the following steps for EACH hospital*
      i. Select MR Letter in the **MR Letter Type:** field
      ii. Enter all "Hospital" information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Hospital" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: hospital information for breast cancer diagnosis not provided [initials]"
   b. Enter any additional notes from the survey in the **MRNotes**: section (e.g. First diagnosis of breast cancer at XX hospital and second at XX hospital; diagnosed by Dr. John Doe; etc.)
10. Initial and date front of survey
11. Place in Orange cabinet according to survey type and in CCSSID order for further processing or if previously noted, give survey to CRA overseeing study

PROCESSING RETURNED SURVEYS: Group 3: Deceased NO Breast Cancer

1. Go to **page 2 question "Person completing this questionnaire is:"**
   a. If the printed name on the survey does not match the name of the proxy on the cover letter, inform the CRA overseeing the study
2. Go to **TRACKING** tab

3. Update **Breast Cancer** field (**survey page 2 question 1**)
   a. If the proxy answered "Yes" or "Unsure," inform the CRA overseeing the study
4. Update **Biopsy** field (**page 2 question 4**)
   a. If the proxy answered "Unsure," inform the CRA overseeing the study

5. If the proxy answered **"Yes" to a diagnosis of breast cancer (question 1)** go to the **MEDICAL RECORD Tracking** section: *If multiple institutions are listed, repeat the following steps for EACH institution*

   a. Select MR Letter in the **MR Letter Type:** field
   b. Update **Mont**" and **Year** fields
      i. If blank on survey, enter note in **MRNotes**: section "m/d/yy: month [and/or] year of breast cancer diagnosis not provided [initials]"
   c. Enter all "Institution" information from survey in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Institution" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
      i. If blank on survey, enter note in **MRNotes**: section "m/d/yy: institution information for breast cancer diagnosis not provided [initials]"
   d. Enter any additional notes from the survey in the **MRNotes**: section (e.g. She was diagnosed with breast cancer in both breasts; She received treatment at St. Jude; etc.)

6. If the proxy answered **"Yes" to a breast biopsy (question 4)** go to the **MEDICAL RECORD Tracking** section: *If multiple institutions are listed, repeat the following steps for EACH institution*

   a. Select Biopsy Letter in the **MR Letter Type**: field
   b. Enter all "Institution" information from survey in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Institution" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
      i. If blank on survey, enter note in **MRNotes**: section "m/d/yy: institution information for breast biopsy not provided [initials]"
   c. Enter any additional notes from the survey in the **MRNotes**: section (e.g. She had 3 biopsies from St. Jude and 1 at MSK; Her biopsy showed a malignant lump; etc.)

7. Initial and date front of survey

8. Place in Orange cabinet according to survey type and in CCSSID order for further processing or if previously noted, give survey to CRA overseeing study

PROCESSING RETURNED SURVEYS: Group 4: DECEASED Breast Cancer

1. Go to **TRACKING** tab
2. Update **Early Biopsy** field (**survey page 3 question 11**)
   a. If the proxy answered "Unsure," inform the CRA overseeing the study
3. Update **Breast Cancer** field (**page 8 question 31**)
   a. If the proxy answered "Yes" to a relapse of breast cancer, inform the CRA overseeing the study

4. Go to **HIPAA-PATH-MR** tab
5. If the proxy answered "Yes" to an early breast biopsy, go to **MEDICAL RECORD Tracking** section: *If multiple institutions are listed, repeat the following steps for EACH institution*

   a. Select Biopsy Letter in the **MR Letter Type**: field
   b. Enter all "Institution" information from survey in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Institution" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
      i. If blank on survey, enter note in **MRNotes**: section "m/d/yy: institution information for breast biopsy not provided [initials]"
   c. Enter any additional notes from the survey in the **MRNotes**: section (e.g. She had 3 biopsies from St. Jude and 1 at MSK; Her biopsy showed a malignant lump; etc.)

6. If the proxy answered **"Yes" to a relapse of breast cancer (question 31)**, go to the **PATH Tracking** section and enter a note "m/d/yy: proxy reported relapse of breast cancer in m/d/yy [initials]"

   a. If any institution (diagnosis, treatment, etc.) information is provided, go to **MEDICAL RECORD Tracking** section: *If multiple institutions are listed, repeat the following steps for EACH institution*
      i. Select MR Letter in the **MR Letter Type**: field
      ii. Update **Month** and **Year** of diagnosis from question 31
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: month [and/or] year of breast cancer relapse not provided [initials]"
      iii. Enter any institution information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s)
      iv. Enter a note in the **MRNotes** section "m/d/yy: proxy reported relapse of breast cancer [initials]"

7. Go to **page 8 question "Where was her breast cancer diagnosed?"**
   a. Go to **MEDICAL RECORD Tracking** section and enter **Hospital/Doctors' Name** (If blank, inform CRA overseeing the study): *If multiple institutions are listed, repeat the following steps for EACH institution*
      i. Select MR Letter in the **MR Letter Type**:" field
      ii. Update **Month** and **Year** of diagnosis from question 18 (page 5)
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: month [and/or] year of breast cancer diagnosis not provided [initials]"
      iii. Enter all "Hospital" information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Hospital" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: hospital information for breast cancer diagnosis not provided [initials]"
      iv. Enter any additional notes from the survey in the **MRNotes**: section (e.g. First diagnosis of breast cancer at XX hospital and second at XX hospital; diagnosed by Dr. John Doe; etc.)

8. Go to **page 8 question "Where was her breast cancer treated?"**
   a. Go to **MEDICAL RECORD Tracking** section and enter **Hospital/Doctors' Name** (If blank, inform CRA overseeing the study): *If multiple hospitals are listed, repeat the following steps for EACH hospital*
      i. Select MR Letter in the **MR Letter Type**: field
      ii. Enter all "Hospital" information in the **ClinicName**:/**Phone**:/**Street**:/**City**:/**State**:/**Zip**:/**Country**: field(s); *If the "Hospital" information is blank, confusing, or only partially complete, inform the CRA overseeing the study*
         1. If blank on survey, enter note in **MRNotes**: section "m/d/yy: hospital information for breast cancer diagnosis not provided [initials]"
   b. Enter any additional notes from the survey in the **MRNotes**: section (e.g. First diagnosis of breast cancer at XX hospital and second at XX hospital; diagnosed by Dr. John Doe; etc.)

9. Initial and date front of survey

10. Place in Orange cabinet according to survey type and in CCSSID order for further processing or if previously noted, give survey to CRA overseeing study

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1	2-7-12	J.Ford	Initial Development
2	5-16-12	J.Ford	Updates
2.1	5/22/12	J.Bates	Formatting

Breast Cancer Study: Managing Group Status

Background

The purpose of the Breast Cancer study is to learn more about the health history of females who were treated with chest radiation as a child. Research has shown that radiation to the chest area can increase a woman's risk of developing breast cancer. Specifically, we are studying factors that may influence the risk of breast cancer.

In this study there are four unique groups. These groups include females who received chest radiation and are alive or deceased and were or were not diagnosed with breast cancer. These groups are titled Alive Breast Cancer (BCAlive), Deceased Breast Cancer (BCDeceased), Alive No Breast Cancer (NoBCAlive), and Deceased No Breast Cancer (NoBCDeceased).

Using standard CCSS recruiting processes, we will mail each participant who is alive a group specific survey (BCAlive or NoBCAlive). For deceased participants, we will identify viable proxies to complete the group specific surveys (BCDeceased or NoBCDeceased). Potential proxies can be spouses, parents, or siblings (not necessarily a sibling LTFU participant)

While recruiting participants and proxies, it is highly likely that a participant's group status will change. For example, alive participants may now be deceased and/or participants identified as not having breast cancer may currently have or previously had breast cancer. This shift in status will not exclude a participant from the study. We will simply adjust the participants study group and recruit accordingly.

Procedures

Managing Group Status Changes

Each participant was assigned a group status code at the beginning of the study. When a participant's group status changes (e.g. Alive to Deceased; No Breast Cancer to with Breast Cancer, etc.), several pieces of information must be updated in the database. Notification of the status change could be from a survey interview (SI) call with the participant or family member (potential proxy), via a note returned with a blank/completed survey, through the online survey system, etc. All group status updates will share common data entry, but subsequent data entry will depend upon if the participant shifted to the deceased group and/or if the survey was completed by the participant/proxy.

Updating Group Status

1. Open form **frmAdmin**
2. Click **Show/Edit Individual Group History**
3. Search by CCSSID
4. Update **Current Group**: code
    a. 1 NoBC_Alive = Alive NO Breast Cancer
    b. 2 BC_Alive = Alive Breast Cancer
    c. 3 NoBC_Deceased = Deceased No Breast Cancer
    d. 4 BC_Deceased = Deceased Breast Cancer
5. Enter current date in **Date Placed in Current Group**:
6. Add a note to **Group History Notes:** *m/d/yy: updated group status to [X] based upon [survey response; note from proxy; SI call, etc.] [initials]*
7. Close form. Proceed as follows, depending on the type of change in group status:
    a. Changing Alive to Deceased
    b. Changing Alive NO BC to Alive WITH BC
    c. Changing Deceased NO BC to Deceased WITH BC

Changing ALIVE to DECEASED Data Entry (after updating Group Status)

1. Go to **PROXY IDENTIFICATION** tab
   a. Enter the contact information for the individual who reported the death in the following fields (as available) **ProxyName**, **Proxy Address**, **ProxyCity/State/Zip**, **Address Date/Source**; **Rank**, **Phone/Email**, **Date**, **Source**
   b. Enter a note in **Proxy ID Notes**:
      i. If the individual did not refuse further contact from LTFU, add a note such as *m/d/yy: activated proxy per [SI/survey/note/etc.]; John Doe reported that pt died on m/d/yy… [initials]*
      ii. If the individual did refuse further contact from LTFU, add a note such as: *m/d/yy: per [SI/survey/note/etc.], John Doe reported that pt died on m/d/yy; refused further participation in LTFU [initials]*
   c. Update **Proxy ID Outcome**: to 1 Confirmed
   d. Update **Proxy ID Outcome Date** to date notification received
   e. Update **Relationship**

2. Open form **frmAdmin.** Click **Maintain Proxy**
   a. Search by CCSSID
   b. Verify that the proxy name that was entered is visible

   c. Update **ProxyStatus**
      i. 2 Refused: Use if individual refused future contact with LTFU
         1. Leave **ProxyID** blank
         2. Enter the current date in the **ProxyStatusDate** field
         3. Close **Maintain Proxy** form
         4. *STOP HERE. Do NOT proceed* to NEXT STEP; a viable proxy must be identified before moving forward (PROCESS TO BE DEVELOPED)

      ii. 1 Confirmed contact updated: Use if individual appears to be a valid potential proxy (i.e. did not refuse to participate)
         1. In the **ProxyID** field, enter the participant's CCSSID and "-1" (e.g. 1111111-1)
         2. Enter the current date in the **ProxyStatusDate** field
         3. Close **Maintain Proxy** form
         4. Proceed to appropriate NEXT STEP, depending on whether proxy completed survey or not.
            a. Proxy did NOT complete and did NOT refuse, or
            b. Proxy completed PAPER survey, or
            c. Proxy completed ONLINE survey

*3. NEXT STEP: If Proxy **DID NOT COMPLETE** the survey and **DID NOT REFUSE** participation:*

a. Go to **CCSS Breast Cancer Main** form
b. Place cursor in **CCSSID** field and refresh screen (press F5 or click **Refresh All**)
c. Search by CCSSID
d. Go to **PROXY** tab
   i. Verify that the proxy name that was entered is visible in **ProxyName.** NOTE: If blank, re-verify that your Maintain Proxy process was complete. You may need to repeat it.
   ii. Click **Update Proxy print table NAME** button
e. Go to **TRACKING** tab. Determine if proxy recruiting should be placed on hold or if a deceased survey can be sent:
   i. Place on hold? (e.g. participant recently passed away and proxy did not refuse to participate)
      a. Update **BC Outcome Code** to 3
      b. Enter current date in **BC Outcome Date**
      c. Add note to **Tracking Notes:** *m/d/yyy: received notification from [proxy name] that participant passed away on m/d/yy; placed case on hold [initials]*
   ii. Send survey? (e.g. participant did not recently pass away and proxy did not refuse to participate or participant recently passed away and proxy expressed a willingness to help)
      a. Enter current date in **Resend Request Date**
      b. Add note to **Tracking Notes**: *m/d/yyy: received notification from [proxy name] that participant passed away on m/d/yy and is willing to participate [initials]*
f. Notify Christie Cooper via email that participant is now deceased and needs new datstat password. Include CCSSID and new group status in the email. She will notify you after datstat and database are updated

*4. NEXT STEP: If the proxy completed the **PAPER** survey:*

a. Go to **CCSS Breast Cancer Main** form. Place cursor in **CCSSID** field and refresh the screen (press F5 or click **Refresh All**)
b. Go to **TRACKING** tab. Update the *previous* Current Group box **G[#] Date Received** and **G [#] Source.** Match paper survey type and Group #
c. Notify Christie Cooper via email that participant is now deceased and needs new datstat password. Include CCSSID and new group status in email
d. *Once a new password is generated,*
   i. Login to the online survey and complete it using the data from the paper survey
   ii. Go to **TRACKING** tab and update Current Group box **G[#] Date Sent/G[#] Date Received** (use the date you submitted the online survey for both fields) and **G [#] Source.** Match the survey type and Group #
   iii. Add a note to **Tracking Notes**: such as *m/d/yy: [proxy name] completed [survey name] on paper; answers from paper survey entered into online [survey name] [initials]*
   iv. Continue data entry following steps from Processing Returned Surveys Procedure

*5. NEXT STEP: If the proxy completed the **ONLINE** survey:*

a. Go to **CCSS Breast Cancer Main** form. Place cursor in "**CCSSID**" field and refresh the screen (press F5 or click **Refresh All**)
b. Go to **TRACKING** tab and update *previous* Current Group box **G[#] Date Received** and **G [#] Source**
c. Update the Current Group box **G[#] Date Sent/G[#] Date Received** (date online survey submitted for both fields) and **G [#] Source**. Be sure to match the survey type and Group #
d. Add a note to **Tracking Notes**: such as *m/d/yy: [proxy name] completed online [survey name]*
e. Continue data entry following steps from Processing Returned Surveys Procedure

Changing Alive NO Breast Cancer to WITH Breast Cancer (after updating Group Status)

1. *If a participant in the Alive No Breast Cancer group reports a diagnosis of breast cancer but **did not complete a survey**:*
   a. Search by CCSSID
   b. Go to **TRACKING** tab
   c. Update **Self-Reported Breast Cancer** field to 1 (Y)
   d. Enter the current date in **Resend Request Date**
2. *If a participant in the Alive No Breast Cancer group completed the **PAPER** survey*:
   a. Search by CCSSID
   b. Go to **TRACKING** tab
   c. Verify that **Processing Returned Surveys** procedures were followed
   d. Enter the current date in **Resend Request Date**
3. *If a participant in the Alive No Breast Cancer group completed the **ONLINE** survey*:
   a. Search by CCSSID
   b. Go to **TRACKING** tab
   c. Update the *previous* Current Group box **G[#] Date Received** and **G [#] Source**
   d. Update the *Current* Group box **G[#] Date Sent/G[#] Date Received** (date online survey submitted for both fields) and **G [#] Source**. Be sure to match the survey type and Group #
   e. Continue data entry following steps from **Processing Returned Surveys** Procedure

Changing Deceased NO Breast Cancer to WITH Breast Cancer (after updating Group Status)

1. *If a proxy or potential proxy for a participant in the Deceased No Breast Cancer group reports a diagnosis of breast cancer and **completed the PAPER NO Breast Cancer survey***:
   a. Search by CCSSID
   b. Go to **TRACKING** tab
   c. Verify that **Processing Returned Surveys** procedures were followed
   d. Enter the current date in **Resend Request Date**

2. *If a proxy or potential proxy for a participant in the Deceased No Breast Cancer group reports a diagnosis of breast cancer and **completed the ONLINE NO Breast Cancer survey***:
   a. Search by CCSSID
   b. Go to **TRACKING** tab
   c. Update the previous Current Group box **G[#] Date Received** and **G [#] Source**
   d. Update the Current Group box **G[#] Date Sent/G[#] Date Received** (date online survey submitted for both fields) and **G [#] Source.** Remember to match the survey type and Group #
   e. Continue data entry following steps from **Processing Returned Surveys** procedure

3. *If a proxy or potential proxy for a participant in the Deceased No Breast Cancer group reports a diagnosis of breast cancer **but did NOT complete a survey**.*
   a. Determine whether the **Proxy Info** is entered into the database: Review the **PROXY IDENTIFICATION** tab.
   b. If the proxy info ***IS already in the database***:
      i. Go to **TRACKING** tab
      ii. Update **Self-Reported Breast Cancer** field to 1 (Y)
      iii. Enter the current date in **Resend Request Date**

c. If proxy info ***IS NOT in the database***, you will need update the information for the proxy and process as follows:
   i. On the **Proxy Identification** tab
      a. Enter the contact information for the individual who reported the diagnosis in the following fields (as available) **ProxyName**, Proxy **Address**, **ProxyCity**/**State**/**Zip**, **Address Date**/**Source**; **Rank**, **Phone**/**Email**, **Date**, **Source**

      b. Enter a note in **Proxy ID Notes**:
         i. If the individual did not refuse further contact from LTFU and appears to be knowledgeable of the participant's health history (determined on a case-by-case basis), add a note such as *m/d/yy: activated proxy per [SI/survey/note/etc.]; John Doe reported that pt diagnosed with breast cancer on m/d/yy… [initials]*
         ii. If the individual did not refuse further contact from LTFU but does not appear to be knowledgeable of the participant's health history (determined on a case-by-case basis), add a note such as *m/d/yy: John Doe reported that pt diagnosed with breast cancer on m/d/yy… but unable to complete survey [initials]*
         iii. If the individual did refuse further contact from LTFU, add a note such as: *m/d/yy: per [SI/survey/note/etc.], John Doe reported that pt died on m/d/yy; refused further participation in LTFU [initials]*

      c. Update **Proxy ID Outcome**: to 1 Confirmed
      d. Update **Proxy ID Outcome Date** to date notification received
      e. Update **Relationship**

   ii. Open form **frmAdmin**. Click **Maintain Proxy.** On the **Maintain Proxy** screen,
      a. Search by CCSSID
      b. Verify that the proxy **Name** that was entered is visible
      c. Update **ProxyStatus**, using:
         i. 1 Confirmed contact updated: Use if individual appears to be a valid potential proxy (i.e. did not refuse to participate)
            1. In the **ProxyID** field, enter the participant's CCSSID and "-1" or "-2" or "-3", etc.; the [- #] should be the next sequential value available if one or more proxy ids are already entered
            2. Enter the current date in the **ProxyStatusDate** field

         ii. 4 Inactive: Use if individual did not refuse to participate but does not appear to be a valid potential proxy (i.e. doesn't know about/recall participant's health history)
            1. Leave **ProxyID** blank
            2. Enter the current date in the **ProxyStatusDate** field

         iii. 2 Refused: Use if individual refused future contact with LTFU
            1. Leave **ProxyID** blank
            2. Enter the current date in the **ProxyStatusDate** field

      d. Close the **Maintain Proxy** form.
      e. In the **Breast Cancer Main** form, place cursor in the CCSSID field and refresh the screen (press F5 or click **Refresh All)**

f. If the **Proxy Status** was updated to a 2 or 4, STOP. Do not update the Self-reported breast cancer field, enter a resend request, or update the proxy print table name, because a viable proxy must be identified before proceeding. (PROCESS TO BE DEVELOPED).

g. If the **Proxy Status** was updated to 1-Confirmed contact updated, on the **CCSS Breast Cancer Main** form, search by CCSSID, then
   i. On the **PROXY** tab, verify that the proxy name was entered is visible in the **ProxyName** field.
      If it is visible, then click the **Update Proxy print table NAME** button. (If it is NOT visible, you will need to repeat the Update Proxy status procedure using the Maintain Proxy form.)
   ii. On the **TRACKING** tab, update the **Self-Reported Breast Cancer** field with 1 (Y)
   iii. On the **TRACKING** tab, enter the current date in **Resend Request Date**

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1	2-7-12	J.Ford	Initial Development
2	5-16-12	J.Ford	Updates
2.1	5/25/12	J.Bates	Formatting

Breast Cancer Study: Medical Records

Background

The purpose of the Breast Cancer study is to learn more about the health history of females who were treated with chest radiation as a child. Research has shown that radiation to the chest area can increase a woman's risk of developing breast cancer. Specifically, we are studying factors that may influence the risk of breast cancer.

In this study there are four unique groups. These groups include females who received chest radiation and are alive or deceased and were or were not diagnosed with breast cancer. These groups are titled Alive Breast Cancer (BCAlive), Deceased Breast Cancer (BCDeceased), Alive No Breast Cancer (NoBCAlive), and Deceased No Breast Cancer (NoBCDeceased).

Using standard CCSS recruiting processes, we will mail each participant who is alive a group specific survey (BCAlive or NoBCAlive). For deceased participants, we will identify viable proxies to complete the group specific surveys (BCDeceased or NoBCDeceased). Potential proxies can be spouses, parents, or siblings (not necessarily a sibling LTFU participant)

While recruiting participants and proxies, it is highly likely that a participant's group status will change. For example, alive participants may now be deceased and/or participants identified as not having breast cancer may currently have or previously had breast cancer. This shift in status will not exclude a participant from the study. We will simply adjust the participant's study group and recruit accordingly.

Procedures

Requesting Medical Records: Initial Request

1. Review batch info from "**qry_JF_BiopsyMRRequestInfo m/d/yy**" document (*info about key fields below*)
    a. **CaseAssignedTo**: Initials of individual responsible for pursing record
    b. **CaseAssignedDate**: Date case assigned to individual
    c. **CurrentGroup**
        i. 1 = Alive NO Breast Cancer
        ii. 2 = Alive Breast Cancer
        iii. 3 = Deceased No Breast Cancer
        iv. 4 = Deceased Breast Cancer
    d. **HIPAAStatus**
        i. 1 = Use Existing LTFU HIPAA (LTFU purple cabinet)
        ii. 3 = Received Signed HIPAA with Study Survey (Breast Cancer orange cabinet)
    e. **MRLetterType**
        i. **1 = Biopsy letter** (**Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\Medical Records**)
            1. For Alive participants (i.e. CurrentGroup 1 or 2) use Biopsy Report Pursuit Letter_MERGED 4-11-12
            2. For Deceased participants (i.e. CurrentGroup 3 or 4), letter depends upon **HIPAAStatus**:
                a. Blank **HIPAAStatus** field = use Biopsy Report Pursuit Letter_Deceased MERGED 5-15-12
                b. "1" in **HIPAAStatus** field = use Biopsy Report Pursuit Letter_MERGED 4-11-12

ii. **2 = Medical Record letter** (**Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\Medical Records**)
1. For Alive participants (i.e. CurrentGroup 1 or 2) use BC MR Letter_MERGED 4-11-12
2. For Deceased participants (i.e. CurrentGroup 3 or 4), letter depends upon **HIPAAStatus**:
a. Blank **HIPAAStatus** field = use BC MR Letter_Deceased MERGED 5-15-12
b. "1" in **HIPAAStatus** field = use BC MR Letter_MERGED 4-11-12

f. **PtPrevName**, **FatherLastName**, **MotherLastName**: These are potential previous last names for the participant; may need to reference these fields when speaking to medical record staff
g. **DiagnosisMonth**: Month the participant was diagnosed with breast cancer
h. **DiagnosisYear**: Year the participant was diagnosed with breast cancer
i. **MRNotes**: Notes pertinent to record pursuit

2. Contact facility via **ClinicPhone** on behalf of St. Jude Children's Research Hospital
a. Confirm contact info (name, phone, fax, and/or email address) for appropriate medical record staff member; *always request a contact name along with a fax number and email address as these are the preferred methods of requesting records*
i. If the institution requires additional information before releasing information (e.g. clinic medical release form, death certificate, etc.), funds for records, or does not possess records, make a note of this in **MRNotes**: field, update **MRRequestOutcome** to 6 Hold, and email the project manager
b. Print appropriate cover letter(s)
i. Mailmerge and print letter(s) or manually update letter(s) and print
*Be aware that each letter contains fields for **DiagnosisMonth** and **DiagnosisYear** but not all CCSSIDs will have this info; for those CCSSIDs without this info, adjust the letter accordingly before printing*
c. Fax and/or email letter(s) and HIPAA(s) (if applicable) to medical records staff contact
i. If unable to fax or email due to facility rules/limitations, sending info via USPS is acceptable
d. Open CCSS Breast Cancer Database, search by CCSSID, and go to **HIPAA-PATH-MR** tab
e. Find corresponding **ClinicName**:
i. May need to scroll through multiple records
f. Enter current date in **MRRequestDate**:
g. Add a note to **MRNotes**: such as "m/d/yy: requested records from [contact name] at [fax and/or email address] [initials]"
h. Update **ClinicName**/**Phone**/etc. as applicable

3. As records are received or as we receive notification that records are unavailable, the project manager will update the **MRReceiveDate**: and **MRRequestOutcome**: fields

CRA

Requesting Medical Records: Tracking Requests and Subsequent Requests

1. Two weeks after assigning cases, project manager will provide staff with a status update on cases (*process will continue until record pursuit is complete*)
    a. "**qry_JF_BiopsyMRRequestTracking m/d/yy**"
    b. New cases will also be assigned in these files
2. Review assigned cases (**CaseAssignedTo**)
3. If record has not been requested (**MRRequestDate**: is blank), proceed to *Initial Request* section steps 2a-2g
4. If record was previously requested (**MRRequestDate**: is not blank):
    a. Review **MRNotes**: for any new, pertinent notes
    b. Review **MRRequestDate**: to see if enough time has passed since initial request (roughly two weeks)
        i. *If yes*: Call medical record staff contact to inquire about the status of record request(s)
            1. Repeat *Initial Request* section steps 2a-2g (Contact Facility) as needed
        ii. *If no*: Add an appointment to your Outlook calendar to contact facility within two weeks

Revision Record Printed 7/13/2012 11:15 AM

Current Filename:		Breast Cancer Study-Medical Records ver2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	2-7-12	J.Ford	Initial Development
2	5-16-12	J.Ford	Updates

Breast Cancer Treatment (BCT) Study Facility Calls

Background

The Breast Cancer Treatment (BCT) Study is an ancillary study of the CCSS that seeks to understand if female survivors of childhood cancer who are subsequently diagnosed with breast cancer (1) receive treatment, (2) experience treatment-related toxicities, and (3) have event-free survival and overall survival comparable with a comparison cohort of treatment-era women. The principal investigator (PI) for this ancillary study is Lucie Turcotte, MD, MS, MPH.

If a CCSS participant, case or sibling from the original or expanded cohort has a confirmed subsequent neoplasm (SN) of breast cancer (BC), the PI will review all available records regarding this SN. If records needed for the BCT Study are missing, the CCSS team will pursue these records as requested by the PI.

Interviewers call the facilities in the following situations:

1. We do not have enough doctor or facility contact information to request records.
2. A request for records has been sent, but we have not received all the needed records.
3. The facility has other special conditions that need to be met before records are released.
4. The project manager (PM) has specific questions to ask of the facility.

This procedure describes how to make and document calls to the doctor's office or medical facility.

Tools Needed:

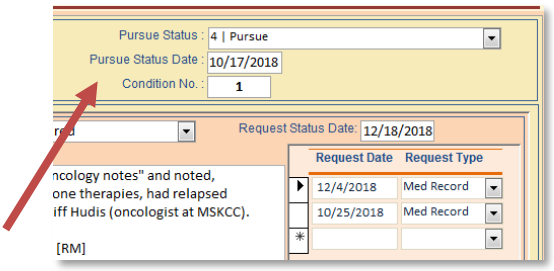
1. CCSS LTFU Participants database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
2. BCT Study database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
3. CCSS SI Assignments database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
4. **LTFU Participant Database Data Entry** SOP, located in the CCSS SOP Library database at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
5. Copies of the request faxes sent to the facilities, located at: *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\BCT Study\BCT Faxes\BCT Study Requests*
6. **New Facility Contact Information Verification Quick Sheet** located at: *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\BCT Study*
7. **SENDING A FAX for SMN or BCT**.docx, located at: *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\BCT Study\BCT Faxes*
8. Access to an online search function, such as Google.

Before the Call:

1. Select a participant to be called. Open the **SI Assignments database** and click the button titled: **BCT Case Facility Call Assignments** (displays all participants for a given facility together) or **BCT Case Facility Call Assignments DLC** (displays assignments sorted by the date of the last call), then enter your SI ID number to view the list assigned to you. Consider the following:
    A. **Participant ID**, **First Name**, **Last Name** and **DOB**.
    B. **Facility Name** = The name of the facility to be called. This sometimes helps determine in which time zone the facility is located.
    C. **Condition #** = Indicates which condition requires a call (when the participant has more than one occurrence of breast cancer.)
    D. **Date Last Fax** = The most recent date a request was faxed to this facility.
    E. **Last BCT Path Call Date** = The most recent date a call was made for this participant for this study.
    F. **Last BCT call outcome** = The outcome of the last call made for this study.

2. Build the call profile from the **LTFU Participants database**:
    A. Locate the participant to be called by name or CCSSID number, and open their record.
    B. Review the Contact Log for any information from previous calls to the designated facility.
    C. Note whether the participant is alive or deceased.

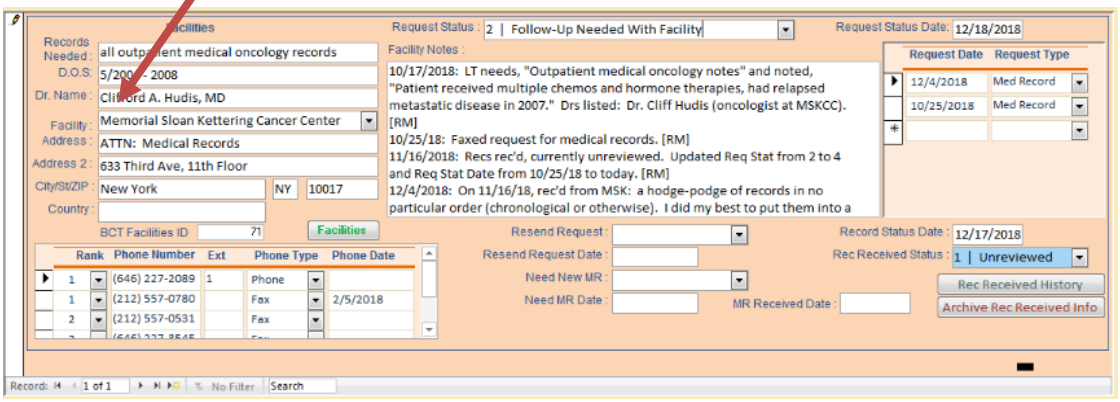
3. Continue building the call profile from the **BCT Study database**:
    A. Locate the **Condition No** for the facility to be called (Remember the participant may have been treated for more than one BC.):
        i. The **Condition No** is in the upper right-hand side of the record under the **Pursue Status:** and **Pursue Status Date:** boxes. There are forward and back arrows at the very bottom, left of the **yellow** window to navigate from one *condition record* to another for the displayed participant.
        ii. The condition should have a **Purse Status: of 4 – Pursue.**



iii. Check the **Condition Notes:** at the very bottom of the **yellow** window.

B. Locate the **Facility** to be called, in the **orange** box in the center of the window. Note that there may be multiple facilities being pursued for a single condition.

i. The **Facility** name should match that from the SI Assignment record. If the first facility visible does not need follow-up, use the arrows at the bottom of the **orange** *Facilities record* to navigate from one *facility record* to another for the displayed condition.



ii. Check the **Request Status** field of the designated facility, which should either be 1 – Need Info From Facility or 2 – Follow-Up Needed With Facility.

iii. Check the **Facility Notes** box in the center of the Facility record.

C. If we **Need Info** from the facility:

i. The **Request Status** will be populated with 1 – Need Info From Facility.

ii. There will be a dated note in the **Facility Notes** box stating the specific need. E.g. "10/6/2017: Contact the facility for fax number for medical record requests."

iii. If there is no **Phone Number** listed under the Facility name and address fields, do an online search for a phone number.

D. If we need to **follow-up with the facility**:

i. The **Request Status:** will be populated with 2 – Follow-Up Needed With Facility.

ii. Review the notes in the **Facility Notes** box to understand the history of our pursuit with this facility and to determine the purpose of the call. (e.g. *"11/15/2017: Faxed request for medical records."* or *"4/19/2016: Please contact the facility to see if another department might have the records in question.")*

iii. Check the **Rank** of the phone numbers listed (if more than one).

iv. Check the **Request Date** and **Request Type** fields to the right of the **Facility Notes** box. The most recent fax will appear at the top.

4. It may be necessary/helpful to **review the actual faxed request** if one has been sent. These are found in the Interviewers folder as specified in the *Tools Needed* section of this document, above. Locate the request by CCSSID number, facility abbreviation, and date. Open the request and note:
    A. The name of the facility on the request.
    B. The wording of the request.
        i. What is the **name of the participant** on the request? If a participant has married, divorced, or changed their name for any reason, the facility may have records under a different name.
        ii. What is the **date range of records** we are requesting? Sometimes our reported dates of service are incorrect, and the facility has the desired records under different dates. Be prepared to ask questions.
        iii. Did we include a signed **LTFU HIPAA authorization and/or a signed facility-specific authorization**? If the participant is deceased, we may have just sent the request.

Make the Call:

1. Call the Facility:
    A. State your name, that you are calling from St. Jude Children's Research Hospital, and the purpose of your call (e.g. the status of a records request or questions about records we received.) You may have to go through a receptionist, or hospital operator and ask to be transferred to the medical records department. Be prepared to give the participant's name and DOB.
    B. If you are unable to reach an appropriate person, gather as much information about when and what is the best way to reach them?
    C. If a request needs to be resent, review contact information (especially fax number) and gather details about any necessary revisions to the request.
2. Note all the information they provide. Thank them for their help.

After the Call:

1. Record the call in the **LTFU database** following the **LTFU Participant Database Data Entry** SOP. Use the following guidelines, which are specific to the BCT Study:
    A. **Contacting:** 11 – Facility
    B. **Name:** Name of the facility as listed in the BCT database
    C. **Project:** 22 – BCT Study
    D. **Contact Reason:** 8 – Additional Records

E. **Outcome:** 2 – No answer, 3 – No answer/ left message, 5 – Resend, 6 – Disconnect, 9 – Will return by mail/online, or 10 – Other
   i. **Outcome**: 2 – No answer, 3 – No answer/ left message, 5 – Resend, 6 – Disconnect, 9 – Will return by mail/online, or 10 – Other
F. **Facility Consecutive ID**: Copy the BCT Facilities ID number from the BCT database record.
G. **Notes:** Make a concise, detailed note of the information gathered.

2. Record the call in the **BCT database**.
   A. When the **facility received our medical records request and will return the records**, simply make a dated note, with SI ID, in the **Facility Notes** box.
   B. When the **SI obtains a new or direct phone or fax number** for the medical records department not currently listed in the facility's phone list:
      i. Confirm the phone or fax number is not already listed.
      ii. **Remember that adding a new number will update this specific facility for every participant who has this facility linked to their condition now or in the future.** For new one-time-use phone or fax numbers, document it in the Facility Notes field ***only***.
      iii. On the first blank phone number line:
         a. Populate **Rank** with the appropriate rank for the new number. If this is the best number to use moving forward, that rank should be 1.
         b. Populate **Phone Number** with the new phone or fax number.
         c. Populate **Ext** with the appropriate extension number if an extension is needed to contact the right department/person.
         d. Populate **Phone Type** with the appropriate choice, Phone or Fax.
         e. Update the **Phone Date** field with the current date.
      iv. Change the **Rank** of any other existing numbers as appropriate. For any given facility, each rank should be used only *once* for fax numbers and *once* for phone numbers. i.e. There should be *ONE* phone number ranked 1 and *ONE* fax number ranked 1.
   C. When the **facility requests a resend and only accepts MAILED requests** (resend will be completed by the PM):
      i. Ensure the fax number with rank "1" is 000-000-0000. This alerts the PM that requests to this facility must be MAILED or EMAILED. The rank for other fax numbers may need to be adjusted accordingly.
      ii. Make a dated note with SI ID in the **Facility Notes** field explicitly describing what is needed from the PM and documenting the "from" and "to" values of all field changes. E. g. 5/10/2018: Updated Phone Number Ranked 1 from (123) 456-7890 to (000) 000-0000 - the facility only accepts MAILED requests. [81]
      iii. Populate the **Resend Request** with 1 – Med Rec Request.
      iv. Populate the **Resend Request Date** with the current date.

v. Populate the **Request Status** with 4 – Project Mgr Action Req'd.
vi. Populate the **Request Status Date** with the current date.
vii. If the request is time-sensitive OR has special considerations, email the details to the PM.

D. When the **facility requests a resend and only accepts EMAILED requests** (resend will be completed by the SI):
   i. Ensure the fax number with rank "1" is 000-000-0000. This alerts the PM that requests to this facility must be MAILED or EMAILED. The rank for other fax numbers may need to be adjusted accordingly.
   ii. Prepare a resend request by following the directions outlined in **SENDING A FAX for SMN or BCT** (See the *Tools Needed* section of this document, above.), but *email* the prepared request document to the facility's email address by attaching it to an email. It is *IMPERATIVE* that the [Encrypt] flag be used in the Subject bar of these emails. See the Call Center Coordinator or a member of the LSI team if guidance is needed on using the [Encrypt] flag.
   iii. Populate the **Request Date –** with the current date.
   iv. Populate **Request Type** – with "Med Record."
   v. Make a dated note with SI ID in the **Facility Notes** field, describing action taken. Document that the [Encrypt] flag was used.
   vi. Document the email in the LTFU Participant database following the **LTFU Participant Database Data Entry** SOP.
   vii. Email details about the email address and requirements for email to the PM. PM will add the email address to the facility record.

E. When the **SI determines the request needs to be sent to a new facility that IS listed in the database facility list:**
   i. Fax the request by following the directions outlined in **SENDING A FAX for SMN or BCT**. See the Tools Needed section of this document, above.
   ii. Click the Facility record arrows at the bottom of the Facilities box to **create a new/ blank record. **NOTE: NEVER change the facility name and address fields on an existing record to a new or different facility. Always start a new facility record.**
   iii. In the new facility record:
      a. Make a dated note with SI ID in the **Facility Notes** box documenting how the facility was identified and that the request was faxed. (e.g. *2/15/19: Memorial Hermann suggested the needed records would be found at MD Anderson. Faxed new request to MD Anderson. [196]*)
      b. Under the **Facilities** header, populate **Records Needed**. Enter the same information used for the previous facilities.
      c. **D.O.S.** – Populate this field using the same information found in the previous facility records.
      d. **Dr. Name** – If known, free-type the provider's name here.

e. **Facility** – Locate the facility in the database with the dropdown arrow or using the **Facilities** button with the search feature. Select the facility to auto-populate the address and phone/ fax number fields. Note: You may have to scroll to a different facility record or condition record, then back again for the phone/ fax numbers to appear.
f. **Request Type** – Populate with "Med Record."
g. **Request Date** – Populate with the current Date.
h. **Request Status** – Populate with 2 – Follow-Up Needed With Facility.
i. **Request Status Date –** Populate with the current date.

iv. Document the fax in the LTFU Participant database following the **LTFU Participant Database Data Entry** SOP.

F. When the **SI determines the request needs to be sent to a new facility that IS NOT listed in the database facility list:**
   i. Verify the facility contact information by phone, referring to the **New Facility Contact Information Verification Quick Sheet**. Once verified, use the **New Facility Contact Information Verification Quick Sheet** for documenting the information obtained and communicating with the PM via email to have the new facility information added to the database.
   ii. Click the Facility record arrows at the bottom of the Facilities box to **create a new/blank record.**
   iii. Make a dated note in the **Facility Notes** box documenting (1) how the facility was identified, (2) the confirmed contact information for medical record requests, (3) that the information was confirmed by phone as accurate for the facility's medical records requests, (4) that the facility is not found in the database, and (5) that an email was sent to the PM to add it. (e.g. *2/15/19: Memorial Hermann suggested the needed records would be at New Horizons Cancer Care, which is not in the db. Per Gloria at New Horizons, their medical records requests can be sent to 123 Fourth Street, Anytown, TX 37111 or fax 555-222-1234. Med recs ph# is 555-333-4567. Emailed PM to add facility. [81]*)
   iv. Under the **Facilities** header, populate **Records Needed** with the same information used for the previous facilities.
   v. **D.O.S.** – Populate with the same information found in other facilities for this condition.
   vi. **Dr. Name** – If known, free-type the provider's name here.
   vii. **Resend Request** – NOTE: If no request has ever been sent to the facility, it is *not necessary* to request a resend to generate the initial request. Resends should only be requested as follow-up to a previous request to the same facility.
   viii. Populate the **Request Status** – with 4 – Project Mgr Action Req'd.
   ix. Populate the **Request Status Date** – with the current date.

G. When the **SI's professional opinion is that all possibility of obtaining the needed records from the facility in question is exhausted**:

i. Populate the **Request Status** – with 4 – Project Mgr Action Required.
ii. Populate the **Request Status Date** – with the current date.
iii. Enter a dated note with SI ID in the **Facility Notes** box, clearly indicating the SI's opinion and how s/he came to this opinion along with all changes (to and from) to the Facilities group's fields.

H. When the Facility advises **a new LTFU HIPAA is required** (e.g. due to signature date):
   i. Populate **Need New MR** – with 2 – LTFU HIPAA.
   ii. Populate **Need MR Date –** with the current date.
   iii. Populate **Request Status** – with 4 – Project Mgr Action Required.
   iv. Populate **Request Status Date** – with the current date.
   v. Make a dated note in the **Facility Notes** box documenting the fields that were changed, what they were changed from and to, and the reason for the changes.

I. When the **Facility advises our LTFU HIPAA is not acceptable, instead a facility-specific medical release is required**:
   i. Populate **Need New MR** - with 1 – Facility MR.
   ii. Populate **Need MR Date** – with the current date.
   iii. Populate **Request Status** – with 4 – Project Mgr Action Required.
   iv. Populate **Request Status Date** – with the current date.
   v. Make a dated note in that **Facility Notes** box documenting the fields that were changed, what they were changed from and to, and the reason for the changes.

J. When there are **other special or unique requirements** to meet before the facility will release records (e.g. fees, verbal authorization from the participant, etc.):
   i. Populate **Request Status** – with 4 – Project Mgr Action Required.
   ii. Populate **Request Status Date** – with the current date.
   iii. Make a detailed, dated note in the **Facility Notes** box explaining what is needed and the best facility representative to contact concerning this or any other special need. Include their contact information if other than the already-recorded facility contact information.

Submitting or Resubmitting a Request for Medical Records

If a request needs to be sent via MAIL, the PM will send the request as described in the After the Call section of this document, above. When a facility requires a new request that can be faxed, the SI will submit the request. **NOTE:** If creating a new request rather than modifying an existing request, use the document **SENDING A FAX for SMN or BCT** along with the appropriate fax template found at *\\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\BCT Study\BCT Faxes* to create an appropriate new request.

Before the fax is sent:

1. **Open the previous fax:**
    A. Go to the copies of request faxes sent (BCT Study Requests folder) as indicated in the Tools Needed section of the document.
    B. Copy the Participant ID number in the *Search BCT Study Requests* search box to locate the fax for your participant. These files are named as follows: PtID#_AbbrevFacilityName_DateofFax.pdf. (For example, the file named **15208797_ErlangerDeptofRadOnc_011519.pdf** is a fax for CCSSID 15208797 to Erlanger - Department of Radiation Oncology, and the fax was sent on 1/15/2019.)
    C. Double-click on the desired file to open it.

2. **Save as** – Save the file as a new document in the same folder - but rename the file by changing the date number to the current date in this way: MMDDYY. If the request is being sent to a new facility, change the facility name as well.

3. **Make any necessary changes** to the request. These may include:
    A. Sender's name
    B. Sender's phone/ fax numbers
    C. Recipient's name and fax number
    D. Date of request
    E. Wording of request

4. **Save the file**.

Send the fax:

Fax the file on your computer by following the directions outlined in **SENDING A FAX for SMN or BCT** See the *Tools Needed* section of this document, above. Alternatively, print the file and fax it manually on the hall fax machine.

After the fax is sent:

1. Record the fax in the **LTFU database**. Make a New Call Log for each fax sent. Populate these fields as follows:
    A. **Contact Mode**: 4 - Fax
    B. **Contacting:** 11 – Facility
    C. **Name:** Name of the Facility as listed in the BCT database.

D. **Time START and END:** Time the fax was sent.
E. **Project**: 22 – BCT Study
F. **Contact Reason:** 8 – Additional Records
G. **Outcome:** 9 – Will return by mail/ online, or 10 – Other.
H. **Facility Consecutive ID**: Copy the BCT Facilities ID number from the BCT database record.
I. **Notes:** Record that the request was refaxed, and any other relevant information.

2. Record the fax in the **BCT database**.
   A. When the **Facility requests a resend of our request to the same fax number**:
      i. Make a dated note with SI ID in the **Facility Notes** box describing the action taken.
      ii. Populate the **Request Date** field with the current date.
      iii. Populate the **Request Type** field with Med Record.

   B. When the **Facility requests a resend of our request to a new fax number:**
      i. Make a dated note in the **Facility Notes** box describing action taken and documenting the new fax number used.
      ii. Populate the **Request Date** field with the current date.
      iii. Populate the **Request Type** field with Med Record.
      iv. If the fax number is to be used for all requests to this facility for all participants from this point forward:
         a. Add the **Rank** of 1.
         b. Add the new fax number under **Phone Number**
         c. Update **Phone Type** – Fax
         d. Populate **Phone Date** with the current date.
         e. Change the **Rank** of the previous number(s) to 2 or greater.

For questions regarding unusual circumstances not addressed within this SOP, see the Call Center Coordinator, LSI team, or PM.

Revision Record

Current Filename:		BCT Facility Calls ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/30/2019	R. Massey, B. Lewis, M. Sanchez	Initial Development

Bulk vs. First Class Mail Guidelines

Bulk mailing

- Must be BOTH at least 200 pieces AND weigh 50 lbs
- Mailroom request: provide 24 hour notice!
- Use envelope with indicia for bulk mailing for mail INSIDE the U.S.
- Only for mail to US addresses
- SORT pieces in zip code order
- Our mailroom requests no more than 500 pieces/day
- USPS regulations, effective 3/29/2009 **require**:
  - Put the MAILING LABEL lower right quadrant of the envelope. It MUST NOT cross the midpoint of the envelope.
  - The example shows large envelopes like the ones used to mail surveys.

First class mail

- Use envelopes without indicia for mailings having less than 200 pieces and weighing less than 50 lbs
- Do not need to place in zip code order

International mail

- Mail to be delivered outside the U.S. is ALWAYS sent First Class.
- Do not use envelope with indicia.
- Separate out of country mail from mail being delivered inside the U.S.

POST OFFICE ADDRESSING PREFERENCES

- Use ALL CAPITAL LETTERS.
- Use a sans serif font such as Helvetica, Arial or Calibri

Schedule a mail pick-up

- Call mailroom at extension 3326.
- If pick-up is after 3pm, mail will be sent the next day

For mail-related questions

- Samantha Watson, extension 4951

Revision Record — Printed 7/9/2012 2:29 PM

Current Filename:		Mail Guidelines ver 2_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	4/8/09	R. Pack	Initial Development
2	5/6/11	J.Bates	Bulk mail label placement; font preferences
2.1	2/22/12	J.Bates	Bulk caps per mailroom

Call Center Appointment Calendar

Background

All HIPAA, permission, and survey appointments made by Survey Interviewers (SIs) with participants are logged on the monthly appointment calendar, centrally posted in the Call Center. The Call Center Coordinator, the Lead Survey Interviewers (LSIs), and the Closing Monitors review the calendar and posted weekly SI schedule daily to ensure appointment coverage.

Procedure

Documenting a Newly Scheduled Appointment on the Call Center Calendar:
All appointments to complete an event such as a verbal HIPAA, sibling permission, or study survey should be documented on the Call Center appointment calendar. This guideline includes appointments scheduled to occur later on the same day. Appointments for a callback should ALSO be documented on the Call Center appointment calendar (e.g. Pt. stated that he is at work and requested to be called back at 4:30 pm). Callback appointments should also be entered in the SI's personal Outlook calendar.

Use the following color coding to write appointments on the Call Center appointment calendar:

- **Black:** ***Ancillary Study Appointments - Original and Expansion Cohort***
- **Green:** ***Expansion Verbal HIPAA or Case Baseline Survey appointments***
- **Blue:** ***Expansion Sibling Permission or Sibling Baseline Survey Appointments***
- **Red:** ***Follow-Up 6 (FU6) Case and Sibling Survey Appointments***

Write the following information on the calendar in the appropriate color from above:

1. The participant's CCSSID or SIBID
2. The TIME of the appointment, in local time (Central Time, CT)
   For example, an appointment for a participant in Los Angeles, California, at 4:30pm Pacific Time will be written on the calendar as 6:30pm.
3. The SI ID (Survey Interviewer identification number) of the Interviewer who made the appointment
   NOTE: If the appointment was made by one SI and needs to be covered by another SI, then send an email with the CCSSID/SIBID and the appointment type/date/time to the LSI team, copying the Coordinator, requesting that the appointment be reassigned. If there is no time to follow this procedure (e.g. The appointment is scheduled for the same day, and the LSI team and Coordinator are out or unavailable before the appointment.):
   i. Coordinate with another SI to handle the appointment.
   ii. Document the covering SI's number with the appointment on the Call Center calendar
   iii. Email details about the appointment and who will cover it to the LSI team, the Coordinator, and the covering SI.

4. Any appropriate appointment type abbreviation codes:
   - **ASK = ASK Skin Cancer Study**
   - **EE = Expired Case Baseline Survey**
   - **EE = Expired Sibling Baseline Survey**
   - **PERM = Expansion Sibling Permission**
   - **VH = Verbal HIPAA**

   NOTE: Do not write "partial" for a survey appointment that was previously partially completed. "Partial" is only used on the calendar as an appointment *outcome*.

Documenting Appointment Outcomes on the Call Center Appointment Calendar

After the SI makes the appointment call, s/he should update the calendar in the following manner:

1. Indicate whether or not the participant answered for the appointment:
   a. If the participant answered the telephone for the appointment, check the appointment's leading box on the calendar.
   b. If the participant did not answer the telephone for the appointment, draw a line through the appointment on the calendar.
   c. If the Call Center neglected to call for the appointment, draw an X in the appointment's leading box on the calendar. Details should be emailed to the Closing Monitor.

2. If the participant answered, indicate the outcome of the appointment.
   a. If the survey or other event was completed, no further indication is necessary.
   b. If a survey was partially completed (i.e. The **Submit** button was not clicked for a survey.), write "partial" beside the appointment.
   c. If the event was rescheduled, write "resched" beside the appointment.
      NOTE: "Rescheduled" is not used for appointments whose outcome is "partial survey", even if the participant scheduled a follow-up appointment to finish the survey.
   d. If the participant answered but did not do a partial survey or otherwise complete an event, did not refuse, AND did not reschedule, write "c/b" (for "call back") beside the appointment.
   e. If the participant refused participation, write "refused" beside the appointment.
   f. For other outcomes, write "other" and email details of the outcome to the Closing Monitor.

Revision Record Printed 8/29/2017 10:23 AM

[197] Current Filename:		Call Center Appointment Calendar ver1_6.docx	
Revision No.	Date	Responsible Author	Change Description
1	3/23/10	B. Benavides	Initial Development
1.1	6/20/12	D. Rinehart	Formatting; SI ID and study updates.
1.2	6/29/12	Procedure Team	Content and format revisions
1.3	5/15/13	R. Massey	Content Revisions Including Sibling Permissions Color
1.4	5/31/14	R. Massey	Updated color coding, updated appt types, defined appt outcomes
1.5	10/23/14	R. Massey, D. Rinehart, A. Oyuela	Content Revision: simplify appointment outcome documentation
1.6	3/20/2017	A. Cobble, R. Daniels, D. Rinehart	Content Revision: Clarifications for appt. made outcome
1.7	8/28/2017	A. Cobble	Content Revision: Updated study projects

CARTOX II: Scanning and Verifying

Background

We assist the St. Jude Life CARTOX II study by scanning and verifying 3 questionnaires that study interviewers complete with each participant: (1) **CARTOX II Medication Inventory**; (2) **CARTOX II Patient History**; and (3) **CARTOX II Family History**. Optimally, we will scan and verify within two weeks of data collection. *Scanning the Medication Inventory instrument has first priority*. The study coordinator cleans instruments prior to our scanning them. A designated person obtains instruments from the study coordinator's office and returns them after verification. While working on the surveys, we hold them in a designated file cabinet on 5th floor. (Over the four year life of the study, about 1,500 St Jude Life participants with cardiac events will be recruited, at the rate of about 30 per month.)

Procedures

Obtaining/Scheduling/Returning Surveys

1. Once each week, a designated person picks up the surveys from the 4th drawer of the file cabinet located in the study coordinator's office (Aimee Santucci, 6th floor) and places them in survey-specific folders designated "To be Scanned," in the holding cabinet on 5th floor.
2. At the same time, the same person returns completed surveys to the coordinator's desk.
3. As the designated person needs help in completing the tasks, other CRAs will be asked to participate in the scanning and verifying.

Scanning

1. Select a survey type for scanning and cut the spline off the batch.
2. Open Teleform *Scan Station, Reader, and Verifier*
3. In Scan Station window, select the appropriate survey type from the drop down menu:
   a. CARTOX II Family History
   b. CARTOX II Medication Inventory
   c. CARTOX II Patient History
4. Once the questionnaire type is selected, go to File and select New Batch.
5. Place the surveys face up in the scanner, and click Start in the Scan Station window.
6. When all pages are scanned, click Accept.
7. Add a sticky note to the batch with the batch number.
8. Staple pages of each individual survey together. Enter your initials, "Scanned," and date on the questionnaire in the bottom left corner above the horizontal line.
9. It is preferable to verify surveys immediately after scanning, but if you cannot verify what you scanned on the same day, place the scanned questionnaires in your Work in Progress drawer (Orange cabinet) and verify them *the next day*.

Verifying and Committing

1. Open Teleform *Verifier* and *Reader*
2. From the Utilities menu, select Batch Management Dialog.
3. Locate questionnaire batch number in *Verifier*, and then click the Process button.

4. Verify and Commit questionnaire using standard CCSS procedures ensuring that the answers on the questionnaire are marked correctly in Teleform *Verifier*.
5. Once questionnaires have been verified, enter your initials, "Verified," and date on the questionnaire in the bottom left corner above the horizontal line next to the "Scanned" date.
6. File the completed work in the survey-specific "Scanned & Verified" folder.

Revision Record Printed 9/19/2012 8:01 AM

Current Filename:		Cartox II Scanning ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	9/13/12	O.McGregor	Initial Development

CCSS Call Center Scheduling Policy

Policy

NOTE: This policy is subject to change as the needs of the Call Center, departmental policy changes, or St. Jude policy changes dictate.

1. The schedule is published two weeks in advance of the schedule's effective date and is based on the entries made by each Survey Interviewer (SI) in the MS Excel workbook titled **ERC Schedule [date range]**. For information on entering a schedule, see the SOP titled **Survey Interviewer Self Scheduling**.
   A. **ERC Schedule [date range]** workbooks will be posted quarterly at *Z:*\...*Interviewers**Work schedules*\ *[yyyy] Pay Periods***.**
   B. Each SI's schedule must be entered in the MS Excel workbook titled **ERC Schedule [date range]** by midnight on the scheduling deadline.
   C. SIs must submit requests for scheduled time off and the requests must be approved by the Coordinator *before* the SI enters the time off in the MS Excel workbook titled **ERC Schedule [date range]**.
      i. If an SI (1) has submitted a request through the TimeOff system before the scheduling deadline but (2) has not received a determination by her/his last shift before the deadline, s/he should enter the time off in the schedule workbook to meet the appropriate total weekly hours. If the request is not approved, the Coordinator will collaborate with the SI to adjust her/his schedule without penalty before the schedule is published.
      ii. If time off is entered into the scheduling workbook but no corresponding request has been submitted through the TimeOff system, the Coordinator will assume it was entered in error, clear the time off, and adjust the SI's schedule to meet the needs of the Call Center.
      iii. If an SI decides *not* to take approved time off after the schedule is published, s/he may work the shift that was scheduled off. The SI should delete the request from the TimeOff system.
   D. Schedules may be entered as far in advance as the system will allow with changes made freely *before* the scheduling period closes.
   E. If the scheduling period has closed and any SI has not entered his or her schedule, the Call Center Coordinator reserves the right to write the schedule for that SI as the needs of the Call Center dictate. The SI will be expected to work the schedule that has been written for them.
   F. For questions, consult a member of the Lead Survey Interviewer (LSI) team and/or the Call Center Coordinator.
2. Each SI must work the number of hours s/he was hired to work each week. For example, if an SI was hired to work 40 hours, s/he cannot work 36 hours one week and add 4 hours the next week. It is

each SI's responsibility to ensure that s/he schedules a combination of hours to equal the total weekly hours for which s/he was hired.

3. **Call Center shifts** are scheduled in 4-, 6-, or 8-hour blocks. (A 6-hour shift is 6.5 hours, and an 8-hour shift is 8.5 hours to include the required 30 minute lunch period.)

   A. There are 5 available shift options on **Sunday**:

Hour	Shift Start	Shift End Time
4	12:30 PM	4:30 PM
4	1:00 PM	5:00 PM
4	3:00 PM	7:00 PM
4	5:00 PM	9:00 PM
6	12:30 PM	7:00 PM
8	12:30 PM	9:00 PM

   B. There are 16 available shift options **Monday-Thursday:**

Hour	Shift Start	Shift End Time
4	8:30 AM	12:30 PM
4	9:00 AM	1:00 PM
4	10:30 AM	2:30 PM
4	11:00 AM	3:00 PM
4	12:30 PM	4:30 PM
4	1:00 PM	5:00 PM
4	3:00 PM	7:00 PM
4	5:00 PM	9:00 PM
6	8:30 AM	3:00 PM
6	9:00 AM	3:30 PM
6	10:30 AM	5:00 PM
6	2:30 PM	9:00 PM
8	8:30 AM	5:00 PM
8	9:00 AM	5:30 PM
8	10:30 AM	7:00 PM
8	12:30 PM	9:00 PM

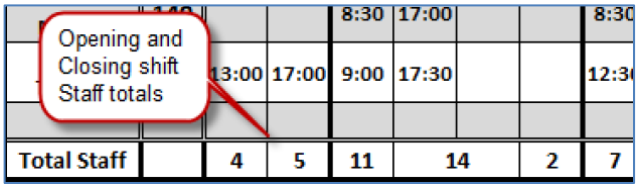
   C. There are 9 available shift options on **Friday:**

Hour	Shift Start	Shift End Time
4	9:00 AM	1:00 PM
4	10:30 AM	2:30 PM
4	11:00 AM	3:00 PM
4	12:30 PM	4:30 PM
4	3:00 PM	7:00 PM
6	9:00 AM	3:30 PM
6	10:30 AM	5:00 PM
8	9:00 AM	5:30 PM
8	10:30 AM	7:00 PM

   D. There are 8 available shift options on **Saturday:**

Hour	Shift Start	Shift End Time
4	9:00 AM	1:00 PM
4	10:30 AM	2:30 PM
4	11:00 AM	3:00 PM
4	12:30 PM	4:30 PM
4	1:30 PM	5:30 PM
6	9:00 AM	3:30 PM
6	10:30 AM	5:00 PM
8	9:00 AM	5:30 PM

4. The Call Center is required to have a minimum of two Survey Interviewers during standard operating hours.
   A. The Survey Interviewer should review the total staff coverage at the bottom of the worksheet, and coordinate their schedule to ensure coverage is adequate at the beginning and end times for each day, particularly if the schedule has already been populated for the week.



   B. Note: if the minimum staff requirement is not met, the Coordinator reserves the right to may make adjustments to the schedule to ensure operational needs of Call Center are met.
5. **Evening and weekend requirements**:
   A. The ***minimum*** number of ***required weekend hours per month**** (based on the Survey Interviewer's full-time employee status) are as follows:
      i. 40 hours per week employees = 16
      ii. 36 hours per week employees = 14
      iii. 32 hours per week employees = 12
      iv. 24 hours per week employees = 8
   B. The ***minimum*** number of ***required evening hours***, Sunday through Thursday, is **4*** hours per week (one **5pm to 9pm** shift).
   C. The ***minimum*** number of ***required evening hours***, Sunday through Friday, is **4*** hours per week (one **3pm to 7pm** shift).
6. **Holidays or vacation days** do not necessarily nullify the minimum evening and weekend obligations. Exceptions may be considered on a case-by-case basis, based on the operational and study project needs of the department and at the discretion of management.
7. **Shift Swaps**
   A. Changes to the schedule after it has been published should be rare. The Coordinator reserves the right to deny or approve a schedule change, or may request the SI to swap shifts with another SI, based on the operational needs of the call center.
   B. The SI also has the option to initiate a shift-swap request, provided they submit a request to the Coordinator at least 24 hours prior to either shift.
   C. The SI desiring the **shift swap** is responsible for making sure the shift is covered. Here is the procedure:
      i. The SI desiring the swap will find someone to cover his or her shift.
      ii. The SI desiring the swap will send the Coordinator an email, copying the LSI team and the SI covering the shift, requesting permission to swap the shifts. If the Coordinator is unavailable or absent, the request will be sent to the LSI on duty, copying the Call Center Coordinator and SI covering the shift.
      iii. The Call Center Coordinator or LSI will reply to all to indicate the swap is approved. (NOTE: If no response has been received within 2 days of the request or within 1 day of

the requested schedule change, follow-up with the Call Center Coordinator or LSI to determine if the swap has been approved.)

iv. Any SI who has agreed to swap shifts with someone to cover his or her shift should watch for an email sent to the Coordinator that clearly explains what the new arrangements are. If this email is not received, it is imperative that s/he follows up to ensure there was not a miscommunication regarding the agreement. Remember that the swap is not in effect until the Call Center Coordinator or LSI sends an approval email.

v. Any SI who has agreed to an approved schedule shift and fails to cover the shift will receive an occurrence.

vi. If these procedures are not followed, the Call Center Coordinator or LSI reserves the right to leave the shift uncovered and the SI requesting the shift off will receive an occurrence.

8. **Tardiness or Absence** (See St. Jude Policy 600.000.):

A. An SI has a 15-minute window from the start time of their shift to clock in. If the SI clocks in before the 15 minute window expires, they will not receive an occurrence of tardiness. *Example: If an SI's shift is scheduled to begin at 8:30am, although s/he is expected to be at their workstation at 8:30am, if s/he clocks in between 8:30am and 8:45am, the SI will not receive an occurrence of tardiness and does not have to notify the Coordinator via phone or email.*

B. If an SI will be more than 15 minutes late for the scheduled shift, s/he must contact the Coordinator via email or phone before the 15-minute window expires. The SI will then have up to 30 minutes after the scheduled shift start time to clock in and will not receive and occurrence of tardiness.
Example: If an SI's shift is scheduled to begin at 8:30am, although s/he is expected to be at their workstation at 8:30am, if s/he contacts the Coordinator via email or phone before 8:45am to let the Coordinator know they are going to be more than 15 minutes late, and if the SI clocks in between 8:30am and 9:00am, s/he will not receive an occurrence of tardiness.

C. If an SI is more than 30 minutes late, *with or without a call*, s/he will receive an occurrence of tardiness.

D. If an SI does not come to work at all, s/he will receive an occurrence.

E. The Call Center Coordinator reserves the right to adjust this policy on an individual basis if it is abused.

9. **Extended Lunch Periods and Making Up Lost Hours**:

A. If an SI needs to take an extended lunch break (more than 30 minutes) or would like to make up hours for being tardy or absent during the week, they will need to submit the request to the Coordinator and wait for approval. If the Coordinator is unavailable, they can contact an LSI for approval via email, and copy the Coordinator.

B. Note: Hours can only be made up for lost time within the same week the hours were scheduled. If a four hour shift was missed this week, the four hours can only be made up in this same week.

10. **Urgent and Emergency Situations** – In the rare event that an SI has an urgent or emergency situation, if possible, they should contact the Coordinator or an LSI at least 24 hours in advance of their shift. The Coordinator reserves the right to not give the SI an occurrence, per St. Jude Policy 600.000.

11. **Inclement Weather** – Review the Inclement Weather Policy St. Jude Policy 400.80 for additional information.

12. **Staff Meetings** – SIs should make an effort to arrange their schedules so that they can attend the bi-weekly staff meetings unless approved in advance with the Call Center Coordinator.

13. **Rest Periods**
    A. Any SI working more than 5 hours at a time will be required to take a *non-paid 30-minute lunch* break. The lunch break must be taken away from the SI's workstation. Not taking a lunch (i.e., working through lunch) is generally not permitted. In a rare situation that may require working through lunch, permission from the Coordinator or LSI is required.
    B. SIs also get a *paid 15-minute break* for every 4-hour shift worked. (Please review the SJ policy.) When planning breaks, SIs should coordinate with colleagues to ensure that someone is available in the Call Center at all times to cover the phones.

**The Call Center Coordinator reserves the right to adjust this policy on an individual basis if a Survey Interviewer works more than the allotted number of weekend or evening hours. The Coordinator also reserves the right to amend the minimum number of required weekend and evening hours to meet project needs. Emergency situations will be addressed on an individual basis.*

Revision Record Printed 3/20/2017 10:43 AM

[213] Current Filename:		CCSS Call Center Scheduling Policy ver 2_7.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development
1.2		A. McDonald	Formatting
1.3	2/20/10	A. McDonald	Formatting
1.4	3/20/12	A. McDonald	Formatting and clarification.
1.5	6/4/12	D. Rinehart, A. McDonald	6 hour shifts added.
1.6	6/20/2012	M. Jackson	Formatting
1.7	12/21/2012	D. Rinehart	Clarification copy added to point 1; 3pm-7pm and 5pm-9pm shifts added
1.8	7/30/2013	R. Massey	Content Update
2.0	10/18/2013	R. Massey	Change scheduling system from Intragale to internal spreadsheet.
2.1	9/9/2014	R. Massey, D. Rinehart	Content Revision: added directive for time off not approved/rejected by deadline, added directives for time off not taken after sched published
2.2	2/12/2015	D. Rinehart	Content Revision: New wording for tardiness or absence directives
2.3	12/10/2015	D. Rinehart	Content Revision: Updated shift information
2.4	2/18/16	D. Rinehart, A. DiScenza, A. Cobble	Content Revision: Updated shift information
2.5	11/16/16	T.Gibson, A.McDonald, D.Rinehart,R.Daniels,A.Cobble	Content Revision: Updated shift information
2.6	11/29/16	D.Rinehart	Content Revision: Updated shifts, Friday and Saturday
2.7	3/20/2017	A. Cobble, R. Daniels, D. Rinehart	Content Revision: Updated shifts, Saturday and Sunday

Change of Vital Status - Recruitment

Background

When we learn that a Recruitment case we thought was alive is deceased, we must record the change of vital status in the CCSS Recruitment database. If the case is still eligible and the proxy has not refused, we also request a change to the online recruitment website. Conversely, if we thought an individual was deceased, but learn that s/he is alive, we must record the change. For St Jude cases (CCSSID starts with "15"), see also **Death Notifications about St. Jude Cases**.

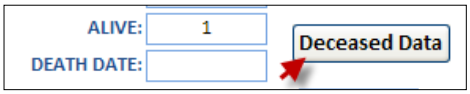
Procedures

Changing Alive to Deceased

1. Access the case's record in the CCSS Recruitment database.

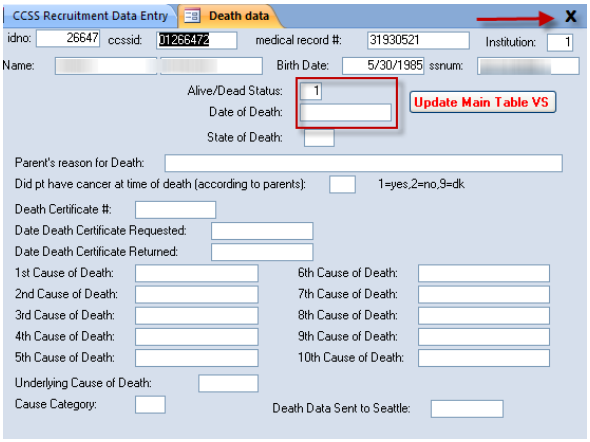
2. Document the vital status change and information source in the **Comments** field of the Quest tab.

3. Click **Deceased Data** button in the record header. This opens the Death data form.

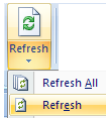


4. On the Death data form, change the 1 in **Alive/Dead Status** to 2.

5. Enter **Date of Death** and any other known information.



6. On the Ribbon, click the **Refresh** button in the Records group of the Home tab.



7. On the Death data form, click the **Update Main Table VS** button.

8. Close the Death data form. NOTE: Use the "X" in the upper right corner of the death data form. Do NOT close the database.

9. Click the Refresh button again, as above. On the main CCSS Recruitment Data Entry form, the record should now show the person's alive status as "2" and date of death (if entered).

10. IF the case is *from institution 26 (University of Michigan)*:
    A. Determine the case's current age.
    B. If not recruited, not refused, and still eligible, use the SOP titled **Updating Michigan Recruitment Print Table Assignments** to remove the case in question from the current Michigan print table and add him/her to the deceased Michigan print table.

11. *IMPORTANT*: If the case is still eligible, not yet recruited, and not a refusal, send a request to the designated departmental IT staff to ensure that the case is in the deceased group for the recruitment *website*. Include the case's USCID and birthdate in the emailed request.

12. If it was reported that the participant had cancer at the time of death, notify the CRA2 handling the Subsequent Malignant Neoplasm (SMN) project for possible follow-up.

13. If the case is *from institution 15 (St. Jude)*, see also **Death Notifications about St. Jude Cases**.

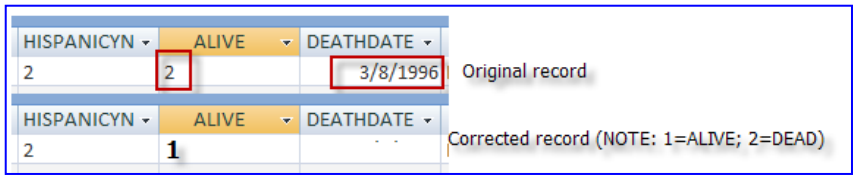
Changing Deceased to Alive

1. Access the case's record in the CCSS Recruitment database.

2. Document the vital status change, the currently recorded date of death (if entered), and information source in the **Comments** field of the Quest tab.

3. NAVIGATE TO THE NEXT RECORD.

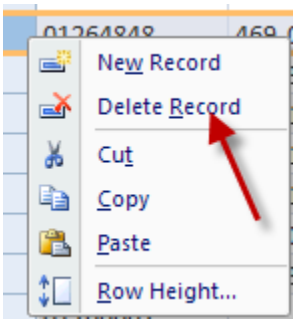
4. Open tblCCSSRecruitmentMain.
    A. Find the record by CCSSID.
    B. Filter the table so that only the CCSSID in question is displayed.
    C. Change the value in **ALIVE** from 2 to 1.
    D. Clear the value in **DEATHDATE**.



    E. Clear the filter, navigate to the previous record, and then close tblCCSSRecruitmentMain.

5. On the CCSS Recruitment Data Entry form, navigate back to the record in question.

6. Click the Refresh button in the Records group of the Ribbon's Home tab. The **ALIVE** field should now display "1" and the date of death should be blank.



7. Open tblDeceased.
    A. Find the record by CCSSID.
    B. Right-click on the record number.
    C. Select Delete Record from the pop-up menu.

D. Ensure you are deleting the correct record as this deletion *cannot be reversed*.

8. IF the person is from *institution 26 (University of Michigan)*:
   A. Determine the case's current age.
   B. If not recruited, not refused, and still eligible, use the SOP titled **Updating Michigan Recruitment Print Table Assignments** to remove the case from Michigan's deceased print table and add him/her to Michigan's appropriate (adult or minor) print table, depending on current age.

9. *IMPORTANT*: If the case is still eligible, not yet recruited, and not a refusal, send a request to the designated departmental IT staff to ensure the case is (a) in the appropriate alive (adult or minor) recruitment website group, and (b) in the appropriate alive DatStat baseline list. Include the case's USCID and birthdate in the emailed request.

10. If the case is *from institution 15 (St. Jude)*, see also **Death Notifications about St. Jude Cases**.

Revision Record Printed 1/15/2015 9:09 AM

[34] Current Filename:		Change of Vital Status-Recruitment ver 2_3.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/5/11	J. Bates	Initial Development
1.1	12/20/11	J. Bates	Updating print table-cross reference SOP
1.2	7/17/12	J. Bates	Add cross reference to StJude case deaths
2.0	12/11/12	J. Bates	IT request for recruitment website; DatStat check
2.1	12/17/12	J. Bates	Note eligible, not refusing, not yet recruited
2.2	6/28/13	J. Bates	Recruit changes to CV using UCSCID
2.3	12/31/14	R. Massey, L. Harrison, J. Ford	Content and Formatting Revision – add SMN directives, updated print table directives

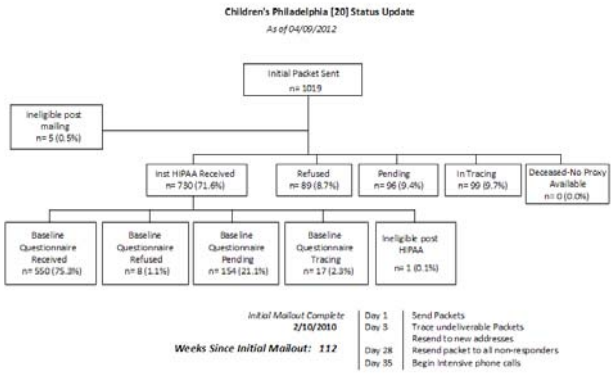
Checking Recruitment Status Updates Reports

Background

The Recruitment database generates institution-level recruitment status update reports on demand. We must check the figures in the reports to make sure the figures add up as they should. When we find a discrepancy, it is usually due to a data entry error in the database. After identifying where the problem is, we make the necessary corrections and then rerun the report. We run the reports once a month, on Tuesdays, and then distribute them in advance of the weekly CCSS Coordinating Center meeting.

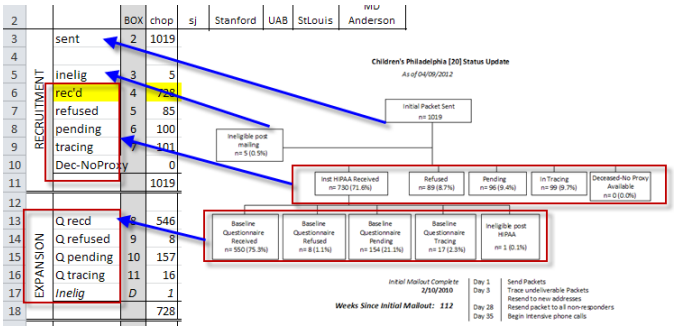
Procedure

1. Locate the report object **rptStatusUpdateReports** in the database object lists.
   a. Double-click the object name to view the report on the screen.
   b. From the File tab on the ribbon, click the Print icon to print the reports. Each institution prints on a separate page. The report presents the institutions in order by the date when the initial mailout was completed (oldest comes first).

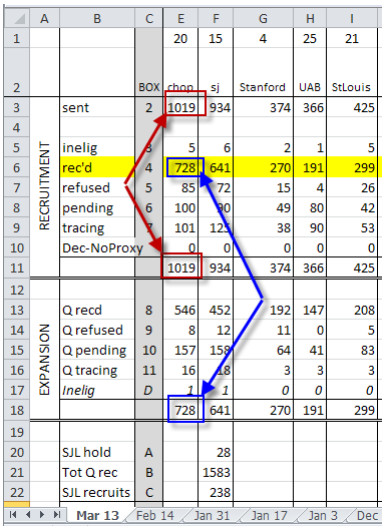


2. Open the Excel file **StatusReport_QC_check**. The sheet contains a separate worksheet for each date we generated the reports. COPY the most recent tab, changing the name of the copy to the current date. The sheet contains a column for each institution, in the same order as the flowcharts are presented.

3. For EACH institution, enter the values from the institution's printed flowchart into the column for that institution, on the row that matches the box. E.g., Initial Packet Sent box goes to the "Sent" row, etc.
   a. NOTE: Do NOT type in row 11 or row 18. These rows contain the checksum formulas.



4. After entering all the data, for *each institution*, inspect the checksum values for each institution.
   a. **Checksum in row 11** equals value in row 3 (**Sent**)
   b. **Checksum in row 18** equals value in row 6 (**Recruitment rec'd**)



	A	B	C	E	F	G	H	I
1				20	15	4	25	21
2			BOX	chop	sj	Stanford	UAB	StLouis
3		sent	2	1019	934	374	366	425
4								
5	RECRUITMENT	inelig	3	5	6	2	1	5
6		rec'd	4	728	641	270	191	299
7		refused	5	85	72	15	4	26
8		pending	6	100	90	49	80	42
9		tracing	7	101	121	38	90	53
10		Dec-NoProxy		0	0	0	0	0
11				1019	934	374	366	425
12								
13	EXPANSION	Q recd	8	546	452	192	147	208
14		Q refused	9	8	12	11	0	5
15		Q pending	10	157	159	64	41	83
16		Q tracing	11	16	18	3	3	3
17		*Inelig*	*D*	*1*	*1*	*0*	*0*	*0*
18				728	641	270	191	299
19								
20		SJL hold	A		28			
21		Tot Q rec	B		1583			
22		SJL recruits	C		238			

Mar 13 | Feb 14 | Jan 31 | Jan 17 | Jan 3 | Dec

5. If either checksum for an institution does NOT equal what it should, troubleshoot the institution's cases to identify which value used to calculate the checksum is off. Use the appropriate query (listed below) to list all the specified institution's records, together with the fields whose values you need to determine the category.
   a. If the Recruitment checksum (row 11) is off,
      i. use **qryStatus_TroubleShooting01-Recruiting**. Open in design view and set instcod to the institution's value.
      ii. If StJude's recruitment checksum is off, use **qryStatus-TroubleShooting03-Recruiting-SJ**
   b. If the Expansion checksum (row 18) is off,
      i. use **qryStatus_TroubleShooting02-Expansion**. Open in design view and set instcod to the institution's value.
      ii. If StJude's expansion checksum is off, use `**\qryStatus-TroubleShooting03-Expansion-SJ**

   c. After opening the appropriate troubleshooting query, use the manual sort, filter, and selection operations to narrow the list to show cases that match the criteria for the row. Then look for cases coded in such a way that they are being counted in two mutually exclusive categories. (E.g., someone who is in tracing, but who has an outcome code.).
   d. For each suspect case you identify, pull up the data entry form to fully review the case. Determine what (if anything) is miscoded. Correct as needed and use the notes field to document what was corrected. Go to the next record. Then return to the query and refresh it. Continue until you've identified and corrected all issues.
   e. Rerun the database report. Page down to the institution you've researched, and reprint just that page. Update the values in the institution's column of the QCcheck file. If you have identified/corrected the issue, the checksums should now match.
   f. If you need further information about the criteria used to generate the values in each box of the status report flowchart, refer to the database request specifications used to build the report.

6. NOTE: if a case is correctly counted twice, document the case in the QCcheck file's notes row to alert you to this persistent issue. E.g., "09279804 ineligible (Austria), but survey completed online; counted 2x in exp"

Revision Record

Printed 7/10/2012 12:40 PM

Current Filename:		Checking Recruitment Status Update Reports ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	4/9/12	J.Bates	Initial Development

CHIIP Study Follow-Up Calls

Background

The **CHIIP** research study (**C**ommunicating **H**ealth **I**nformation and **I**mproving Coordination with **P**rimary Care) has been designed for adult survivors of childhood cancer who may be at higher risk of heart problems due to their prior cancer treatment.

The purpose of this research is to see if problems like high blood pressure, high blood cholesterol, and high blood sugar are more common among study participants (pts), and to improve the way participants work with their primary healthcare providers to improve heart health.

Important: the ***CHIIP study password*** in the CHIIP study tracking database ***IS NOT*** the same as the CCSS pt password in the LTFU Participant Database. Be sure to provide the ***CHIIP password***, when needed.

General Eligibility Criteria

- The study seeks to enroll 650 CCSS pts who are over 18 years of age
- Live in the U.S., within 50 miles of a designated EMSI center
- Can read, write and speak English
- Ability to understand and agree to participate via an informed consent.

Around 11 cities will be targeted that have 100+ pts Consult with an LSI, Coordinator or Project Manager, if a pt moves outside the 50-mile range.

Mailing Plan

All eligible participants get a $25 check up front in their initial **CHIIP** packet. An additional $25 to $50 will be given for the study activities that a participant completes. Follow-up calls begin to all non-responders after twenty-one days.

Pts *must* complete the consent AND the baseline survey, either on paper, over the phone or online to be *fully enrolled*. The HIPAA must be signed by the pt, either electronically, or on paper and returned by mail. If the signed HIPAA is returned before call rotation begins, the SI will skip the HIPAA step in **REDCap** during the follow-up.

Recruitment Approach

Initially, a standard approach packet was sent to all eligible participants (Minneapolis). But since the enrollment rate was low, it was decided that three simultaneous approach methods will be piloted for the next couple of sites to see which approach yielded the best enrollment. Detailed descriptions and documents are included in the Appendix section at the end of this SOP. As of 5/17/18, all participants in the subsequent sites in this study (including Boston) will receive the Standard Approach Packet.

1. **Standard Approach**: a "Full Packet" is mailed which include the following:
   - $25 check
   - Brochure
   - Introduction letter
   - I do not want to participate form
   - Consent Form
   - Contact Update Form

- Primary Healthcare Provider Info Form
- HIPAA/ Release or Obtain PHI form
- Baseline Questionnaire
- Participant copy and HIPAA copy
- Fred Hutch Return Envelope

2. **Short Approach**: a smaller packet is mailed which excludes the baseline questionnaire. After receiving the consent, Fred Hutch will mail the Questionnaire and a return envelope to the pt.
3. **Tiered Approach**: Study participation will be broken into two phases and each phase will have a consent form.
    a. **Phase 1 Consent and Approach Packet**: The approach packet for Phase 1 will include all items in the Standard Approach EXCEPT for the questionnaire and brochure and will have the shorter consent form which will cover the first home visit and baseline questionnaire. Pts who complete the **Phase 1 Consent** will be mailed the questionnaire with a return envelope by Fred Hutch.
    b. **Phase 2 Consent and Approach Packet:** After a pt consents to and completes the first home visit for **Phase 1**, Fred Hutch will send the test results to the pt.
        i. If all their test results are *normal*, their study participation is concluded.
        ii. If an *abnormal result* is found, test results are sent to the pt with a letter that explains the **Phase 2 Study** inviting them to participate. This letter will explain the follow-up study and includes the **Phase 2 Consent** and a return envelope. The Phase 2 consent will describe all the components of the follow-up study, which include the 30-minute counseling session, the 4-month follow-up call with the counselor, the second home visit and a 20 minute questionnaire.
            - Pts who complete the **Phase 2 Consent** will be randomized to Group A or Group B and sent a letter explaining which group they are in with a description of the next study activities.

Max EMSI Call Follow-Up

The home visit is facilitated by EMSI. Occasionally, if EMSI is unable to reach the pt (Max Calls), a Survey Interviewer will be asked to re-connect with the pt. The SI will obtain the best phone number/day/time to call, and (if possible) transfer the pt directly to the **EMSI Hotline** at **(866) 581-3674**. If possible, leave a message with the pt's contact information and ask EMSI to contact the pt. If EMSI is unavailable,

1. Abort transfer attempt.
2. Thank the participant for their patience
3. Explain that their preferred day/time contact information will be sent to EMSI, and,
4. Tell the participant that they should receive a call from EMSI within the next several days
5. After the call, forward the pt's preferred contact information via email to the CHIIP Project Manager (Koko Kochar), and copy the Research Scientist (Aaron McDonald), and the Coordinator of the Survey Interviewers (Dayton Rinehart). If a message was left for EMSI to contact the pt, also include that in the email.

(*for more information, see* **Max EMSI Call Follow-Up***, located in the section,* **"After the Call"***)*

Project or LTFU Study Refusal

The pt may also elect to opt-out or refuse the CHIIP study at any time, or refuse all further participation in the LTFU Study.

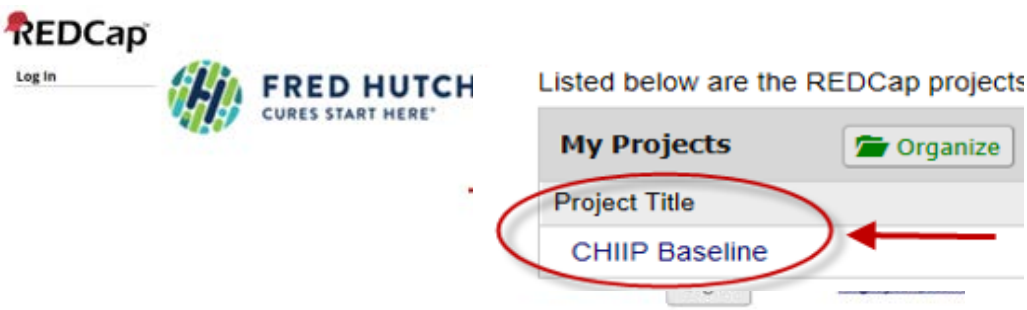
Tools Needed:

1. **CCSS SI Assignments Database** (*Located in Sharepoint, Workspaces, ECC, Databases and Systems, https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
2. **CCSS LTFU Participant Database** (*Located in **Sharepoint…***)
3. The SOP, **LTFU Participant Database Data Entry** (*Located in Sharepoint…SOP Library*)
4. **CHIIP Database** (*Located in Sharepoint…*)
5. Online access to the **RedCap** database (*Located at,* https://cdsweb07.fhcrc.org/redcap/index.php)
6. **Pre-Post Call Checklist – CHIIP Study Calls** (*Located in Sharepoint…SOP Library*)
7. **Document 201 Recruitment Phone Script CLEAN** (*located at, \Z…Interviewers\CHIIP\Scripts*)
8. **Document 102 CCSS Verbal Consent Script CLEAN 1.17.18** (*located at \Z…Interviewers\CHIIP\Scripts. Blank paper copies are available in file cabinet "A", in the folder,* "**CHIIP Consent Form-Blanks"**)
9. **CHIIP Enrollment Email Template.docx**, (*located at \Z…Interviewers\CHIIP\Email Templates*)
10. **Emailing CHIIP Survey Links**

Procedure

Before the Call

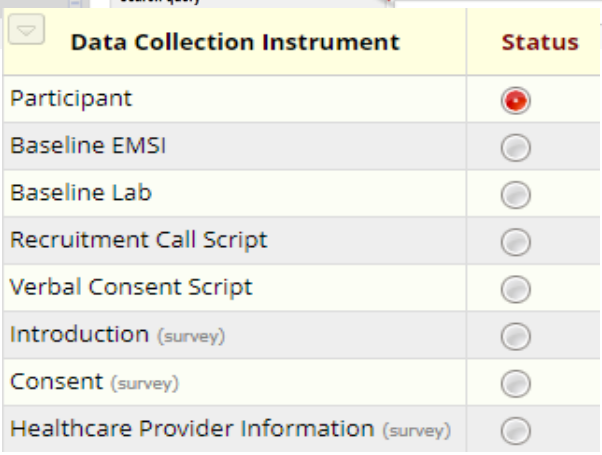
1. Obtain a blank "**Document 102 CCSS Verbal Consent Script CLEAN 1.17.18** "
2. Review call assignments
   a. Open the **CHIIP Call Assignments**, located in the **CCSS SI Assignments** database
   b. Review the pts on the list, referencing the **Pre-Post Call Checklist – CHIIP Study Calls**
3. Begin building a profile for the pt, continuing to reference the corresponding sections of the **Pre-Post Call Checklist – CHIIP Study Calls**
   a. Locate and review the pt record in the **CCSS LTFU Participant Database**
   b. Locate and review the pt record in the **CHIIP** database, **Tracking tab,** and determine if the pt needs to be called.
   c. Locate and review the pt record in the online **RedCap** database
   (REDCap is a secure web application for building and managing online surveys and databases. The REDCap website contains records for all CHIIP participants and is used to complete the CHIIP Enrollment Process and Baseline Survey.)
      i. Navigate online to, https://cdsweb07.fhcrc.org/redcap/index.php, and log in.



ii. Click on "**CHIIP Baseline**" under, **My Projects**

iii. From the Navigation pane on the left sidebar, click on, "**View/Edit Records**" to locate the pt

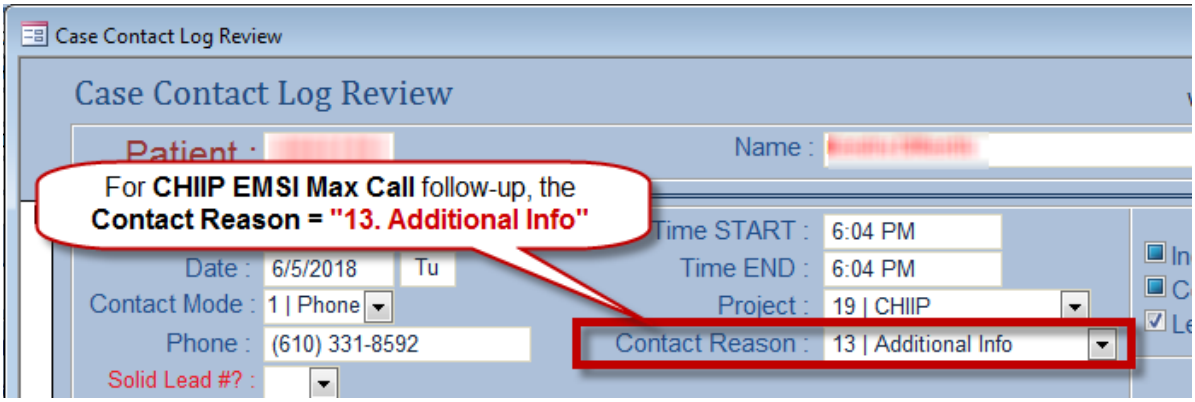
iv. Beginning at the Recruitment Call Script, click on the first clear radio button to begin completing the CHIIP enrollment process with the participant.



During the call:

Participant Database - See the SOP,. **LTFU Participant Database Data Entry** for full instructions

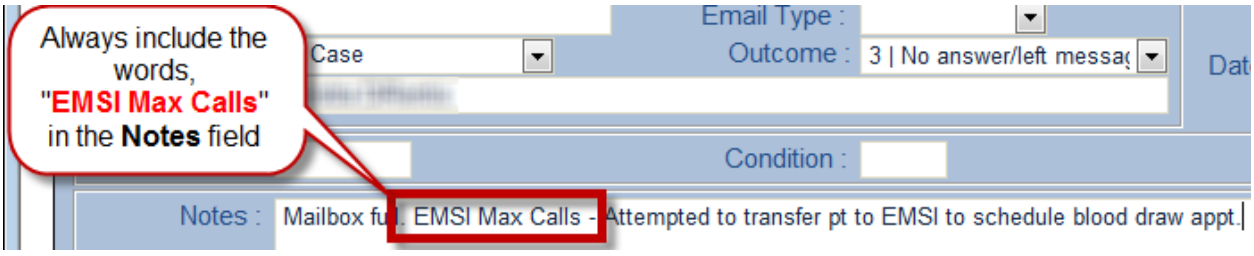
1. Verify/confirm the identity of the pt.
2. Verify/confirm all **contact information** for the pt and his/her associates. Update the **LTFU**
3. Create a new **Contact/Trace Log**
   A. **Project** field – Populate with **19-CHIIP**.
   B. **Contact Reason** field – Populate,
      i. **4 Survey** – For CHIIP survey calls
      ii. **5 HIPAA** – Calls to pts who have not yet completed the HIPAA
      iii. **8 Additional Records** – Calls to complete the CHIIP Consent *only*
      iv. **13 Additional Info** – "EMSI Max Calls", pt follow-up



C. **Outcome** field:
   i. Survey calls –
      1) Completed surveys - **1 Completed**
         Please note: Once a participant verbally consents to the CHIIP Study and has completed the Baseline Questionnaire over the phone, do *NOT* transfer the pt to an EMSI representative at this stage. EMSI will not have the participant in their system.
      2) Partially completed surveys - **10 Other**
   ii. HIPAA calls – **9 Will return by mail/online** (If the pt says they will complete or have already mailed the HIPAA)
   iii. Additional record calls - **1 Completed** (After the pt completes the consent over the phone)
   iv. Additional Info calls - **1 Completed** (If best time/day/phone contact information was received, whether the call was successfully transferred to EMSI or not)
   v. Ineligible - **10 Other** (review the call with the Project Manager and copy the Research Scientist, before using this outcome)

D. **DB Change** field. If the call outcome is,
   i. **Partial Survey** – Update the **DB Change** field, **8 Partially Complete**
   ii. **Ineligible** – (review the call with the Project Manager and copy the Research Scientist, before using this outcome) **-** See the SOP, **LTFU Participant Database Data Entry** for full instructions.
   iii. **Deceased** – If it was discovered that the pt is now expired. In addition, always complete an **Expired Participant Information Sheet** and place the completed form in file cabinet **A**, and send an update via email to the Project Manager, and copy the Research Scientist, LSI and the Coordinator. Do not pursue participation.

E. **Notes** field.
   i. **EMSI Max Calls** – Include the words, "EMSI Max Calls", whenever making a call to attempt to re-connect the pt with EMSI to schedule the home visit.

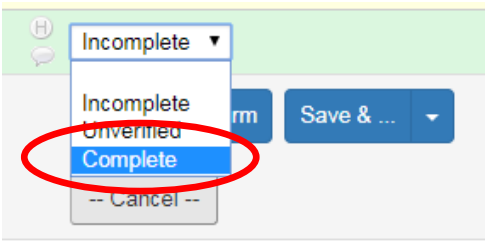


Survey Interviewer

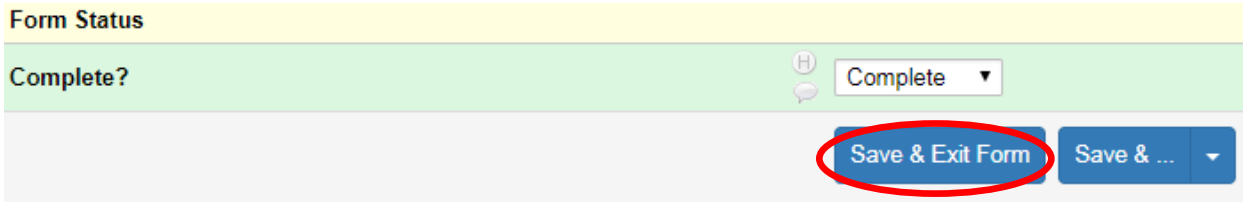
REDCap database –

For recruiting new **CHIIP Study** pts over the phone, use the online **Recruitment Call Script** in **REDCap** to record the pt's responses.

1. As you go through the script and record the participant's responses, *automatic skip logic* will provide an opportunity to record additional information from the pt, or skip to the next question, based on the pt's responses.
2. Once finished, change the form status at the bottom to complete.



3. Be sure to always click **SAVE**.



4. If **REDCap** is unavailable, complete the paper script, **Document 201 Recruitment Phone Script CLEAN**, and transfer the pt's responses into **REDCap** at the first available opportunity. Be sure to place the paper document in the shredder afterwards, if it is no longer needed. Consult with an LSI, the Coordinator, the Project Manager

CHIIP Database

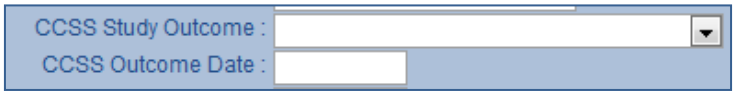
1. If the pt reports s/he has **already returned** the baseline/enrollment survey:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. If a paper copy was returned more than one month ago, it may be lost. Offer to complete the survey over the telephone to avoid further losses.
      ii. If a paper copy was returned less than one month ago, it may still be in route. Thank the pt for their involvement and advise that the study team will follow up if the survey is not received.
      iii. If an online survey was returned before today but the **Date Baseline Received** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday and Saturday will have the **Date Baseline Received** field populated the following Monday.
   C. Confirm the pt is referring to the **CHIIP** baseline survey. The pt could be thinking of another study in which s/he participates.
   D. Try logging in to the online survey to determine the survey status. It may be that the pt neglected to click the **Submit** button.
      i. If an online survey was returned today, the **Date Baseline Received** field will be populated on the next business day (Monday through Friday). Thank the pt for

their involvement and advise that the study team will follow up if the survey is not received.

2. Determine if pt received a copy of the consent form.
   A. Case received packet – Advise that his/her copy of the informed consent is in the materials received and should be kept on file.
   B. Case did NOT receive packet – Advise that we will send a copy of the informed consent via email (preferred) or on hard copy. Determine which format the pt needs. (Determine how the case would like to complete the enrollment survey (telephone, online, or paper). If appropriate, begin the consent script and then the survey.
3. If the pt **refuses**:
   A. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
   B. If it is unclear if the pt is refusing just the CHIIP Study or all further participation in the LTFU Study, clarify.
4. Thank the pt for taking our call.

After the Call

1. **Refusal** – If the pt refused the **CHIIP** or **LTFU** study:
   A. **Update the LTFU Participant Database** –
      i. **Refused CHIIP study *ONLY*** – Update **Contact Log** only.
      ii. **Refused All Else** (i.e. the case refused all further participation in the LTFU Study) –
         a. Update the **CCSS Study Outcome** and **CCSS Outcome Date** fields in the header.

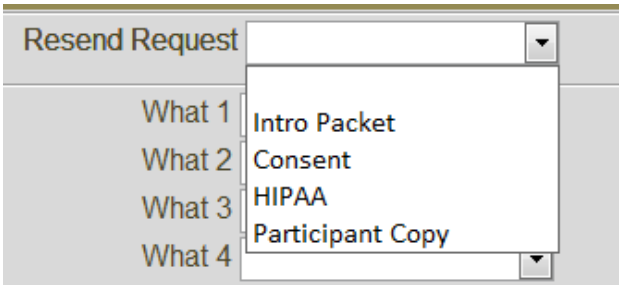


         b. Add a dated note with SI ID in the **Notes** field on the Participant tab.
   B. **Update the CHIIP Database** –
      i. If the pt **refused all further participation in either the CHIIP Study or in the entire LTFU Study**, go to the Tracking tab:
         a. **Notes** – Add a dated note with SI ID documenting the refusal outcome**.**
   C. **Email the Project Coordinator** – to advise of the refusal. Copy the Research Scientist, Call Center Coordinator, and LSI team.

2. **Requesting CHIIP Survey Resends**
   A. **Paper Survey**:
      i. In the **CHIIP** database, on the **Tracking** tab,
         a. **Request Date** – Populate with the current date.

b. **Resend Request** – Use the drop-down menu to choose the hardcopy materials to be resent.

c. **Notes** – Add a dated note with SI ID documenting the resend requested.



B. **Emailing Survey Links** - If the pt requested to complete the **CHIIP** survey online, follow the instructions in the SOP, **Emailing CHIIP Survey Links,** and send an email with the appropriate link, using the email template, **CHIIP Enrollment Email Template.docx.** Remember to send the pt the **CHIIP study password** from the **CHIIP study tracking database**.

3. **Partially Completed Survey**

A. **Online Survey** – Review every completed page of the online survey for accuracy and completeness before closing the partially completed survey.

B. **LTFU Participant Database** –

i. **Contact/Trace Log** – see instructions under the previous section, **During the Call**

C. **CHIIP Database, Tracking Tab**

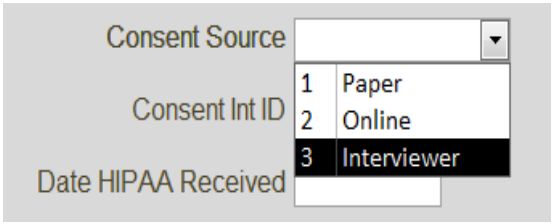
i. **Notes** – Add a dated comment with SI ID documenting the partially completed survey.

ii. **Consent Source** - Populate with "3 Interviewer".

iii. **Consent Int ID** - Populate the field with your SI ID.

iv. **Baseline Int ID** – Do NOT populate.

v. **Baseline Source** – Do NOT populate.



D. **Update the Call Center Appointment Calendar** – If an appointment was made to complete the survey later, note the partially completed survey outcome on the **Call Center Appointment Calendar** according to the SOP titled **Call Center Appointment Calendar**.

E. **Email the Closing Monitor** – the pt ID, SI ID, and a note indicating the unscheduled partially completed survey, for the closing report.

F. **Update the Dry Erase Board (DEB)** – Add a tick mark with a "P" to indicate the partially completed CHIIP Survey.

G. File the CHIIP Study Informed Consent form in the folder, "**CHIIP Completed Consents**", in file cabinet "**A**".

H. If the pt indicated during the call a preferred or best time time/day for EMSI to call the pt to set up the blood draw,

i. Add the information in the CHIIP (tracking) Database, Notes field, AND,

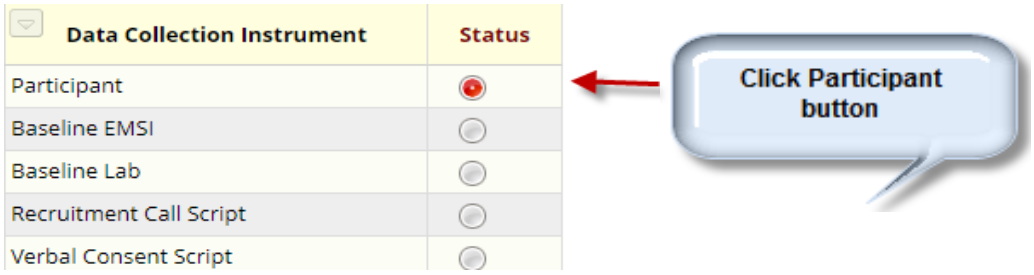
ii. **Email the Project Coordinator**, who will then forward the information to the EMSI Coordinator, and copy the Research Scientist, Call Center Coordinator, and LSI team.

4. **Completed Survey**
   A. Before submitting the **CHIIP survey** online, review each question for accuracy and completeness.
   B. **CHIIP Database**, **Tracking Tab**
      i. **Consent Source** - Populate with "**3 Interviewer**".
      ii. **Consent Int ID** – Populate the field associated with the Informed Consent.
      iii. **Baseline Int ID** – Populate the field with your **SI ID**.
      iv. **Baseline Source** – Populate with "**3 Interviewer**".
      v. **Notes** – Add a dated note with **SI ID** specifying which survey was completed.
   C. **Completed *Scheduled* Surveys** – Place a check mark on the **Call Center appointment calendar** to indicate the kept appointment. See the SOP titled **Call Center Appointment Calendar** for full details.
   D. **Completed *Un-Scheduled* Surveys** –Email the pt ID to the closing monitor to include the completed survey in the closing report.
   E. **Update the Dry Erase Board (DEB)** – Note the completed CHIIP survey with a tally mark on the Dry Erase Board (DEB).
   F. **File the CHIIP Study Informed Consent form** – **Document 102 CCSS Verbal Consent Script CLEAN 1.17.18 ,** in the folder, "**CHIIP Completed Consents**", in file cabinet "**A**".
   G. If the pt indicated during the call a preferred or best time time/day for EMSI to call the pt to set up the blood draw,
      i. Add the information in the CHIIP (tracking) Database, Notes field, AND,
      ii. **Email the Project Coordinator**, who will then forward the information to the EMSI Coordinator, and copy the Research Scientist, Call Center Coordinator, and LSI team.

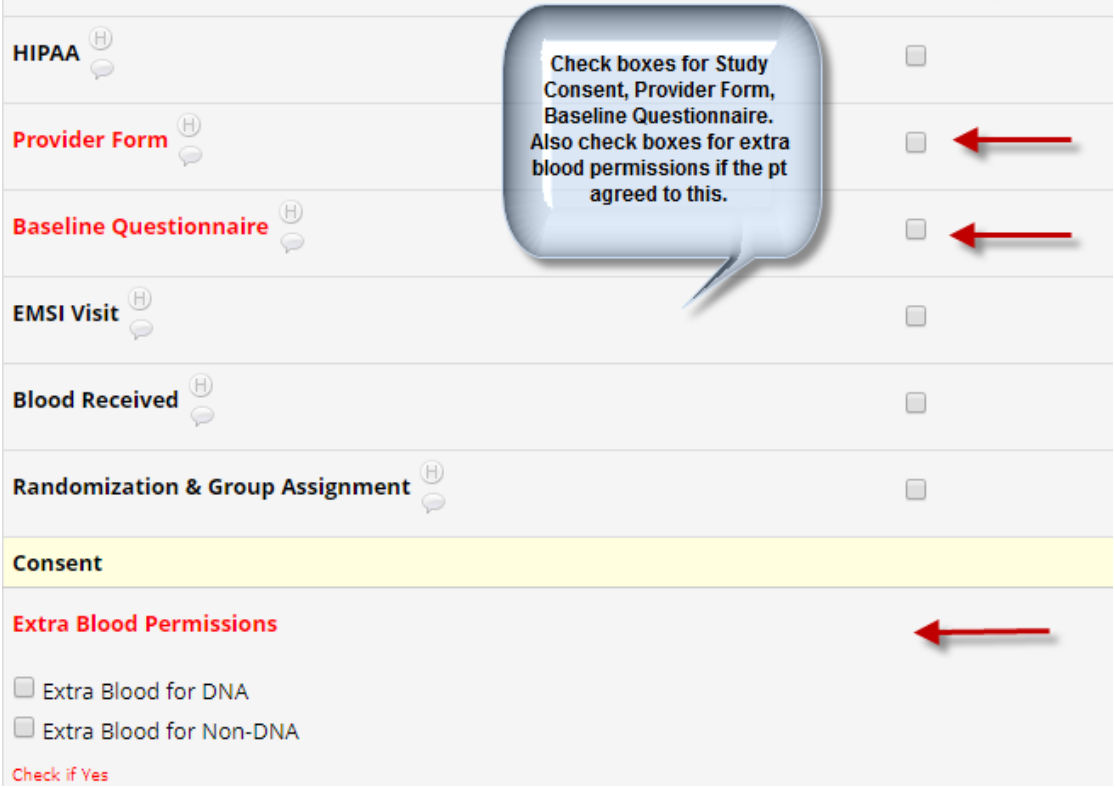
Updating REDCap:

Once the SI has filled out the **verbal consent instrument** and/or completed the **baseline questionnaire** in **REDCap** over the phone, the SI needs to go into the **Participant Screen** and check the boxes for **Study Consent, Provider Form** and **Baseline Questionnaire** accordingly. Also check the **Extra blood permissions boxes** if the participant agreed to this.

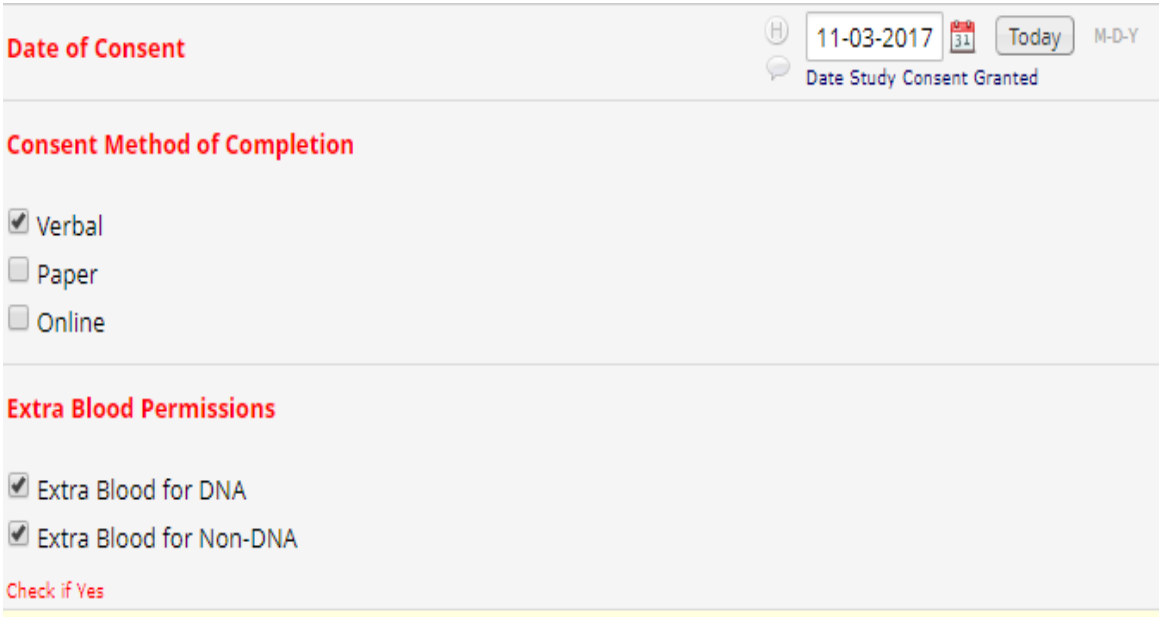
1. Navigate to the **Participant** screen

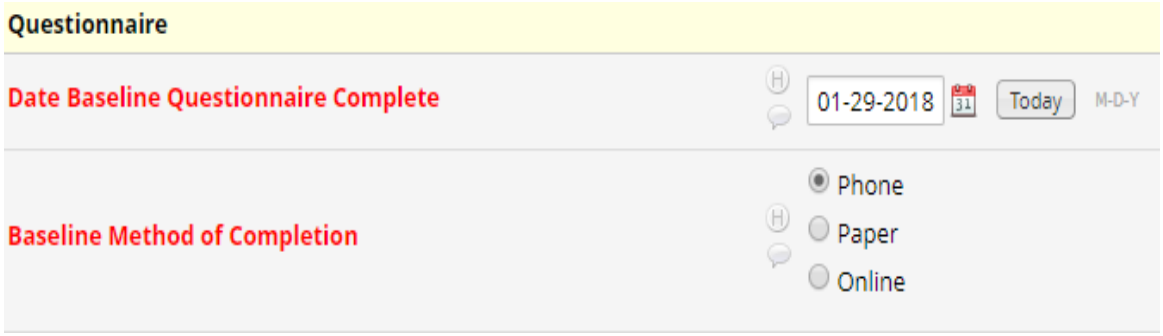


2. Check the appropriate boxes. **Interviewer Tracked items are in Red. (See below)**



3. Ensure that the **Consent Method of Completion** and the **Baseline Method of Completion** is filled out appropriately. (See example below.)





4. Before exiting the record, if a participant provides new contact info, click the "**Contact Information Update**" instrument.
    a. This displays the contact info currently in **REDCap** and provides a place to record updated contact information.
    b. Change the form status to complete and click **Save** once you are done.

Max EMSI Call Follow-Up

CHIIP database –

Once the pt has been reached,

1. If the call was successfully transferred to EMSI,
    A. Populate the **Sent to EMSI** field with the date of transfer
    B. Add a note in the **Notes** field, indicating the pt was reached, the call was transferred to EMSI and the Sent to EMSI field was populated
    C. Send an email to the Project Manager, indicating the CHIIP EMSI Max Call pt was reached and transferred to EMSI and the CHIIP database has been updated
2. If the pt was reached, but not transferred to EMSI,
    A. Obtain the best time/day/phone number for EMSI to call the pt
    B. Add a note in the **Notes** field, indicating the pt was reached and provided contact information, but was not able to be transferred to EMSI
    C. Send the information to the Project Manager
    D. The Project Manager will send the information to the EMSI Project Coordinator and will then populate the **Sent to EMSI** field

Appendix Section

FH would like to pilot 3 simultaneous methods to see if these will improve our enrollment rate. These methods include:

Standard Approach

1. Sending the **full approach packet** which is what we are currently using. (+ Brochure)

Short Approach

2. Sending a **smaller approach packet without the questionnaire**. The size of the packet that we currently send could be a bit daunting so we would like to see if this option is more attractive to some people. The smaller packet will contain the approach letter, the consents (HIPAA and Provider form), participant copy and a return envelope. Participants who return the consents in the mail, or complete them online, will be mailed the questionnaire with a return envelope. (+ Brochure)

Tiered Approach

3. Using a tiered consent. Study participation will be broken into two phases and each phase will have a consent form.

   Phase 1 Consent and Approach Packet
   The Phase 1 consent will cover the first home visit and baseline questionnaire. The approach packet for Phase 1 will include the introduction letter, the Phase 1 consent, HIPAA and Provider Form. It will **not include a questionnaire**. Participants who return the Phase 1 consents will be mailed the questionnaire with a return envelope.

   Phase 2 Consent and Approach Packet
   After a participant consents to and completes the first home visit for Phase 1, we will send them their home visit test results. If all their test results are normal they are done with the study.

   If an abnormal result is found, we will send their home visit test results and a letter to ask if they would like to participate in the follow-up study which is Phase 2. This letter will explain the follow-up study and include the Phase 2 consent with a return envelope. The Phase 2 consent will describe all the components of the follow-up study, which include the 30 minute counseling session, the 4 month follow-up call with the counselor, the second home visit and a 20 minute questionnaire.

   Participants who return the Phase 2 consent will be randomized to Group A or Group B and then we will send them a letter telling them which group they are in with a description of the next study activities.

Using these 3 methods will not impact our ability to complete the aims of the study. If one of these enrollment methods can be shown to improve accrual, this will increase the validity of the research.

NEW CHIIP STUDY DOCUMENTS

Document 100a: CHIIP Tiered Consent, Phase 1

The Phase 1 consent will only include the first home visit and baseline questionnaire.

Document 100b: CHIIP Tiered Consent, Phase 2

The Phase 2 consent will describe all the components of the follow-up study, which include the 30 minute counseling session, the 4 month follow-up call with the counselor, the second home visit and 20 minute questionnaire.

Document 200a: CHIIP Intro for Approach Option 2, No Questionnaire Enclosure

This introductory letter does not include the questionnaire.

Document 200b: Tiered Consent Intro Letter

This approach letter describes Phase 1 and includes the Phase 1 study consent, HIPAA, Provider Form and a return mailer.

Document 209: Cover Letter with Questionnaire and Return Mailer

This cover letter asks participants who have consented to the study to mail in the enclosed questionnaire with the return envelope provided.

Document 210: CHIIP Study Brochure

This brochure has general information and will accompany the approach letter and consent forms. It will not be used with people in the tiered approach group as their enrollment path is different. (The tiered approach is described above.)

Revision Record Printed

Current Filename:		CHIIP Study Follow-Up Calls ver 1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	5/22/2018	A. Cobble, F. Ford, D. Rinehart, K. Kochar, R. Daniels	Initial Development
1.1	6/12/2018	D. Rinehart, K. Kochar	Content revision, CHIIP and LTFU Study password distinction, Max Call procedure, when EMSI is unavailable.
1.2	7/17/2017	A. Cobble	Updated EMSI contact information
1.3	8/2/2018	D. Rinehart	Content/format revision, EMSI Max Call instructions/screen shots.

Closing Activities for Call Center Monitor

Background

A Survey Interviewer (SI) is assigned as the Closing Monitor for each closing shift in the Call Center. The Closing Monitor for any given day can be determined by reviewing the published weekly schedule located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Work schedules* for the monitor indicator.

The Closing Monitor is responsible for various closing activities including securing all Protected Health Information (PHI), producing the day's closing report and submitting it to all stakeholders, and general end-of-day procedures to close the office. This procedure outlines all Closing Monitor responsibilities.

Procedures

Ensuring Privacy and Safety

Prior to closing, the Closing Monitor will ensure privacy by securing all PHI and will ensure safety by performing general end-of-day procedures to close the office as follows:

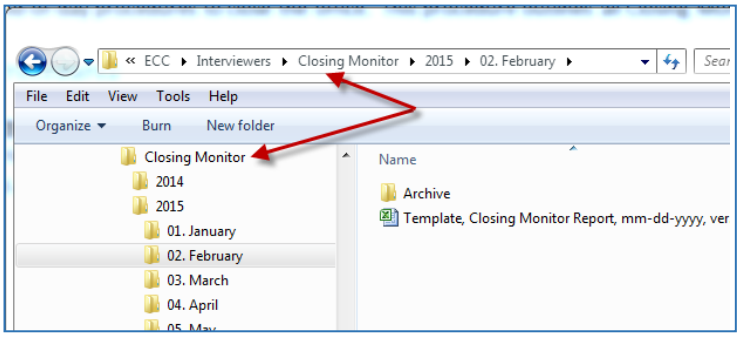
1. Ensure all SIs have put away/stored any participant-related information by 15 minutes before the end of the closing shift.
2. Lock all file cabinets, especially those used to store participant information.
3. Ensure no confidential participant information is lying out or posted anywhere. *This includes the printers and the copy machine*. If PHI is found, secure it in a locked cabinet.
4. Place any trash or recycling with PHI in the shred collection box.
5. Place the cabinet keys in the designated overhead cabinet and close its cover. Do not lock the overhead cabinet.
6. Ensure both Call Center doors are locked.
7. Turn off all coffee pot burners and all lights.
   NOTE: If Environmental Services employees are in the Call Center, leave the *lights* on as a courtesy and request that the employee(s) turn them off when leaving.

Completing and Submitting the Closing Monitor Report

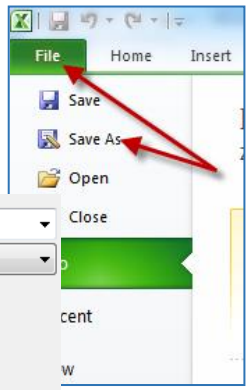
Prior to closing, the Closing Monitor will produce the closing report and email the report to all stakeholders as follows:

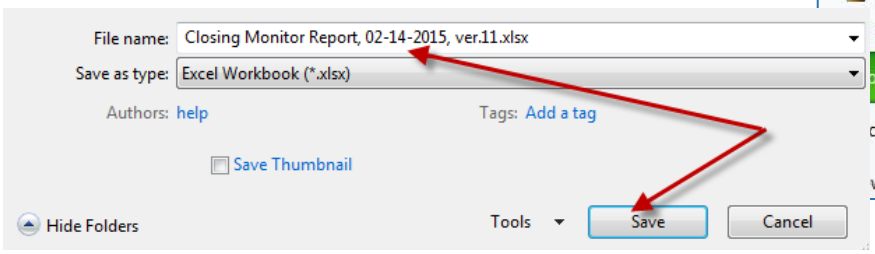
1. Gather information from the following sources:
   A. Call Center Appointment Calendar – Make a note of all information on the calendar for the current day and the next business day.
   B. Email notifications – SIs that completed unscheduled events during the day should have emailed the details of these events to the designated Closing Monitor.

C. Dry Erase Board (DEB) - The SI team should have updated the appropriate cell of the DEB with a vertical line (for completed events) or with a "p" (for partial surveys) when a scheduled or unscheduled event occurred.



2. Prepare the Closing Monitor Report:
   A. Open the template for the closing report at *Z:\SJShare\SJCOMMON \ECC\Interviewers \Closing Monitor*.
      i. Open the current year's folder then the current month's folder.
      ii. Open the Excel file named **Template, Closing Monitor Report, mm-dd-yyyy**.
   B. In the report template, save the report with the current date *before saving any data*.
      i. On the File tab, select the **Save As** option.
      ii. In the **File name** field, modify the file name to remove the word "Template" and change "mm-dd-yyyy" to the current date (e.g., Closing Monitor Report, 02-14-2015).
      iii. Click the **Save** button to save the file.





   C. Populate the **Date** and **SI 1 ID** light-green cells in the header of the worksheet. If two SIs work on the closing report, populate both the **SI 1 ID** and **SI 2 ID** fields.

CCSS Call Center Closing Monitor Report

Date:	2/14/2015	SI 1 ID:	166	SI 2 ID:	

   D. If applicable, enter the information for **Today's Scheduled Appointments** using information gathered from the Call Center calendar.
      i. Appointments should be documented in the same order in which they appear on the Call Center calendar.
      ii. All cells in the row should be populated for each appointment. Blank cells should be explained in the **Unusual Occurrences** cell (row 11).
      iii. Appointments may include appointments scheduled the same day. In such cases, the **Today's Scheduled Appointments** section of the current report will not match the **Tomorrow's Appointments** section of the previous day's report. The previous day's report should *not* be retroactively updated with these appointments.
      iv. **Did Pt Answer At Appt?**

a. Yes – If the participant answered for the appointment, even to reschedule or refuse, choose the "Yes" option.
b. No – If the participant did not answer for the appointment, choose the "No" option.
c. n/a
   1. The "n/a" option should only be used when the Call Center did not keep the scheduled appointment. If the Call Center called at the appointment time, "n/a" is not an appropriate selection.
   2. If the "n/a" option is used, enter an explanation in the **Unusual Occurrences** cell (row 11).

13	Today's Scheduled Appointments (Calendar Order):	CCSSID or SIBID	SI Who Set Appointment	SI Who Covered Appointment	Appointment Type	Did Pt Answer At Appt?	Outcome
14	1	12345678	81	156	FU5 Survey	No	No Answer

v. **Outcome** – Choose the most appropriate selection for the appointment's outcome.
   a. If the participant partially completed a survey *and* rescheduled the rest of the survey, choose the "Partial Survey" outcome.
   b. If the option "Other" is selected, enter an explanation in the **Unusual Occurrences** cell.
   c. If an appointment's outcome is not documented on the calendar, check the contact log and record the appointment outcome documented therein.

E. If applicable, enter the information for **Today's Unscheduled Events** using emails received from SIs throughout the day.

30	Today's Unscheduled Events:	CCSSID or SIBID	Event Type	SI ID	Outcome
31	1	98765432	ASK Survey	168	ASK Survey

i. If the participant partially completed a survey *and* rescheduled the rest of the survey, choose the "Partial Survey" outcome.
ii. If the "Other" option is selected in the **Outcome** cell, enter an explanation in the **Unusual Occurrences** cell.

F. If applicable, enter the information for **Tomorrow's Appointments** using information gathered from the Call Center calendar.
   i. Appointments should be documented in the same order in which they appear on the Call Center calendar.

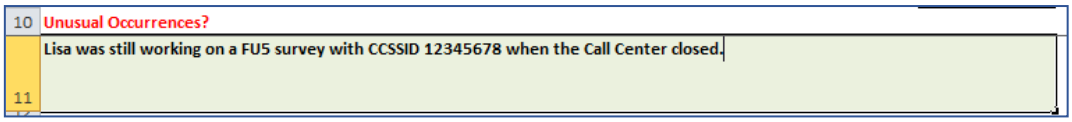
47	Tomorrow's Appointments	Appointment Time (Calendar Order)	CCSSID or SIBID	SI ID Who Set Appointment	SI ID Sched to Cover Appt	Appointment Type
48	1	5:00:00 PM	23456789	170	170	FU5 Survey
49	2	11:00:00 AM	87654321	166	163	Expired Case Baseline

ii. All cells in the row should be populated for each appointment. Blank cells should be explained in the **Unusual Occurrences** cell (row 11).

G. Populate the **Unusual Occurrences** cell (row 11) with any appropriate notes.
   i. The Closing Monitor will compare tallies on the DEB with events reported in the closing report header. If the data does not match, the Closing Monitor will:

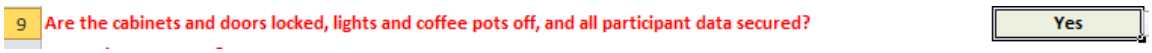
a. Verify that the entries in the closing report match the Call Center calendar and the emails received from SIs during the day.
b. If the imbalance remains unresolved, **report the imbalance** in the **Unusual Occurrences** cell (row 11). *EXAMPLE: DEB indicates 3 FU5 surveys. Calendar events plus emails received indicate 2 FU5 surveys.*

ii. Explain blank cells in the row for any appointment.
iii. Explain "Other" outcomes.
iv. Document all other unusual circumstances.
EXAMPLE 1: Lisa was still working on a FU5 survey with CCSSID 12345678 when the Call Center closed.

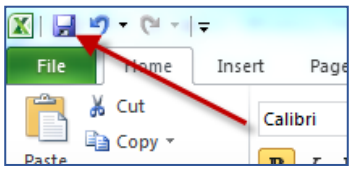


EXAMPLE 2: The power went out at 8:30pm.

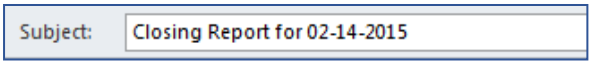
H. After ensuring that the cabinets and doors are locked, the coffee pot burners are turned off, and all participant data has been secured, populate the appropriate light-green cell (G9) with "Yes".



I. Click the Save icon in Excel, then close the report.



3. Email the closing report to the Research Scientist, the Coordinator, the LSI team, and the Closing Monitor for the next business day.
A. Create a new email.
B. In the Subject bar, type, "Closing Report for MM-DD-YYYY", substituting the current date for "MM-DD-YYYY".



C. Attach a copy of the saved closing report to the email.
D. In the body of the email, type, "Please see the attached closing report for MM-DD-YYYY.", substituting the current date for "MM-DD-YYYY".
E. Send the email.

Revision Record
Printed 9/3/2015 3:10 PM

Current Filename:		Closing Activities for Call Center Monitor ver2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.2	7/8/10	D. Rinehart	Revision of procedure developed by B. Benavides
1.3	5/4/12	Procedure Team	Formatting and content revisions
1.4	9/12/12	D. Rinehart, B. Carson, D. Bowen.	Added Closing Monitor template Procedure
1.5	9/17/12	A.McDonald, D.Rinehart	Revised Closing Monitor template and procedure
1.6	9/19/12	A.McDonald, D.Rinehart	Content and formatting revisions
1.7	12/21/12	D.Rinehart	Addition of Dry Erase Board
1.8	5/15/13	R. Massey	Content Revision Including Sibling Permissions
1.9	10/17/2014	R. Massey, D. Rinehart	Content Revision: Updated Report Template
2.0	8/8/2015	R. Massey	Content Revision: Clarified Outcome Field

Closing Monitor Report: Audit Procedure

Background

The daily closing report provides information on the Call Center's activities including important events such as verbal HIPAAs, sibling permissions, partial surveys, completed surveys, and various appointments. Training opportunities are identified through an audit of the closing report. This enables the Call Center to self-regulate for errors before these errors affect other aspects of CCSS operations.

Each closing report will be reviewed by a Lead Survey Interviewer (LSI) to identify errors, provide training to the Survey Interviewer (SI) team, and maintain quality in the service the Call Center provides to the CCSS.

Procedures

1. Confirm the closing email was sent to the correct list of recipients: Research Scientist, Call Center Coordinator, LSI team, and closing monitor for the next day.

2. Confirm the **Date**, **SI ID**(s), and security cells of the report are populated correctly:
   A. **Date** should be the date of the report.
   B. **SI ID** should be the ID of the closing monitor completing the report. There may be up to 2 SI IDs if the report was coordinated by two SIs.
   C. The security cell should indicate "Yes" to confirm that the cabinets and doors were locked, the lights and coffee pots were turned off, and all participant data was secured.

3. Check the **Unusual Occurrences** cell for occurrences that need to be reviewed and/or that require follow up.

4. Confirm the appointments and the outcomes documented on the report in the sections labeled "Today's Scheduled Appointments" and "Tomorrow's Appointments" match the information on the Call Center calendar for those dates. Confirm that any blank cell in an appointment row of these sections is explained in the **Unusual Occurrences** cell.

5. Confirm that any **Outcome** of "Other" in the "Today's Scheduled Appointments" and "Today's Unscheduled Events" sections is explained in the **Unusual Occurrences** cell.

6. For each scheduled and unscheduled verbal HIPAA, use the document **Verbal HIPAA Audit Checklist**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI\QA Audits*, to audit the event. If no errors are found, consider sending a "good job" note to the responsible SI. If training opportunities are identified, address these with the SI, then document the opportunity and action taken in the **SI Training Opportunities** spreadsheet, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI\Training*.

7. For each scheduled and unscheduled sibling permission, use the document **Sibling Permission Quality Assurance**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI\QA Audits*, to audit the event. If no errors are found, consider sending a "good job" note to the responsible SI. If training opportunities are

identified, address these with the SI, then document the opportunity and action taken in the **SI Training Opportunities** spreadsheet, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI\Training*.

8. Confirm the number of events on the report (in the report header cells labeled **Completed FU5 Surveys**, **Completed CASE Baseline Surveys**, **Completed SIBLING Baseline Surveys**, **Partial Surveys**, **Completed HIPAAs**, **Completed Sib Permissions**, **Completed ASK Surveys**, and **Completed EMPOWER Surveys**) matches the number of events tallied on the Dry Erase Board (DEB). If they do not match, this discrepancy should have been noted by the closing monitor in the **Unusual Occurrences** cell, per the SOP titled **Closing Activities for Call Center Monitor**.

9. If no errors are found on the closing report in the previous steps, consider sending a "good job" note to the responsible SI closing monitor. If training opportunities are identified, address these with the SI then document the opportunity and action taken in the **SI Training Opportunities** spreadsheet, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI\Training*.

Revision Record Printed 3/3/2015 1:19 PM

[256] Current Filename:		Closing Monitor Report Audit Procedure ver 1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/23/2013	R. Massey	Initial Development
1.1	2/28/2015	R. Massey	Content Revision to match new closing report template and procedures

Coding Guidelines & Tips

Background

This document presents general guidelines to follow when coding surveys, as well as useful tips.

Guidelines and Tips

1. **ALWAYS CODE IN RED INK.** Use **red ink** to code surveys/questionnaires.

2. **Initial and date the survey.** The first step when coding LTFU surveys is to put your initials and the current date on the bottom right box of the front page of the survey. (See the exception for certain St Jude Life surveys.)

3. **Use the coding key**. Be sure to follow the coding key in order to code only the appropriate boxes.

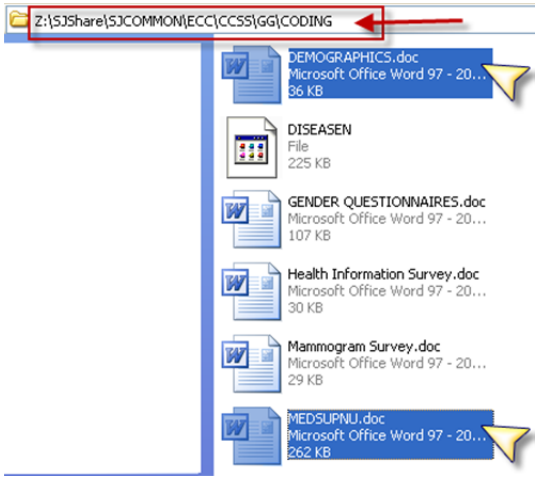
4. **Where to find code references.** Coding surveys require codes from **three coding sources** (ICD-9 (Use 3M Encoder), Demographic List, and MEDSUPNU (Drug) List).

    - The Demographic and Drug lists are Word documents. Find them on the server at **Z:\SJShare\SJCOMMON\ECC\CCSS\GG\Coding.** Look for:

        i. Demographics

        ii. MEDSUPNU

    - To get to the 3M Encoder, go to the **St. Jude Intranet** and click on **Clinician Applications**. Then click on **MILLI Apps** (and log in). After logging in, double click the **3M** icon and follow the steps to get to the **3M Encoder**. (If you do not see the 3M icon, you will need to request access to this function.)



5. **What do you code?**

    - Try to code ALL the information in a specified coding box. The concept is that if a statement is written, then code it.

    - **When you do NOT code something written; what to do.** For instances where the statement cannot be coded, or the participant's information does not apply to the question being asked, (e.g. "I do not understand"), then *put a small red check mark in*

the corner of the box. This signals that you did not overlook the statement (which would be considered a coding error).

6. **ST JUDE LIFE SURVEYS TAKE PRIORITY.** ***Always*** remember to ***first*** code **St. Jude Life surveys** brought to you when a patient is in the clinic or going to be in the clinic that day. Immediately after coding, give them to the staff so that they can be scanned right away. ***Do not let them sit on your desk***.

    - For SJ Life Psychosocial and Health Habits, *only* code front page with the Demographic code. Use the Demographic list.
    - The SJ Life Home survey requires more extensive coding using all three coding lists: ICD-9, Demographic list, and MEDSUPNU (Drug) list.
    - For SJLIFE Psychosocial, Health Habits and Home Survey, you initial and date ONLY the Home Survey. Place your initials and the coding date on the bottom right of the Home Survey.

7. **ERRORS:** If an error is made on a code, strike one line through the code. Initial and date the mistake and then write the correct code.

8. **Medication codes.**

    - In the medication section, sometimes a patient may circle the drug names that are printed above the box where they are supposed to write the name of drug being used. If this is the case, do put the appropriate medication code in the box.
    - If the patient states one drug with two reasons, code the drug code twice with both the reasons codes (e.g. Ibuprofen – cramps and headaches, codes will be 0410, 729.82 and 0410, 784.0).
    - If a patient indicates they cannot remember the drug name in Question B8.10 or B10.12, use the "unspecified, not specified" MEDSUPNU code which is 3184.
    - In question B8 1-9 (LTFU) and B10 1-11(SJ Life Home) only use the medication MEDSUPNU code. Do not use ICD-9 codes here. In addition, if a patient lists birth control and no specific drug name, then apply the "Birth control NOS" MEDSUPNU code.
    - Only put commas between diagnoses and medication codes for Question B8.10 (LTFU) and B10.12 (SJ Life) survey. For the purpose of scanning, it is very important to separate the medication and diagnosis code with a comma and align the 2 codes side by side (e.g. Clozal – Crohn's disease/ 2802, 555.9).
    - Always place the MEDSUPNU code before the ICD-9 code.

9. **ICD-9 Codes**. Always include decimal points in ICD-9 codes (unless they are only 3 digits) so that they are not mistaken for medication codes.

10. **Gender-specific boxes.** If you are coding a box that refers to a woman or man, make sure the encoder has the correct sex selected in order to select the correct code or select undetermined.

11. **E & M Codes.** All E & M codes should be written in parenthesis. A regular ICD-9 diagnosis code always goes before an E or M code.

    - For consistency, include **M codes** on all cancers/tumors. M codes are formatted slightly differently than regular diagnosis codes because the decimal point goes after the 4th digit (e.g. – M9530.0).

    - For consistency, include **E Codes** on all injuries e.g. coding wrist fracture – 814.00, (E887). E codes are formatted with either no decimal point or the decimal point used after the 3rd digit (e.g. – E887 or E888.9).

12. **Pain**. If pain is further specified in Question K23 (LTFU Survey), go ahead and code using ICD-9 the type of pain in the specific area (e.g. low back pain – 724.2). If patient writes "None" in the space, then just put a small check mark besides comment since this cannot be coded. The checkmark indicates you have not overlooked what was written.

13. **Surgical Procedures.** In the Surgical procedures section of the survey, only code procedures.

    - Do not use V Codes.

    - But if a diagnosis, M and/ or V code is necessary, *put parentheses around it* in this section.

14. **Coding Boxes Too Small.** When there are many codes listed and they do not fit in the allotted space in the coding boxes, write codes to the side in a neat format. *If there is still not enough space,* type out participant's responses on a Word document along with the designated codes. Attach this to the back of the survey. Write "See attached" in the box of the survey. On the Word document, write the name of the participant, the section the information has come from and the CCSSID/SJL ID/ MRN number on the top of the form.

15. **Adding Drugs to the Drug List (MEDSUPNU).** When adding drugs to the drug list be sure to remember that descriptions may be added only if you cannot find anything else in the list. You may need to look up the drug name from Drugs.com to see if there is a similar name or generic/brand name of a drug. Compare this with the drug list codes to make sure the drug is not listed twice.

16. **V-codes**. Generally Vcodes should not be used, but there may be exceptions to this if there is no other way to code a patient's statement. Usually this occurs in section B7 and B10.12 of SJ Life

Home Surveys and in section B7 and B8.10 in the LTFU surveys. V codes are formatted with the decimal point used after the 2nd digit or 3rd character (e.g. – V45.29).

17. *It is imperative that coding be done **as if the patient currently has** the condition.* This greatly reduces the use of V codes which we are trying to minimize. E.g. Coding for allergies – instead of using V15.09 (Personal history of allergy), use code 995.3 (Allergy, unspecified, NEC).

18. **Genetic Conditions, Conditions at Birth**. When coding the Genetic Conditions and Conditions at Birth sections of the surveys, write M codes in parenthesis where needed.

19. **Fractures (question E11).** *Only code fractures in question E11* (LTFU survey). Many times a patient will put hormone information in the E11 box. If this occurs, write "(See Box E12)" and place the ICD-9 code in the E12 box. Also write in the E12 box "(See Box E11)". This will indicate where the information was collected. Do the same for this section in the SJ Life Home survey as well.

20. **Finished? Check again!** After you have finished coding a survey, make sure you go over and check that coding was done accurately. (All codes should represent the statement written/entered by the participant.) Also ensure that the codes you wrote were written correctly, and in the proper sequence.

Revision Record Printed 7/9/2012 1:09 PM

Current Filename:		Coding Guidelines and Tips ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/20/11	K.Kochar	Initial Development

Coding Guidelines for St Jude Life MHQ/WHQ

Procedure

1. Use red ink when coding the MHQ/WHQ surveys. Put your initials and the date you coded the survey on the front page in the right lower portion of the survey.

2. Use the MHQ survey coding key guide to help you determine what type of codes will be used for each section of the survey. MHQ/WHQ surveys require codes from three coding sources: Gender Questionnaire list, ICD-9 codes (Use 3M Encoder), and Drug list codes (MEDSUPNU list). Have these documents or programs open when you first start coding. The Gender (**Gender**) and Drug list (**Medsupnu**) files are found on the server at **Z:\SJShare\SJCOMMON\ECC\CCSS\GG\Coding**.

3. If a response to a question is written in a "coded" box, but the participant selects "not applicable" or "not at all" for the associated question, then enter a check mark.

4. When coding the *Men's Health Questionnaire*, be sure to first code the procedure and then the diagnosis. Separate the two codes with a "comma". All ICD-9 **E & M Codes** should be coded in parentheses. For example, patient states he had prostate cancer with Prostatectomy, code sequence will be as follows: 60.69, 185 (M8000.3)

5. Always include decimal points when using ICD-9 codes (unless they are only 3 digits) so that they are not mistaken for medication codes.

6. If a response to a question is written in a "coded" box, but the response elaborates on a selection not associated with the requested information in the box, go ahead and code what is there.

7. If you do not see a response that appropriately states the patient's remarks, create a new entry for their unique response in the Gender Questionnaire list.

8. Make sure you always check the last few pages for drugs or diagnosis codes. They are easy to miss since many patients don't usually reply in this section.

9. If an error is made on a code, strike one line through the code. Initial and date the mistake and then write the correct code.

10. When you are finished with the surveys, place them in the yellow cabinet drawer that says "Ready for scanning".

SJLIFE Men's Health Questionnaire (MHQ) Coding Guide

Question	Coding Source	Section
A1	3M Encoder	**ICD-9 Diagnosis**
A2	3M Encoder	**ICD-9 Procedure, ICD-9 Diagnosis**
B7	Gender Questionnaire	**Reason for Discontinuing Testosterone/Estrogen**
D3	Gender Questionnaire	**Learned of Infertility, Low Testosterone, or Sexual Dysfunction Another Way**
D4	Gender Questionnaire	**Learned Of Infertility, Low Testosterone, Or Sexual Dysfunction In Another Setting**
F4	Gender Questionnaire	**Issues (Other than Health) Preventing Additional Pregnancy**
F7	Gender Questionnaire	**Other Types of Fertility Specialists**
F8	Gender Questionnaire	**Problem Identified By Fertility Specialist**
F14	Gender Questionnaire	**Other Reason for Decision to Not Freeze Sperm (MHQ)**
F19	Gender Questionnaire	**Other Reason for Decision to Not Use Frozen Sperm (MHQ)**
G2	Gender Questionnaire	**Other Reason for No Sexual Activity**
G5	Gender Questionnaire	**Other Desirable Sexual Activity**
G6	Gender Questionnaire	**Other Sexual Activity Causing Arousal**
G8	Gender Questionnaire	**Engagement in Other Sexual Activity**
G12	Gender Questionnaire	**Other Problems with Sexuality**
G15	Gender Questionnaire	**Other Factors Influencing Sexual Activity**
I2	MEDSUPNU	**Medication Code**
I3	3M Encoder	**ICD-9 Procedure**
I4	3M Encoder	**ICD-9 Procedure**
I5	Gender Questionnaire	**Complementary or Alternative Medical Treatment for Sexual Dysfunction/Erectile Dysfunction**

SJLIFE Women's Health Questionnaire (WHQ) Coding Guide

Question	Coding Source	Section
B9	Gender Questionnaire	**Reason for Discontinuing Testosterone/Estrogen**
D3	Gender Questionnaire	**Learned of Infertility, Low Testosterone, or Sexual Dysfunction Another Way**
D4	Gender Questionnaire	**Learned Of Infertility, Low Testosterone, Or Sexual Dysfunction In Another Setting**
F4	Gender Questionnaire	**Issues (Other than Health) Preventing Additional Pregnancy**
F7	Gender Questionnaire	**Other Types of Fertility Specialists**
F8	Gender Questionnaire	**Problem Identified By Fertility Specialist**
F10	Gender Questionnaire	**Other Type of Treatment (WHQ)**
H2	Gender Questionnaire	**Other Reason for No Sexual Activity**
H5	Gender Questionnaire	**Other Desirable Sexual Activity**
H6	Gender Questionnaire	**Other Sexual Activity Causing Arousal**
H8	Gender Questionnaire	**Engagement in Other Sexual Activity**
H12	Gender Questionnaire	**Other Problems with Sexuality**
H15	Gender Questionnaire	**Other Factors Influencing Sexual Activity**
I2	MEDSUPNU	**Medication Code**
I3	Gender Questionnaire	**Complementary or Alternative Medical Treatment for Sexual Dysfunction/Erectile Dysfunction**

Revision Record Printed 7/9/2012 2:05 PM

Current Filename:		Coding Guidelines for MHQ and WHQ ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/21/11	K.Kochar	Initial Development
1.1	3/7/12	K.Kochar	Add coding guides

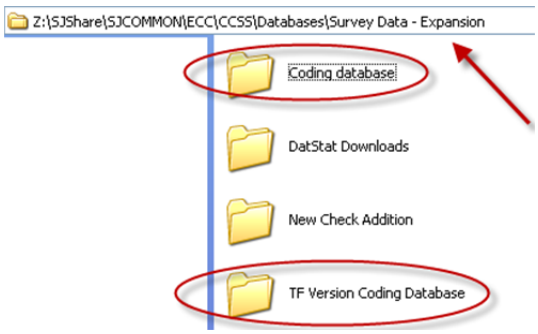
Coding Online and Teleform Surveys

Background

To code Expansion Baseline surveys submitted online, we use a coding database form. We use a similar coding database form to code already scanned (Teleform) surveys.

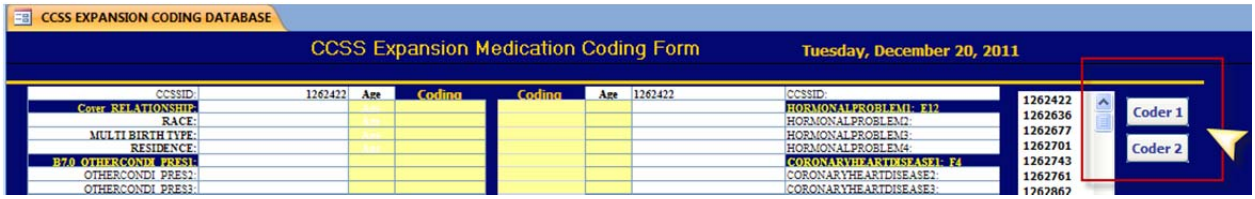
Procedure: Coding

1. Coding in the database requires codes from three coding sources which are:
    a. ICD-9 (Use 3M Encoder)
    b. Demographic List
    c. MEDSUPNU (Drug) List
2. The 2 coding databases are located on the server at: **Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data – Expansion**. Each database is in its own folder:
    a. **Coding Database** folder contains the Expansion Survey Coding database for surveys submitted online.

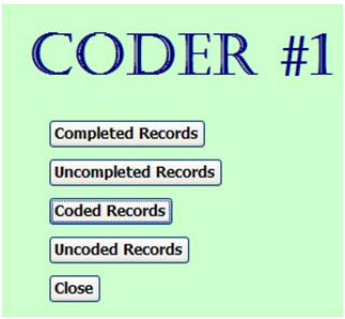


    b. **TF Version Coding Database** folder contains the Teleform (TF) version which has records that require only procedures codes not captured during initial coding.

3. Once the main entry form appears, click on the "**Coder 1**" or "**Coder 2**" button for your assigned list of surveys to code.

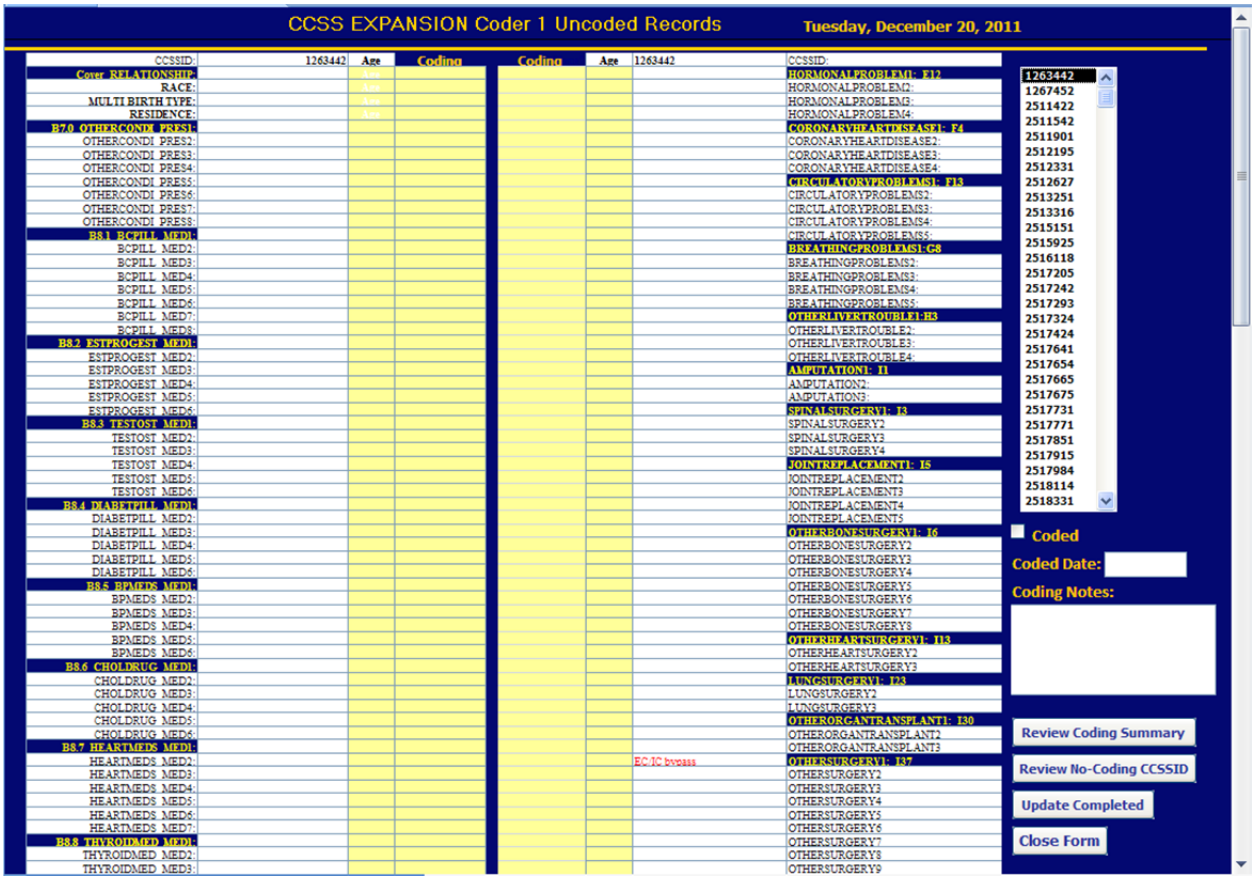


4. From the Coder# form, click the appropriate button (e.g., Uncompleted Records, Uncoded Records).



5. Once the selected coding form appears, select the CCSSID you are going to code, from the list of CCSSID numbers situated on the right to code each survey.

    a. TIP: To keep up with and determine where you are while coding surveys, it is best to keep a written list/log of CCSSID numbers you start and stop with each day. Also if you have any coding issues with a particular survey, you can write it down and go back to it when ready to complete.



6. As you look through each survey in the coding database, there will be 4 columns. The different sections of the survey and the participant answers / statements will be in the **white** columns

and the age and codes that need to be entered will be in the **yellow** columns. (The 2 WHITE columns show the NAME of the field in BLACK and the participant answers/statements in RED. The 2 YELLOW columns are for Age and Coding.)

7. When coding the online Expansion Surveys, code this just like a regular LTFU survey which requires ICD-9 (diagnosis and procedure codes), Demographic , and MEDSUPNU codes for all answers/statements.

    a. All codes are entered in the yellow column.

    b. Do not forget to enter the age where specified.

8. In the TF Version Coding Database, many of the surveys will already have codes in the white section of the survey.

    a. To eliminate any coding and data entry errors, look through the codes to make sure that the codes are entered correctly. Make your corrections in the yellow section of the coding form.
    b. Check each section for V codes that can be changed to procedure or diagnosis codes where possible.
    c. Go down the coding form and code the demographic, diagnosis, medication or procedures that do not have any codes. For example if you see any demographic information in the "Other residence" that has not been coded, go to the Demographic word document, locate the applicable demographic code for the response, and key it in the yellow coding column.

9. If there is some difficulty interpreting the patient response, be sure to make your remarks as to why you did or didn't code the response in the "Coding Notes" box on the right.
    a. TIP: If a patient comment is long and/or you are having trouble reading the statement, then click anywhere in the field you are trying to read and press Shift and F2. This will zoom in to the comment. Press "OK" to get out of the zoom.

10. When you are done with a survey,

    a. Click on the "**Coded**" button on the right side of the screen.

    b. In the "**Coded date**" box, enter the date the survey was coded. You can also click on the calendar icon that is situated on the right of the "Coded date" box to enter the date.

11. Now you are ready to click on the next survey listed in the column on the right. Click on the next CCSSID number to start this process over again.

12. TIP: To review how many surveys you have coded, click the "Review Coding Summary". This will also let you know if there are any new codes that have been added to your assigned group to

code. It would be a good rule of practice to write down the listed numbers and keep track of the number of coded surveys you have done for the day.

Procedure: QA

QA Coded Records in Coding Database (10%)

1. Open coding database.

2 Click the "**Review Coding Summary**" button to determine how many surveys have been coded and/or completed.

CCSS Expansion Coding Analytical Summary

All Records	
Total records	2369
Total No Coding Records	0
Total Coding Records	2369
Total coded records	147
Total uncoded records	2222
Total completed records	0
Total uncompleted records	2369
Coder 1 Records	
Coder 1 total records	1457
Coder 1 coded records	112
Coder 1 uncoded records	1345
Coder 1 completed records	0
Coder 1 uncompleted records	1457
Coder 2 Records	
Coder 2 total records	912
Coder 2 coded records	35
Coder 2 uncoded records	877
Coder 2 completed records	0
Coder 2 uncompleted records	912

3 Go back to the main entry form. Click on each individual coder's entry form to continue QA process. For example, to view coder 1's records, click the "View Coder 1" button. Then select the "Uncompleted" button. When you select a CCSSID, look at the Completed checkbox. If it is checked, this means that the survey has already been coded AND gone through the QA process.

4. Navigate through 10% of the batch by clicking on the CCSSID numbers of the uncompleted records and check for any errors such as missing codes, incorrect codes, etc.

    a. Make any corrections in the yellow column of the coding database form.

    b. Once the survey has been QA'd and reviewed, check the box for "**Completed**" and enter current date in the **Completed Date** box.

Revision Record
Printed 7/9/2012 1:11 PM

Current Filename:		Coding Online and TF Surveys ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	12/20/11	K. Kochar	Initial development

Color Copiers and Laser Printer Supply and Service

General Information

Copier Name	*Description*	*Serial #*	*Unit ID#*	*Service Agency*	*Service phone #***
EPI color COPIER 1	BizHub C654	A46507	9335 3837	Konica Direct	1-800-456-5664
EPI color COPIER 2	BizHub C654	A2X1011005911	9338 7388	Konica Direct	1-800-456-5664

**Also call this number to order supplies

Procedure – Color Copiers

1. Call the service agency (see table for phone number)
2. Follow the menu for placing a service order (or ordering supplies)
3. Indicate you are calling from St. Jude
4. Identify the unit by Unit ID Number
5. Give your name and phone number
6. Describe what service is needed.
7. Tape a note that a service call has been placed onto the printer.

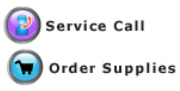
LOCATION OF SUPPLIES: Supplies are in the 5th floor storage room. Supplies for the copiers are identical (i.e. both copiers use the same type of toners, imaging units, staples, etc).

NOTES

1. Call these numbers for service as well as for all supplies and to replace any equipment such as Emptying the toner waste box, replacing Imaging Units, Image Transfer Belt and any other printing errors**
2. We (study team) replace the toner when it is low. We also replace the staples when they run out. (A service call is not needed for this). **We do NOT change the toner waste box**!
3. Instruction booklets are in a pocket at the back of each unit.

Procedure – Online

Service calls and supply orders may be submitted online. The URL is http://www.MyKMBS.com (username AndersonA; password "survivor"). NOTE this lists ALL copiers under contract, so scroll to find the specific copier (you may also use the search feature).



Revision Record Printed 1/21/2015 11:50 AM

[108] Current Filename:		Color Copiers Supply and Service ver 1_7.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/17/09	C. Harris	Initial Development
1.1	2/12/10	C.Harris	Updates
1.2	6/9/10	J.Bates	Add new service contract
1.3	8/12/10	A. McDonald	Revise supply information
1.4	9/24/12	J.Bates	Clarify changing staples; waste toner box needs service call
1.5	4/29/13	J.Bates	Copier2 no longer in service; replaced w/ new unit AKA Color Copier 2
1.6	5/15/13	J.Bates	Online service; remove copier3and defunct copier2; add serial#s
1.7	1/15/15	J. Ford	Updated Copier1 info

Connecting to Color Copiers

Background

If the color copiers used to print survey booklets are not available when you access the print menu on the work station you normally use, or another workstation in our area, it will be necessary to establish (or re-establish) the connection. While the process is straightforward, the interface differs depending on whether the work station is using Windows XP or Windows 7.

Procedures

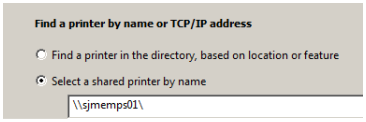
For XP workstations:

1. After you log-in to the workstation:
   a. Click the **Start** button/**Settings/Printers and Faxes**
2. Click **Add a Printer** from the left hand menu (usually under the Printer Tasks heading)
3. The Add a Printer Wizard will open.
   a. Click **Next** at the first screen
4. Make sure the radio button is selected for **A Network Printer**
   a. Click **Next**
5. Make sure the radio button for **Find Printer in Directory** is selected
   a. Click **Next**
6. In the **Name** field, type epi
   a. Click **Find Now**
7. Printers will display at the bottom of the form
   a. Scroll down to find **epi_c-copier1** (or 2 if desired)
   b. Click this copier once to highlight it
   c. Click the **OK** button
8. Mark Yes or No to set this printer as the default printer
   a. Click **Next**
9. Click **Finish**

The printer should now be installed. Repeat the process at step 2 above to install a second copier.

For Windows 7 workstations:

1. Click the **Start** button, then **Devices and Printers**
2. Click **Add a printer**
3. Click **Add a network, wireless or Bluetooth Printer**
4. In the Select a Printer list, click **The printer that I want isn't listed**
5. In Find a printer by name or TCP/IP address, be sure the radio button for **Select a shared printer by name** is clicked, then type in **\\sjmemps01** in the space provided (be sure to include the final '\')



epi_c-copier_1
epi_c-copier_2

6. When the list of printers in the directory appears, scroll to **epi_c-copier_1** (or **epi_c-copier_2**), click on it to highlight it and click **Next**.
7. When the drivers are installed, indicate whether you want to set this printer as the default printer.

Revision Record
Printed 11/15/2012 9:53 AM

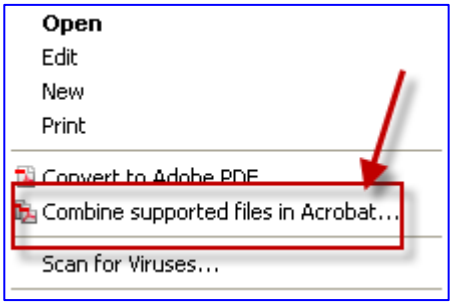
Current Filename:		Connecting to Color Copiers ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	11/15/12	A. McDonald	Initial Development

Converting a Group of Files to pdf

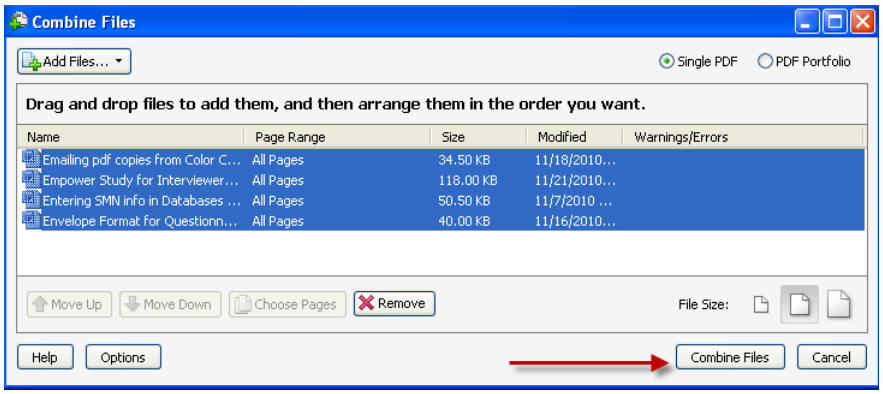
Background

When we need to merge a group of the same type of files into a single pdf, we can use the "Combine supported files in Acrobat…."

Procedure



1. Putting the group of files in the SAME FOLDER is helpful. There can be other files in the folder as well.
2. Select the files you want to combine (single-click the first, then ctrl-click each additional file)
3. Right-click on the group. From the pop-up menu, select **Combine supported files in Acrobat….**
4. On the Combine Files screen, select **Combine Files**.
5. After the combined file is created, it displays in Adobe Acrobat. Save the file.
6. For additional information, the **Help** button on the Combine files screen is useful.



*For **Alchemy Files**, the following has been useful*

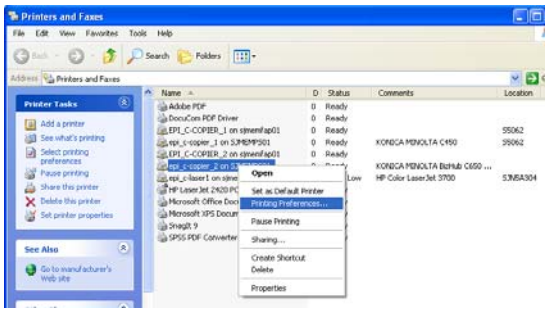
1. Create 2 folders on your Desktop and name them Tiff and PDF
2. Open "Tiff" folder.
3. Find the right document in Alchemy. After you open it, highlight all pages and drag them to "Tiff" folder.
4. Highlight the pages in "Tiff" folder and right click on your mouse. Select " Combine supported files in Acrobat"
5. When new window is open select "Combine files"
6. Name the new pdf file and save in "PDF" folder (or another preferred folder)
7. Delete the pages from the "Tiff" folder.

Current Filename:		Converting File Group to pdf ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	3/29/11	J. Dowdy	Initial Development

Creating a Booklet Property set for the epi_c-copier_2 on SJMEMPS01

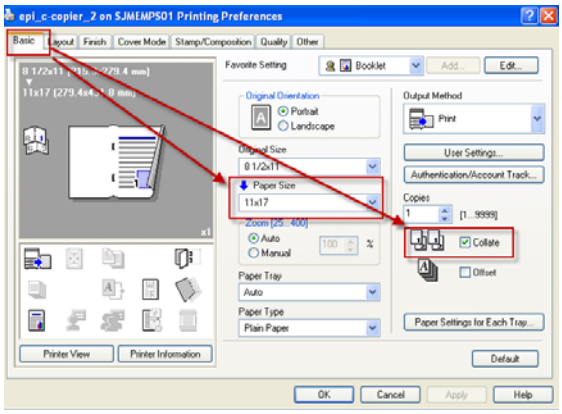
From the Start menu, select Settings and then Printers and Faxes

Right-click on epi_c-copier_2 on SJMEMPS01 to select Printing Preferences…



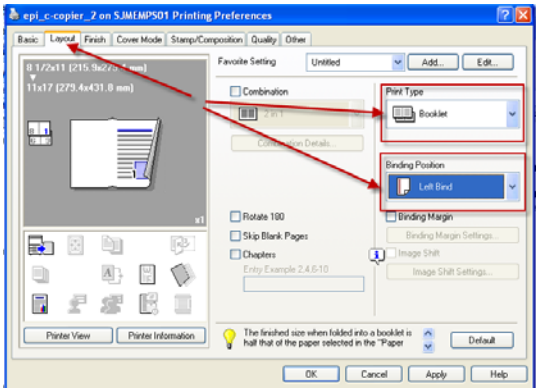
On the Basic tab,

- Ensure that the **Original Size** is set to 8 ½ x 11.
- Select 11x17 in **Paper Size** drop down box
- Check the check box for Collate

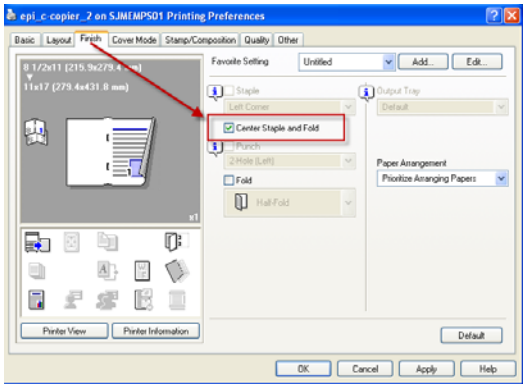


On Layout tab,

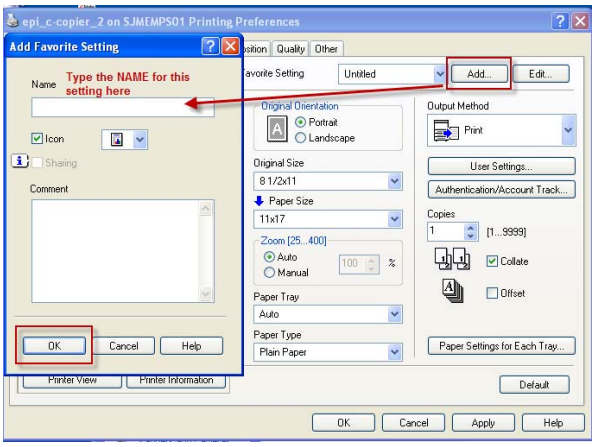
- select Booklet for **Print Type**,
- and Left Bind for **Binding Position**.



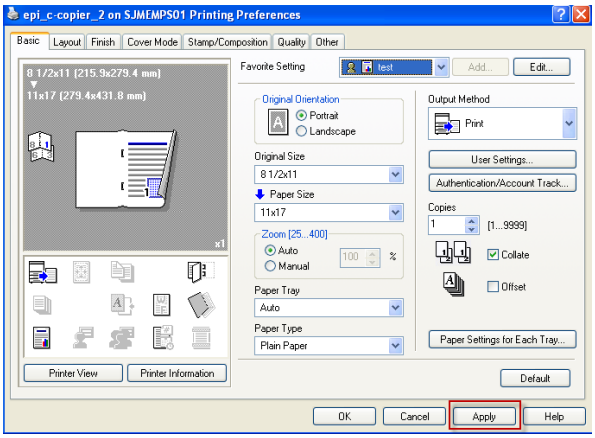
On Finish tab, check the box for Center Staple and Fold



To the right of the Favorite Setting window, click the Add… button to add these settings to your favorites. Type in a Name for the setting. (e.g., "Booklet"), then click the OK button.



Then on the Main Printing Preferences screen, click the Apply button.



The next time you need to print a booklet, simply select the epi_c-copier_2 from the print dialog box. Click the Properties button, and from the Favorite Setting dropdown box, select Booklet.

Revision Record

Printed 12/11/2012 9:23 AM

Current Filename:		Creating a Booklet Property set for the epi ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	11/12/10	J.Bates	Initial Development
1.1	12/11/12	J.Bates	Check Original Size

Creating and Updating Procedure Documents for the SOP Manual

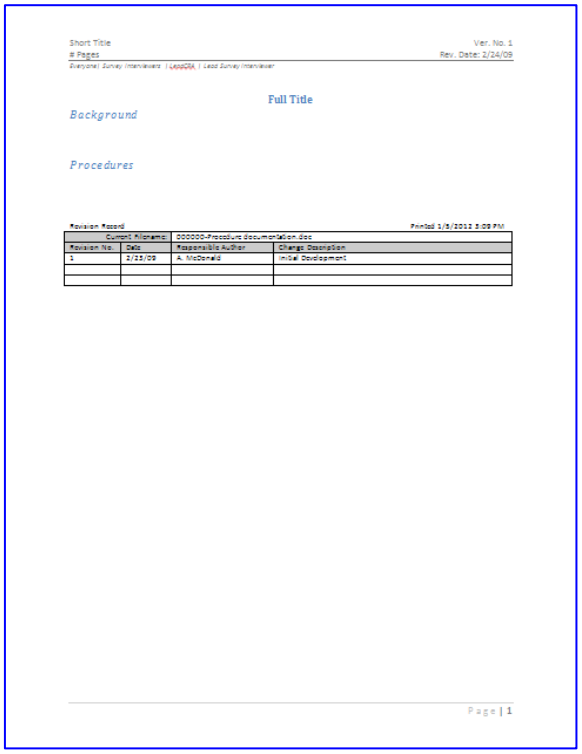
Background

In general, the person responsible for a process is also responsible for making sure the procedure document for the SOP Manual is created and, once created, kept up to date. New procedures and procedure revisions are reviewed by the appropriate lead person to ensure accuracy and clarity. All procedure documents use the Procedure Documentation "shell" which contains placeholders for standard information, basic formatting including header placeholders, and a starter Revision Record table. When a new procedure is submitted, the librarian reviews formatting, publishes the procedure, and updates the card catalog. When a revised procedure is submitted, the librarian archives the previous version, publishes the revision, and updates the card catalog.

Procedures

To Create a New Procedure Document

1. Start with the procedure shell
2. Complete the DOCUMENT HEADER with a **Short title**, **#** pages, version **number**, and revision **date**.
3. Key in the **Full Title** for the procedure.
4. Write the background, and then delineate the procedure.
5. In the Revision record, replace 2/23/09 with the current **Date**, put your name in **Responsible Author**. **Change Description** will read "Initial Development."
6. When the procedure has been reviewed and approved by the appropriate parties, email the procedure to the SOP Librarian.
7. The SOP Librarian will update the current filename, check formatting, publish the procedure, and add the document to the SOP library holdings.


Short Title Ver. No. 1
Pages Rev. Date: 2/24/09
Everyone | Survey Interviewers | LeadQA | Lead Survey Interviewer

Full Title

Background

Procedures

Revision Record Printed 1/8/2012 5:09 PM

Current Filename:	000000-Procedure documentation.doc		
Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development

Page | 1

Everyone

To Update An Existing Procedure Document

1. Start with the CURRENT VERSION of the procedure which you may request from the procedure librarian. This document is in Word. (Once you submit the revised procedure, the librarian will archive the previous version.) Revise the document on your local computer.

2. REVISION FILENAME: As you start the revisions, SAVE the document AS a new file name. Use the same words in the filename as the previous version, and change ONLY the version number that occurs at the end of the file name. If the revision is a MAJOR revision, increase the integer; otherwise, increase the decimal (the number following the underscore in the filename). E.g., for a minor revision, when existing version is 1_0, the revision would be version 1_1. For a major revision, when existing version is 1_0, the revision would be version 2_0. Do NOT use periods in filenames.

3. DOCUMENT HEADER: Inside the document, in the header:

   a. Update the version **number** and version **date**

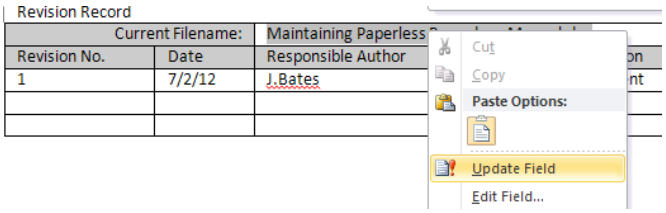
   b. Double check header shows correct number of **pages**

   c. Double check the groups procedure is "**for**"

4. REVISION RECORD:

   a. Enter the **Revision No**, **Date**, **Responsible author**, and a VERY BRIEF **Change Description** in the next available row in the revision record table. (Add new row if needed)

   b. Right-click the cell with the filename and select **Update Field** from the popup menu. This will automatically put the name of the file in the cell. DO NOT MANUALLY edit the name of the file.



5. Save the file

6. Email the SOP Librarian and attach the procedure document. The Librarian will archive the current procedure and update the card catalog.

Revision Record Printed 7/18/2012 3:02 PM

Current Filename:		Creating and Updating Procedures for the SOP Manual ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	7/16/12	J.Bates	Initial Development

Creating the Dana Farber Age Reference List

Background

Due to their institutional IRB restrictions, Dana Farber Cancer Institute (DFCI) staff members recruit their own former patients to the expanded cohort. The DFCI (institution 05) staff members send the LTFU Coordinating Center only limited information about each case (e.g., no date of birth, gender, etc.). They do indicate if the case is under/over 18 and alive/deceased at the time of recruitment.

As a result, the LTFU Coordinating Center uses a special process to generate a file showing if a DFCI case is under/over 18 at the time of recruitment. This list is a resource for Survey Interviewers (SIs) calling former DFCI cases to pursue the baseline questionnaire. This process only covers alive cases; deceased cases are handled separately.

Procedure

Once per month, a Lead SI or the Coordinator's designee will create an Excel file with the DFCI age reference list for the Survey Interviewer (SI) team and save it to the shared network. The LSI or designee will:

1. Add a recurring appointment to his/her Outlook calendar for a monthly reminder to update the Dana Farber Age Reference List.
2. Open the Expansion Tracking database.
3. Open the Navigation Pane, and select Queries from the drop-down category menu.
4. In the Search bar, type "DFCI" (without the quotation marks) to locate the query named qry_DFCI_AgeReferenceList_mm-dd-yyyy. NOTE: Check the query name carefully as a similarly named query exists.
5. Double-click on the query name to run the query.
6. On the Access Ribbon's External Data tab, select the Excel icon from the Export group (*not* the Excel icon in the Import & Link group).
7. In the Export Excel-Spreadsheet window:
    a. Click the **Browse** button.
    b. Save the file in the Dana Farber folder located at *Z:\SJShare\SJCOMMON\ECC\Interviewers \Expansion Survey Calls\Dana Farber*.
    c. In the **File Name** field, replace the date marker "mm-dd-yyyy" with the current date (e.g., "qry_DFCI_AgeReferenceList_08-02-2014").
    d. Click the **Save** button.
    e. Check the **Export data with formatting and layout** and **Open the destination file after the export operation is complete** checkboxes.
    f. Click the **OK** button to open the query results in an Excel spreadsheet.
8. Close the query results in the database.
9. Close the next dialogue box *without* saving the export routine steps when prompted.
10. Close the Navigation Pane.
11. Review the file for accuracy by checking randomly selected CCSSIDs from the beginning, middle, and end of the Excel file to ensure the query results are consistent with the database.
12. Close the Excel file.

13. From the Dana Farber subfolder at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Dana Farber*, archive the previous version of the query.
14. Email all Survey Interviewers and copy the Coordinator to note that the Dana Farber Age Reference List for alive participants has been updated.

Revision Record Printed 7/23/2014 3:35 PM

Current Filename:		Creating the Dana Farber Age Reference List ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	4/26/12	A. McDonald/D. Rinehart	Initial Development
1.1	4/30/12	A. McDonald	Formatting
1.2	5/3/2012	D. Rinehart	Updated query and Excel file name
1.3	7/23/2014	R. Massey	Content Update

Daily Expansion Tracking Data Entry - Cases

Background

For quality control purposes, only Lead Survey Interviewers (LSIs), the Call Center Coordinator, or the Coordinator's designee(s) perform(s) post-survey data entry and updates at the Access table level of the Expansion Tracking database. Data may come from a variety of sources which the LSI, Coordinator, or approved designee will review and use to make the necessary changes to the database. These procedures will be performed on a daily basis from Monday through Friday.

Procedures

Baseline Surveys Completed Online

When a baseline survey is completed online, with or without the assistance of a Survey Interviewer (SI), certain data must be updated in the Expansion Tracking database. Before beginning the post-survey update process:

1. Use the SOP titled **Extracting Online Expansion Survey Data** to capture information about expansion baseline surveys completed either (1) online without the assistance of an SI or (2) via telephone with an SI.
2. Gather the informed consent forms from the hanging file folder labeled "Daily Informed Consents", located in the top drawer of the short file cabinet. Forms where the **Survey Completed** boxes are populated represent surveys completed with the assistance of an SI.
3. Gather the **Expired Participant Information Sheets** from the hanging file labeled "Refusals and Deceased", located in the top drawer of the short file cabinet.

Alive Baseline Surveys

1. For expired expansion baseline surveys conducted by SIs with the proxy of deceased participants, see the section of this document titled *Deceased Baseline Surveys*, below.

2. **Baseline Tab**
   - A. **Baseline Outcome** - If there is any value in this and the related **Baseline Outcome Date** fields, evaluate if these should be cleared.
   - B. **MR status** - Populate with 6-Send Medical Release. If this field is already populated, do not change the existing value.
   - C. For surveys done online without an SI (no informed consent form):
     - i. If the directed fields, below, are already populated, do not change the existing values. Instead, make a note in the **Tracking Comments** field regarding the alternate values. Consult the Coordinator with questions.
     - ii. **Date Consent Signed** - Populate with the exact date the survey was completed.
     - iii. **Consent Status** - Populate with 1-Complete.
     - iv. **Share CCSS Data** - Populate using the DatStat response (1=yes; 2=no).
   - D. For surveys done with an SI (NOTE: These surveys will have a paper informed consent form in the "Daily Informed Consents" folder.):
     - i. If the directed fields, below, are already populated, do not change the existing values. Instead, make a note in the **Tracking Comments** field regarding the alternate values. Consult the Coordinator with questions.

ii. **Date Consent Signed** - Populate with the date informed consent was obtained, as indicated in the **Consent Obtained** boxes of the form.
iii. **Consent Status** - Populate with 10-Verbal.
iv. **Consent INT ID** - Populate with the ID of the SI who completed the informed consent, as indicated in the **Consent Obtained** boxes of the form. This may be different from the SI who completed the survey.
v. **Share CCSS Data** - Populate using the response on the informed consent form, and confirm the same value was entered in Datstat (1=yes; 2=no in share column of results). If this field is already populated with another value, consult with the Coordinator.
vi. **Interviewer ID -** Populate with the ID of the SI who completed the survey with the participant, as indicated in the **Survey Completed** boxes on the consent form. If this field is already populated with another ID, consult with the Coordinator.
NOTE: If the survey was begun by interviewer A and completed by interviewer B, enter the ID for interviewer B. SIs obtaining a partial survey, such as interviewer A, have been instructed to log this time in their **Journal**.
vii. **Interview Status** - Populate with 1-Complete (changing from <null> or 9-Partially Completed).
viii. **Tracking Comments**
a. For surveys completed with someone other than the survivor, ensure there is a dated note with SI ID specifying the name and relationship of the proxy that completed the survey. *Example: 6/15/2015: SI 162 completed baseline survey with minor case's mother, Marsha Brady. [123]*
b. For surveys completed in Spanish (indicated in the DB Change request form - See the SOP titled **Using the ERC Admin Asst Database** for details.), ensure there is a note clearly documenting that the survey was completed in Spanish.
(*Example: 1/27/15: Baseline survey completed in Spanish with case. [170]*)

3. **Header**
A. Date of Birth:
i. Review the CONFIRMDOB column (1 = correct, 2 = incorrect) in the survey results. If the DOB is incorrect, the correct DOB should appear in the CORRECTDOB column.
ii. If the participant indicated a corrected date of birth, use the SOP titled **Updating Date of Birth** to update the case's record.
B. Gender:
i. Review the CONFIRMGENDER column (1 = correct, 2 = incorrect) in the survey results. The GENDER column contains the gender the participant indicated to be correct or incorrect.
ii. If the participant indicated a corrected gender, use the SOP titled **Updating Gender** to update the case's record.
C. For surveys completed in Spanish (indicated in the DB Change request form - See the SOP titled **Using the ERC Admin Asst Database** for details.), ensure the SI has clearly documented:
i. The case's status in the **SPANISH STATUS** field
ii. That the survey was completed in Spanish in the call log notes

4. **Quest Tab**
A. **Tracing Status** - Remove values in this and the related **Tracing Date** fields, if applicable.

B. **Send Q-aire To** - Populate with the appropriate code:
   i. For anyone under 18, choose the number that corresponds with mother, father, both parents, etc. Without further information, typically choose 4-both (pt. under 18).
   ii. For anyone 18 or older, typically choose 1-patient, but there are also option for 7-LAR, 6-parent, eventhough pt. over 18, etc., where appropriate.

C. Contact Information – Address, Phone Number(s), and Email Address(es)
   i. See the SOP titled **Expansion Baseline Survey Calls** for details on how to update the Expansion Tracking database with confirmed contact information.
      a. If the survey was done online without the assistance of an SI, use "Survey" as the confirmation source.
      b. If the survey was completed via telephone with an SI, use "Phone contact w/pt" or "Phone contact w/family", as appropriate, as the confirmation source.
   ii. Address
      a. Click on the button **See DatStat Address**. This is the address the participant has confirmed as correct or incorrect in the ADDRCORR column (1 = correct, 2 = incorrect).
      b. New address information is provided in the UPDATEADDRESS, UPDATECITY, UPDATESTATE, and UPDATEZIP columns.
   iii. Phone
      a. Click on the button **See DatStat Address**. This is the phone number the participant has confirmed as correct or incorrect in the PHONECORR column (1 = correct, 2 = incorrect).
      b. New home phone and cell phone information is provided in the UPDATEHOMEPHONE and UPDATECELLPHONE columns.
   iv. Email – If the participant indicates that s/he has an email address in the EMAILYN column (1 = yes, 2 = no), the email address(es) will be in the UPDATEEMAIL and UPDATEEMAIL_2 columns.
   v. **Special note about former St. Jude patients:** If the CCSSID# begins with 15 and any contact information has changed, send screen-prints of changes made to the CRAII in charge of SJ Life Recruitment.

D. **Comments** – For surveys completed with someone other than the survivor, ensure there is a dated note with SI ID specifying the name and relationship of the proxy that completed the survey. *Example: 6/15/2015: SI 162 completed baseline survey with minor case's mother, Marsha Brady. [123]*

5. **Additional Contact Info Tab** – If the participant has authorized an additional contact during the baseline survey, the contact's information will be listed in the CONTACT NAME, CONTACTRELATIONSHIP, CONTACTADDRESS, CONTACTCITY, CONTACTSTATE, CONTACTZIP, CONTACTPHONE and CONTACTPHONE_2 columns. Use this information to update the database according to the SOP titled **Expansion Baseline Survey Calls**.

6. Review the SURVEY_**COMMENTS** column of the survey results:
   A. For any survey comments that contain questions or may otherwise require attention from a study doctor, psychologist, social worker, etc., email the CCSSID and the comment to the Coordinator, copying the LSI team, for review.

B. If the participant requests no newsletter:
   i. **Outcome** field on the Reg tab - Populate with 42-Wants Surveys But No Newsletters.
   ii. **Outcome Date** field on the Reg tab - Populate with the current date.
   iii. **Comments** field on the Quest tab - Enter a dated note with SI ID indicating this data change.

7. **Informed Consent** – File the informed consent form appropriately:
   A. If the form indicates the participant did not receive a copy of the informed consent *and* the **Participant Copy Sent** boxes are blank, file the form in the "Needs Consent" folder in the top drawer of the short file cabinet.
   B. If the form indicates that the participant did receive a copy of the informed consent *or* if the **Participant Copy Sent** boxes are populated, file the form in the appropriate institutional folder in file cabinet 2.

Deceased Baseline Surveys

1. For alive expansion baseline surveys, see the section of this document titled *Alive Baseline Surveys*, above.

2. **Baseline Tab**
   A. Non-Completed Surveys: Leave the **Baseline Outcome** field blank**.** Do *NOT* select 38-Deceased.
   B. Completed surveys (survey was completed with proxy of deceased case):
      i. If the directed fields, below, are already populated, do not change the existing values. Instead, make a note in the **Tracking Comments** field regarding the alternate values. Consult the Coordinator with questions.
      ii. **Date Consent Signed** - Populate with the date informed consent was obtained, as indicated in the **Consent Obtained** boxes of the form.
      iii. **Consent Status** - Populate with 10-Verbal.
      iv. **Consent INT ID** - Populate with the ID of the SI who completed the informed consent, as indicated in the **Consent Obtained** boxes of the form. This may be different from the SI who completed the survey.
      v. **Share CCSS Data** - Populate using the response on the informed consent form and confirm the same value was entered in Datstat (1=yes; 2=no in share column of results). If this field is already populated with another value, consult with the Coordinator.
      vi. **MR status** - Populate with 6-Send Medical Release.
      vii. **Interviewer ID -** Populate with the ID of the SI who completed the survey with the proxy, indicated in the **Survey Completed** boxes on the consent form. If this field is already populated with another ID, consult with the Coordinator.
      NOTE: If the survey was begun by interviewer A and completed by interviewer B, enter the ID for interviewer B. SIs obtaining a partial survey, such as interviewer A, have been instructed to log this time in their **Journal**.
      viii. **Interview Status** - Populate with 1-Complete (changing from <null> or 9-Partially Completed).
      ix. **Date Survey Sent** - If blank, populate with the date 12/12/1812.
      x. **Baseline Outcome** - Populate with 38-Deceased. If this field is already populated with another value, consult with the Coordinator.
      xi. **Baseline Outcome Date** - Populate with the current date. If this field is already populated with another value, consult with the Coordinator.

xii. **Tracking Comments –**

a. Ensure there is a dated note with SI ID specifying the name and relationship of the proxy that completed the survey. *Example: 5/17/2015: SI 163 completed the expired baseline survey with case's mother, Mimi Kim. [158]*

b. For surveys completed in Spanish (indicated in the DB Change request form - See the SOP titled **Using the ERC Admin Asst Database** for details.), ensure there is a note clearly documenting that the survey was completed in Spanish. (*Example: 1/27/15: Expired baseline survey completed in Spanish with case's mother, Jennifer Lopez. [170]*)

3. **Header**

A. Date of Birth:

i. Review the CONFIRMDOB column (1 = correct, 2 = incorrect) in the survey results. If the DOB is incorrect, the correct DOB should appear in the CORRECTDOB column.

ii. If the proxy indicated a corrected date of birth, use the SOP titled **Updating Date of Birth** to update the case's record.

B. Gender:

i. Review the CONFIRMGENDER column (1 = correct, 2 = incorrect) in the survey results. The GENDER column contains the gender the proxy indicated to be correct or incorrect.

ii. If the proxy indicated a corrected gender, use the SOP titled **Updating Gender** to update the case's record.

C. For surveys completed in Spanish (indicated in the DB Change request form - See the SOP titled **Using the ERC Admin Asst Database** for details.), ensure the SI has clearly documented:

i. The correct status in the **SPANISH STATUS** field

ii. That the survey was completed in Spanish in the call log notes

4. **Quest Tab**

A. **Tracing Status** - Remove values in this and the related **Tracing Date** fields, if applicable.

B. **Send Q-aire To** - Populate with the appropriate code: 5-Parent (Pt. Has Died) or 7-LAR.

C. Contact Information – Address, Phone Number(s), and Email Address(es)

i. See the SOP titled **Expansion Baseline Survey Calls** for details on how to update the Expansion Tracking database with confirmed information. Since expired surveys are completed via telephone with an SI, use "Phone contact w/family" as the confirmation source.

ii. Address

a. Click on the button **See DatStat Address**. This is the address the proxy has confirmed as correct or incorrect in the ADDRCORR column (1 = correct, 2 = incorrect).

b. New address information is provided in the UPDATEADDRESS, UPDATECITY, UPDATESTATE, and UPDATEZIP columns. This information can also be found on the **Expired Participant Information Sheet**. Compare to ensure consistency.

iii. Phone

a. Click on the button **See DatStat Address**. This is the phone number the proxy has confirmed as correct or incorrect in the PHONECORR column (1 = correct, 2 = incorrect).

b. New home phone and cell phone information is provided in the UPDATEHOMEPHONE and UPDATECELLPHONE columns. This information can also be found on the **Expired Participant Information Sheet**. Compare to ensure consistency.

iv. Email – If the proxy indicates that s/he has an email address in the EMAILYN column (1 = yes, 2 = no), the email address(es) will be in the UPDATEEMAIL and UPDATEEMAIL_2 columns.

D. **Comments** – Ensure there is a dated specifying the name and relationship of the proxy that completed the survey. *Example: 5/17/2015: SI 163 completed the expired baseline survey with case's mother, Mimi Kim. [158]*

E. Click the **Open Death Data Form** button to open the form, then complete (see next section).

5. **Death Data Form** – Using the **Expired Participant Information Sheet**:
   A. **Alive/Dead Status** – Populate with 2 (2 = Deceased).
   B. **Date of Death** – Populate, if known. If only the year of death is known, then use the fictitious month and/or day of 7/15. If the year is not known, then leave this field blank.
   C. **State of Death** – Populate, if known.
   D. **Parent's reason For Death** – Populate, if given.
   E. **Did pt have cancer at time of death (according to parents) –** Enter appropriate answer, if given.
   F. Close the Deathdata form.

6. **Reg Tab** (Completed Surveys ONLY)
   A. **Outcome** - Populate with 38-Deceased.
   B. **Outcome Date** - Enter or update to be the current date.

7. **Processing Newsletter Requests** (Completed Surveys ONLY) – Newsletters are not automatically mailed to proxies of expired cases. If the proxy of a deceased case would like to receive the LTFU newsletters, as noted by checking the "Newsletter" box at the top of the **Expired Participant Information Sheet**:
   A. Open the workbook **LTFUNewsletter Additional Names**, located at *Z:\SJShare\SJCOMMON \ECC\CCSS\Newsletter*.
   B. Manually add the proxy's name and address to the appropriate worksheet.
   C. Save and close the file.
   D. NOTE: Call Center Coordinator designees for data entry who are not LSIs should email the LSI team to do this process. Access to this spreadsheet is restricted.

8. **Notify the St. Jude Life Study Coordinator (Institution 15 Only) -** If a case from St. Jude (institution 15) was listed in the database as alive but has now been determined to be expired:
   A. Send an email to the St. Jude Life study coordinator within 2 working days informing of the vital status change.
   B. See the SOP titled **Death Notifications about St. Jude Cases** for more details.

9. **Informed Consent** – File the informed consent form appropriately. If the **Participant Copy Sent** boxes are:
   A. Blank - File the form in the "Needs Consent" folder in the top drawer of the short file cabinet.
   B. Populated - File the form in the appropriate institutional folder in file cabinet 2.

Partially Completed Surveys

When a Survey Interviewer at a minimum gathers informed consent but does not complete the survey, s/he will update the appropriate fields in the Expansion Tracking database (See the **Expansion Baseline Survey Calls** SOP.) and file the informed consent form in the folder labeled "Daily Informed Consents".

Before beginning the post-partial survey procedures, the LSI or designee will:

1. Use the SOP titled **Using the ERC Admin Asst Database** to capture information about expansion baseline surveys partially completed via telephone with a Survey Interviewer, as noted in the **DB Change** field of the call log.
2. Gather informed consent forms from the hanging file folder labeled "Daily Informed Consents", located in the top drawer of the short file cabinet. The forms where the **Survey Completed** boxes are blank represent surveys partially completed with the assistance of an SI.

Once preparation is complete:

1. **Baseline Tab**
   A. If the directed fields, below, are already populated, do not change the existing values. Instead, make a note in the **Tracking Comments** field regarding the alternate values. Consult the Coordinator with questions.
   B. **Date Consent Signed** - Populate with the date informed consent was obtained, as indicated in the **Consent Obtained** boxes of the form.
   C. **Consent Status** - Populate with 10-Verbal.
   D. **Consent INT ID** - Populate with the ID of the SI who completed the informed consent, as indicated in the **Consent Obtained** boxes of the form. This may or may not be the SI who completes the survey.
   E. **Share CCSS Data** - Populate with the response indicated on the informed consent form. If this field is already populated with another value, consult with the Coordinator.
   F. **Interview Status** - Populate with 9-Partially Completed.
   G. **Tracking Comments** - Add a dated note with SI ID indicating the partial survey. *Example: 1/9/2015: SI 166 gathered informed consent, gained partial survey with case [137]*)

2. **Quest Tab**
   A. **Tracing Status** – Ensure values in this and the related **Tracing Date** fields have been removed, if applicable.
   B. **Send Q-aire To** – Ensure this is populated with the appropriate code:
      i. For anyone under 18, choose the number that corresponds with mother, father, both parents, etc. Without further information, typically choose 4-both (pt. under 18).
      ii. For anyone 18 or older, typically choose 1-patient, but there are also options for 7-LAR, 6-parent, eventhough pt. over 18, etc., where appropriate.
      iii. For deceased cases, populate with 5-Parent (Pt. Has Died) or 7-LAR, as appropriate.
   C. Ensure all addresses, phone numbers, and email address are updated based on the call log notes. See the SOP titled **Expansion Baseline Survey Calls** for details.
   D. Verify that the SI has added a dated note in the **Comments** field. (*Example: 1/9/2015: Gathered informed consent, gained partial survey with case [166]*)

3. **Informed Consent** – File the informed consent form appropriately.

A. If the informed consent indicates the participant did not receive a copy of the informed consent *and* the **Participant Copy Sent** boxes are blank, file the form in the "Needs Consent" folder in the top drawer of the short file cabinet.
B. If the informed consent indicates that the participant did receive a copy of the informed consent *or* if the **Participant Copy Sent** boxes are populated, file the form numerically in the "Partially completed surveys" folder in the bottom drawer of the short file cabinet.

Refusals at Baseline

Refusals at the expansion baseline survey may be made either online by the participant without the assistance of an SI or via telephone to an SI. For telephone refusals, the SI will document the refusal in the **Outcome** field of the call log.

The LSI or designee will:

1. Use the SOP titled **Extracting and Processing Expansion Baseline DatStat Refusals** to capture expansion baseline survey refusals made via DatStat *and* to process those refusals.
2. Use the SOP titled **Using the ERC Admin Asst Database** to capture information about expansion baseline survey refusals made via telephone with an SI, as noted in the **Outcome** field of the call log.
    A. Examine each refusal to ensure all refusal documentation, as outlined in the SOP titled **Expansion Baseline Survey Calls**, has been completed.
    B. Review the **Date Survey Returned** field on the Baseline tab for each case to determine if the baseline survey was completed:
        i. If the survey was NOT completed:
            a. **Baseline Outcome** – Should be populated with 7-Refused
            b. **Baseline Outcome Date** – Should be populated with the date of the refusal
        ii. If the survey WAS completed, the **Baseline Outcome** and **Baseline Outcome Date** fields should be blank.

Survey Links Sent at Verbal HIPAA

On occasion, participants will request a link to the baseline survey at the time of a verbal HIPAA. In these cases, the interviewer will send the link and choose option 12-Verbal HIPAA-Sent Survey Link in the **Outcome** field of the call log. The LSI or designee will use this outcome to document the emailed link in the Expansion Tracking database on the next business day after the record rolls over.

1. Use the SOP titled **Using the ERC Admin Asst Database** to capture information about expansion baseline survey links sent at the time of the verbal HIPAA, as noted in the **Outcome** field of the call log.
2. Use the SOP titled **Expansion Baseline Survey Calls** to document the emailed link in the participant's record of the Expansion Tracking database.

Ineligibles

1. When a Survey Interviewer believes a participant to be ineligible, s/he will document the suspected ineligibility by choosing the option 4-Ineligible in the **DB Change** field of the call log.
2. The LSI or designee will use the SOP titled **Using the ERC Admin Asst Database** to capture information about possible ineligibles noted in the **DB Change** field of the call log.
3. The LSI or designee will consult with the Coordinator for an eligibility determination.

4. If an ineligible status is determined to be appropriate, the LSI or designee will update the appropriate fields using the SOP titled **Documenting Ineligibility**.

Database Change Requests

Survey Interviewers (SIs) will log LSI-level Expansion Tracking database change requests such as gender changes, vital status changes, name changes, etc., in the **DB Change** field of the call log. The LSI or designee will collect and process these requests using the SOP titled **Using the ERC Admin Asst Database**.

Incarcerated Cases

When a case is found to be incarcerated, consult with the Coordinator or Research Scientist regarding the proper coding.

1. Those cases that are expected to have shorter terms, as determined by the leadership team, will be coded with a hold code.
2. Those participants who are expected to have longer or indefinite terms, as determined by the leadership team, should be coded on the Baseline tab as follows:
   A. **Baseline Outcome** – Populate with 25-Unavailable.
   B. **Baseline Date** – Populate with the current date.
   C. **Tracking Comments** – Add a dated note with SI ID explaining the circumstances of availability and documenting the member of the leadership team authorizing the outcome.

Completion of Data Entry

After all data entry is completed (including sibling data entry and data entry for other databases - See separate SOPs.), an email should be sent to the applicable CRAs, the Call Center Coordinator, the LSI team, and any other specified designees.

Example:
Subject Line: Databases Updated

Message Body:
The databases have been updated from the following sources:

- *Surveys completed online (baseline and FU5, cases and siblings)*
- *Database change requests*
- Expired Participant Information Sheets
- *Emails (up to 12:11pm)*
- *DatStat refusals (cases and siblings)*

Suicidal ideation has also been reviewed for baseline and FU5 surveys.

Revision Record Printed 12/3/2014 9:25 AM

[257] Current Filename:		Daily Expansion Tracking Data Entry - Cases ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/24/2013	B. Carson, R. Massey, D. Rinehart	Replaces archived SOP, Expansion Tracking Database Data Entry from Calls and Online Surveys ver 1.7 (call number 152)
1.1	8/22/2013	R. Massey	Content Revision: Baseline Outcome and Consent INT ID fields
1.2	1/7/2014	R. Massey	Content Revision: pt requests no newsletter, ineligibles, MR/consent fields already populated
1.3	11/15/2014	R. Massey	Content Revision

Daily Expansion Tracking Data Entry - Siblings

Background

For quality control purposes, only Lead Survey Interviewers (LSIs), the Call Center Coordinator, or the Coordinator's designee(s) perform(s) post-survey data entry and updates at the Access table level of the Expansion Tracking database. Data may come from a variety of sources which the LSI, Coordinator, or approved designee will review and use to make the necessary changes to the database. These procedures will be performed on a daily basis, Monday through Friday.

Procedures

Sibling Baseline Surveys Completed Online

When a sibling baseline survey is completed online, with or without the assistance of a Survey Interviewer (SI), certain data must be updated in the Expansion Tracking database. Before beginning the post-survey update process:

1. Use the SOP titled **Extracting Online Expansion Survey Data** to capture information about sibling expansion baseline surveys completed either (1) online without the assistance of an SI or (2) via telephone with an SI.
2. Gather the informed consent forms from the hanging file folder labeled "Daily Informed Consents", located in the top drawer of the short file cabinet. Forms where the **Survey Completed** boxes are populated represent surveys completed with the assistance of an SI.
3. Gather the **Expired Participant Information Sheets** from the hanging file labeled "Refusals and Deceased", located in the top drawer of the short file cabinet.

Alive Sibling Baseline Surveys

1. For expired sibling baseline surveys conducted by SIs with the proxy of deceased sibling participants, see the section of this document titled *Deceased Sibling Baseline Surveys*, below.

2. **Sib Baseline Tab**
   - A. **Baseline Outcome** – If there is any value in this and the related **Baseline Outcome Date** fields, evaluate if these should be cleared.
   - B. **MR status** – Populate with 6-Send Medical Release. If this field is already populated, do not change the existing value.
   - C. For surveys done online without an SI (no informed consent):
     - i. If the directed fields, below, are already populated, do not change the existing values. Instead, make a note in the **Tracking Comments** field regarding the alternate values. Consult the Coordinator with questions.
     - ii. **Date Consent Signed** – Populate with the exact date the survey was completed.
     - iii. **Consent Status** – Populate with 1-Complete.
   - D. For surveys done with an SI (NOTE: These surveys will have a paper informed consent form in the "Daily Informed Consents" folder.):
     - i. If the directed fields, below, are already populated, do not change the existing values. Instead, make a note in the **Tracking Comments** field regarding the alternate values. Consult the Coordinator with questions.

ii. **Date Consent Signed** – Populate with the date informed consent was obtained, as indicated in the **Consent Obtained** boxes on the form.
iii. **Consent Status** – Populate with 10-Verbal.
iv. **Consent INT ID** – Populate with the ID of the SI who completed the informed consent, as indicated in the **Consent Obtained** boxes of the form. This may be different from the interviewer who completed the survey.
v. **Interviewer ID –** Populate with the ID of the SI who completed the survey, as indicated in the **Survey Completed** boxes on the consent form. If this field is already populated with another ID, consult with the Coordinator.
NOTE: If the survey was begun by interviewer A and completed by interviewer B, enter the ID for interviewer B. SIs completing a partial survey, such as interviewer A, have been instructed to log this time in their **Journal**.
vi. **Interview Status** – Populate with 1-Complete (changing from <null> or 9-Partially Completed).
vii. **Tracking Comments**
a. For surveys completed with someone other than the sibling, ensure there is a dated note with SI ID specifying the name and relationship of the proxy that completed the survey. *Example: 6/15/2015: SI 156 completed baseline sibling survey with adult sibling participant's mother and LAR, Jada Smith. [123]*
b. For surveys completed in Spanish (indicated in the DB Change request form – See the SOP titled using the **ERC Admin Asst Database** for details.), ensure there is a note clearly documenting that the survey was completed in Spanish. (*Example: 7/23/15: Sibling baseline survey completed with sib pt in Spanish. [137]*)

3. **Header**
A. Date of Birth:
i. Review the CONFIRMDOB column (1 = correct, 2 = incorrect) in the survey results. If the DOB is incorrect, the correct DOB should appear in the CORRECTDOB column.
ii. If the participant indicated a corrected date of birth, use the SOP titled **Expansion Sibling Cohort Survey Calls** to update the participant's record.
B. There is no need to review/update the sibling's **gender**. The 5th floor automatically harvests this information from online and paper surveys.
C. For surveys completed in Spanish (indicated in the DB Change request form - See the SOP titled **Using the ERC Admin Asst Database** for details.), ensure the SI has clearly documented:
i. The participant's status in the **SPANISH STATUS** field
ii. That the survey was completed in Spanish in the call log notes

4. **Sib Info Tab**
A. **Tracing Status** - Remove values in this and the related **Tracing Date** fields, if applicable.
B. **Send Q-aire To** – Populate with the appropriate code:
i. For anyone under 18, you will choose the number that corresponds with mother, father, both parents, etc. Typically, without further information you will choose 4-Both(sib under 18).
ii. For anyone 18 or older, typically choose 1-Sibling, but there are options to send to 6-Parent (Even Though Sib over 18), 7-LAR, etc., where appropriate.
C. Contact Information – Address, Phone Number(s), and Email Address(es)

i. See the SOP titled **Expansion Sibling Cohort Survey Calls** for details on how to update the Expansion Tracking database with confirmed contact information.
   a. If the survey was done online without the assistance of an SI, use "Survey" as the confirmation source.
   b. If the survey was completed via telephone with an SI, use "Phone contact w/sibling" or "Phone contact w/family", as appropriate, as the confirmation source.

ii. Address
   a. Click on the **See DatStat Address** button. This is the address the participant has confirmed as correct or incorrect in the ADDRCORR column (1 = correct, 2 = incorrect).
   b. New address information is provided in the UPDATEADDRESS, UPDATECITY, UPDATESTATE, and UPDATEZIP columns.

iii. Phone
   a. Click on the button **See DatStat Address**. This is the phone number the participant has confirmed as correct or incorrect in the PHONECORR column (1 = correct, 2 = incorrect).
   b. New home phone and cell phone information is provided in the UPDATEHOMEPHONE and UPDATECELLPHONE columns.

iv. Email – If the participant indicates that s/he has an email address in the EMAILYN column (1 = yes, 2 = no), the email address(es) will be in the UPDATEEMAIL and UPDATEEMAIL_2 columns.

v. **Special note about former St. Jude patients:** If the SIBID# begins with 15 and any contact information for the associated case or case associates has changed, send screen-prints of changes made to the CRAII in charge of SJ Life Recruitment.

D. **Comments** – For surveys completed with someone other than the sibling, ensure there is a dated note with SI ID specifying the name and relationship of the proxy that completed the survey. *Example: 6/15/2015: SI 156 completed baseline sibling survey with adult sibling participant's mother and LAR, Jada Smith. [123]*

5. **Sib AddlContact Tab** – If the sibling participant has authorized an additional contact during the sibling baseline survey, the contact's information will be listed in the CONTACT NAME, CONTACTRELATIONSHIP, CONTACTADDRESS, CONTACTCITY, CONTACTSTATE, CONTACTZIP, CONTACTPHONE and CONTACTPHONE_2 columns. Use this information to update the database according to the SOP titled **Expansion Sibling Cohort Survey Calls**.

6. Review the SURVEY_**COMMENTS** column of the survey results:
   A. For any survey comments that contain questions or may otherwise require attention from a study doctor, psychologist, social worker, etc., email the SIBID and the comment to the Coordinator, copying the LSI team, for review.
   B. If the sibling participant requests no newsletter, update the Sib Reg tab:
      i. **Sibling Outcome** - Populate with 42-Wants Surveys But No Newsletters.
      ii. **Sibling Outcome Date** - Populate with the current date.
      iii. **Sibling Outcome Note** - Enter a dated note with SI ID indicating this data change.

7. **Informed Consent** – File the informed consent form appropriately:

A. If the form indicates the sibling participant did not receive a copy of the informed consent *and* the **Participant Copy Sent** boxes are blank, file the form in the "Needs Consent" folder in the top drawer of the short file cabinet.
B. If the form indicates that the sibling participant did receive a copy of the informed consent *or* if the **Participant Copy Sent** boxes are populated, file the form in the appropriate institutional folder in file cabinet 2.

Deceased Sibling Baseline Surveys

1. For alive expansion sibling baseline surveys, see the section of this document titled *Alive Sibling Baseline Surveys*, above.

2. **Sib Baseline Tab**
   A. Non-Completed Surveys: Leave the **Baseline Outcome** field blank. Do *NOT* select 38-Deceased.
   B. Completed surveys (survey was completed with proxy of deceased sibling participant):
      i. If the directed fields, below, are already populated, do not change the existing values. Instead, make a note in the **Tracking Comments** field regarding the alternate values. Consult the Coordinator with questions.
      ii. **Date Consent Signed** – Populate with the date informed consent was obtained, as indicated in the **Consent Obtained** boxes on the form.
      iii. **Consent Status** – Populate with 10-Verbal.
      iv. **Consent INT ID** – Populate with the ID of the SI who completed the informed consent, as indicated in the **Consent Obtained** boxes on the form. This may be different from the SI who completed the survey.
      v. **MR status** – Populate with 6-Send Medical Release.
      vi. **Interviewer ID** - Populate with the ID of the SI who completed the survey with the proxy, indicated in the **Survey Completed** boxes on the consent form. If this field is already populated with another ID, consult with the Coordinator.
      NOTE: If the survey was begun by interviewer A and completed by interviewer B, enter the ID for interviewer B. SIs obtaining a partial survey, such as interviewer A, have been instructed to log this time in their **Journal**.
      vii. **Interview Status** – Populate with 1-Complete (changing from <null> or 9-Partially Completed).
      viii. **Date Survey Sent** - If blank, populate with the date 12/12/1812.
      ix. **Baseline Outcome** – Populate with 38-Deceased. If this field is already populated with another value, consult with the Coordinator.
      x. **Baseline Outcome Date** – Populate with the current date. If this field is already populated with another value, consult with the Coordinator.
      xi. **Tracking Comments** –
         a. Ensure there is a dated note with SI ID specifying the name and relationship of the proxy that completed the survey. *Example: 12/27/2015: SI 152 completed the expired survey with sibling participant's mother, Marsha Brady. [137]*
         b. For surveys completed in Spanish (indicated in the DB Change request form – See the SOP titled using the **ERC Admin Asst Database** for details.), ensure there is a dated note clearly documenting that the survey was completed in Spanish. (*Example: 7/23/15: Completed the expired survey in Spanish with sibling participant's mother, Jennifer Lopez. [158]*)

3. **Header**
   A. Date of Birth:
      i. Review the CONFIRMDOB column (1 = correct, 2 = incorrect) in the survey results. If the DOB is incorrect, the correct DOB should appear in the CORRECTDOB column.
      ii. If the proxy indicated a corrected date of birth, use the SOP titled **Expansion Sibling Cohort Survey Calls** to update the participant's record.
   B. There is no need to review/update the sibling's gender. The 5th floor team automatically harvests this information from online and paper surveys.
   C. For surveys completed in Spanish (indicated in the DB Change request form - See the SOP titled **Using the ERC Admin Asst Database** for details.), ensure the SI has clearly documented:
      i. The correct status in the **SPANISH STATUS** field
      ii. That the survey was completed in Spanish in the call log notes

4. **Sib Info Tab**
   A. **Tracing Status** - Remove values in this and the related **Tracing Date** fields, if applicable.
   B. **Send Q-aire To** – Populate with the appropriate code: 5-Parent (Sib. Has Died) or 7-LAR.
   C. Contact Information – Address, Phone Number(s), and Email Address(es)
      i. See the SOP titled **Expansion Sibling Cohort Survey Calls** for details on how to update the Expansion Tracking database with confirmed information. Since expired surveys are completed via telephone with an SI, use "Phone contact w/family" as the confirmation source.
      ii. Address
         a. Click on the button **See DatStat Address**. This is the address the proxy has confirmed as correct or incorrect in the ADDRCORR column (1 = correct, 2 = incorrect).
         b. New address information is provided in the UPDATEADDRESS, UPDATECITY, UPDATESTATE, and UPDATEZIP columns. This information can also be found on the **Expired Participant Information Sheet**. Compare to ensure consistency.
      iii. Phone
         a. Click on the button **See DatStat Address**. This is the phone number the proxy has confirmed as correct or incorrect in the PHONECORR column (1 = correct, 2 = incorrect).
         b. New home phone and cell phone information is provided in the UPDATEHOMEPHONE and UPDATECELLPHONE columns. This information can also be found on the **Expired Participant Information Sheet**. Compare to ensure consistency.
         c. Email – If the proxy indicates that s/he has an email address in the EMAILYN column (1 = yes, 2 = no), the email address(es) will be in the UPDATEEMAIL and UPDATEEMAIL_2 columns.
   D. **Comments** – Ensure there is a dated note in the **Comments** field specifying the name and relationship of the proxy that completed the survey. *Example: 12/27/2015: SI 152 completed the expired survey with sibling participant's mother, Marsha Brady. [137]*
   E. Click the **Death Data Form** button to open the form, then complete (see next section).

5. **Death Data Form**– Using the **Expired Participant Information Sheet**:
    A. **Alive/Dead Status** - Populate with 2 (2 = Deceased).
    B. **Date of Death** - Populate, if known. If only the year of death is known, then use the fictitious month and/or day of 7/15. If the year is not known, then leave this field blank.
    C. **State of Death** - Populate, if known.
    D. **Parent's reason For Death** - Populate, if given.
    E. **Did sibling have cancer at time of death (according to parents) -** Enter appropriate answer, if given.
    F. Close the Deathdata form.

6. **Sib Reg Tab** (Completed Surveys ONLY)
    A. **Sibling Outcome** – Populate with 38-Deceased.
    B. **Sibling Outcome Date** - Enter or update to be the current date.

7. **Processing Newsletter Requests** (Completed Surveys ONLY) **–** Newsletters are not automatically mailed to proxies of expired sibling participants. If the proxy of a deceased sibling participant would like to receive the LTFU newsletters, as noted by checking the "Newsletter" box at the top of the **Expired Participant Information Sheet**:
    A. Open the worksheet **LTFUNewsletter Additional Names**, located at *Z:\SJShare\SJCOMMON \ECC\CCSS\Newsletter*.
    B. Manually add the proxy's name and address to the appropriate worksheet.
    C. Save and close the file.
    D. NOTE: Call Center Coordinator designees for data entry who are not LSIs should email the LSI team to do this process. Access to this spreadsheet is restricted.

8. **Informed Consent** – File the informed consent form appropriately. If the **Participant Copy Sent** boxes are:
    A. Blank - File the form in the "Needs Consent" folder in the top drawer of the short file cabinet.
    B. Populated - File the form in the appropriate folder in file cabinet 2.

Partially Completed Surveys

When a Survey Interviewer at a minimum gathers informed consent but does not complete the survey, s/he will update the appropriate fields in the Expansion Tracking database (See the SOP titled **Expansion Sibling Cohort Survey Calls**.) and file the informed consent form in the folder labeled "Daily Informed Consents".

Before beginning the post-partial survey procedures, the LSI or designee will:

1. Use the SOP titled **Using the ERC Admin Asst Database** to capture information about expansion sibling baseline surveys partially completed via telephone with a Survey Interviewer, as noted in the **DB Change** field of the call log.
2. Gather informed consent forms from the hanging file folder labeled "Daily Informed Consents", located in the top drawer of the short file cabinet. The forms where the **Survey Completed** boxes are blank represent surveys partially completed with the assistance of an SI.

Once preparation is complete:

1. **Sib Baseline Tab**

A. If the directed fields, below, are already populated, do not change the existing values. Instead, make a note in the **Tracking Comments** field regarding the alternate values. Consult the Coordinator with questions.
B. **Date Consent Signed** - Populate with the date informed consent was obtained, as indicated in the **Consent Obtained** boxes of the form.
C. **Consent Status** - Populate with 10-Verbal.
D. **Consent INT ID** - Populate with the ID of the SI who completed the informed consent, as indicated in the **Consent Obtained** boxes of the form. This may or may not be the SI who completes the survey.
E. **Interview Status** - Populate with 9-Partially Completed.
F. **Tracking Comments** - Add a dated note with SI ID indicating the partial survey. *Example: 1/9/2015: INT 121 gathered informed consent, gained partial survey with sibling participant [123]*)

2. **Sib Info Tab**
   A. **Tracing Status** – Ensure values in this and the related **Tracing Date** fields have been removed, if applicable.
   B. **Send Q-aire To** – Ensure this is populated with the appropriate code:
      i. For anyone under 18, choose the number that corresponds with mother, father, both parents, etc. Without further information, typically choose 4-Both(sib under 18).
      ii. For anyone 18 or older, typically choose 1-Sibling, but there are also options for 7-LAR, 6-Parent(Eventhough sib over 18), etc., where appropriate.
      iii. For deceased cases, populate with 5-Parent(sib has died) or 7-LAR, as appropriate.
   C. Ensure all addresses, phone numbers, and email address are updated according to the call log notes. See the SOP titled **Expansion Sibling Cohort Survey Calls** for details.
   D. Verify that the SI has added a dated note in the **Comments** field. (*Example: 1/9/2015: Gathered informed consent, gained partial survey with sibling participant [121]*)

3. **Informed Consent** – File the informed consent form appropriately.
   A. If the informed consent indicates the sibling participant did not receive a copy of the informed consent *and* the **Participant Copy Sent** boxes are blank, file the form in the "Needs Consent" folder in the top drawer of the short file cabinet.
   B. If the informed consent indicates that the participant did receive a copy of the informed consent *or* if the **Participant Copy Sent** boxes are populated, file the form numerically in the "Partially completed surveys" folder in the bottom drawer of the short file cabinet.

Refusals at Baseline

Refusals at the expansion sibling baseline survey may be made either online by the sibling participant without the assistance of an SI or via telephone to an SI. For telephone refusals, the SI will document the refusal in the **Outcome** field of the call log.

The LSI or designee will:

1. Use the SOP titled **Extracting and Processing Expansion Baseline DatStat Refusals** to capture expansion sibling baseline survey refusals made via DatStat *and* to process those refusals.
2. Use the SOP titled **Using the ERC Admin Asst Database** to capture information about expansion sibling baseline survey refusals made via telephone with an SI, as noted in the **Outcome** field of the call log.

A. Examine each refusal to ensure all refusal documentation, as outlined in the SOP titled **Expansion Sibling Cohort Survey Calls**, has been completed.
B. Review the **Date Survey Returned** field on the Baseline tab for each sibling participant to determine if the sibling baseline survey was completed:
    i. If the survey was NOT completed:
        a. **Baseline Outcome** – Should be populated with 7-Refused
        b. **Baseline Outcome Date** – Should be populated with the date of the refusal
    ii. If the survey WAS completed, the **Baseline Outcome** and **Baseline Outcome Date** fields should be blank.

Ineligibles

1. When a Survey Interviewer believes a sibling participant to be ineligible, s/he will document the suspected ineligibility by choosing the option 4-Ineligible in the **DB Change** field of the call log.
2. The LSI or designee will use the SOP titled **Using the ERC Admin Asst Database** to capture information about possible ineligibles noted in the **DB Change** field of the call log.
3. The LSI or designee will consult with the Coordinator for an eligibility determination.
4. If an ineligible status is determined to be appropriate, the LSI or designee will update the appropriate fields using the SOP titled **Documenting Ineligibility**.

Database Change Requests

Survey Interviewers (SIs) will log LSI-level Expansion Tracking database change requests in the **DB Change** field of the call log. The LSI or designee will collect and process these requests using the SOP titled **Using the ERC Admin Asst Database**.

Incarcerated Sibling Participants

When a sibling participant is found to be incarcerated, consult with the Coordinator or Research Scientist regarding the proper coding.

1. Those participants that are expected to have shorter terms, as determined by the leadership team, will be coded with a hold code.
2. Those participants who are expected to have longer or indefinite terms, as determined by the leadership team, should be coded on the Sib Baseline tab as follows:
    A. **Baseline Outcome** – Populate with 25-Unavailable.
    B. **Baseline Date** – Populate with the current date.
    C. **Tracking Comments** – Add a dated note with SI ID explaining the circumstances of availability and documenting the member of the leadership team authorizing the outcome.

Completion of Data Entry

After all data entry is completed (including case data entry and data entry for other databases - See separate SOPs.), an email should be sent to the applicable CRAs, the Call Center Coordinator, the LSI team, and any other specified designees.

Example:
Subject Line: Databases Updated

Message Body:
The databases have been updated from the following sources:

- *Surveys completed online (baseline and FU5, cases and siblings)*
- *Database change requests*
- Expired Participant Information Sheets
- *Emails (up to 12:11pm)*
- *DatStat refusals (cases and siblings)*

Suicidal ideation has also been reviewed for baseline and FU5 surveys.

Revision Record Printed 12/3/2014 9:28 AM

[258] Current Filename:		Daily Expansion Tracking Data Entry - Sibling ver1_4.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/25/2013	R. Massey, D. Rinehart	Initial Development
1.1	7/26/2013	J. Bates, D. Rinehart	Content revision
1.2	8/22/13	R. Massey	Content Revision: Baseline Outcome and Consent INT ID fields
1.3	1/17/14	R. Massey	Content Revision
1.4	11/29/14	R. Massey	Content Revision

Daily LTFU Participant and Ancillary Database Updates

Background

To maintain the integrity of Long Term Follow-Up (LTFU) Study participant information, study personnel must update the LTFU Participant and ancillary databases from online FU5 survey results and database change requests submitted by Survey Interviewers (SIs). Auditing documentation of terminal events such as ineligibility, long-term incarceration/unavailability, and study refusals also ensures clean data and prevents losing participation unnecessarily.

To protect data reliability, only members of the LSI team, the Coordinator, or the Coordinator's designee will perform post-survey and change request database updates and audit terminal events.

Procedures

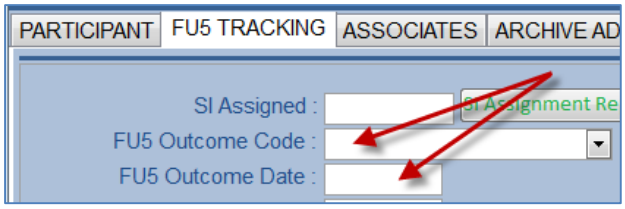
Open the ERC Admin Asst. Database, located at *S:\ECC\Interviewers\Administrative\Daily Database Updates*. Click the **Run All Macros** button, then click the **Yes** button at all pop-up windows. Upon completion, click the **LTFU DB Forms** button to open the forms for the LTFU Participant database (or click the **Open All Forms** button to open the forms for all databases, including the LTFU Participant database). Use these forms to update the LTFU Participant database as follows.

Completed FU5 Surveys

This process will be completed every day from Monday through Friday. Because other actions necessary to populate the update forms are not completed on weekends, this process is not done on Saturdays or Sundays.

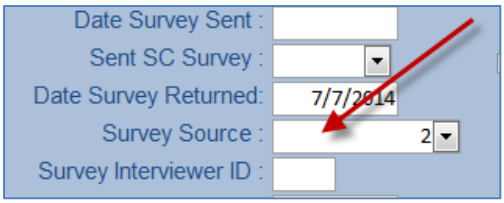
The Post FU5 Survey Database Updates form (labeled qry_DR_Post_FU5_Updates on the form tab) displays a record for each FU5 survey completed online, with or without an SI, that has not yet been reviewed. For each record, open the participant's record in the LTFU Participant database and make the following updates:

1. FU5 Tracking Tab
   A. If there is any value in the **FU5 Outcome Code** field (and the related **FU5 Outcome Date** field), evaluate whether or not this value should be removed. Document any changes in the **Notes** field.



   B. If the survey was completed BEFORE the iPad letter was sent:
      i. **Date Intro Letter Sent** – Populate with the date the survey was completed. This prevents future mailings and ensures the participant is in the appropriate iPad drawing.
      ii. **Notes** – Add a dated note with SI ID indicating why the **Date Intro Letter Sent** field was populated.
   C. Populate the **Survey Source** and **Interview Status** fields, as appropriate.
      i. For surveys completed with an SI (**Survey Interviewer ID** field is populated and the **Notes** field indicates the survey was completed with an SI):
         a. **Survey Source** – Populate with 3-Interviewer.

b. **Interview Status** – Populate with 2-Complete.



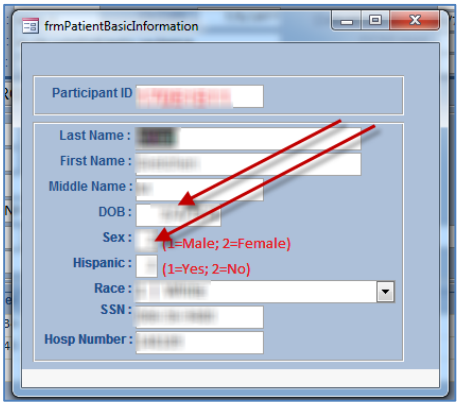
ii. For surveys completed without an SI (**Survey Interviewer ID** field is <null> the **Notes** field does not indicate the survey was completed with an SI):
   a. **Survey Source** – Populate with 2-Online.
   b. **Interview Status** – Do not populate.

2. Header

A. If the participant indicates a **name change** in the **First**, **Middle**, and/or **Last** fields of the Updates column (or the UPDATE_FIRST, UPDATE_MID, or UDPATE_LAST fields of the table), see the SOP titled **Updating Database for Name Changes** for instructions to make the change.

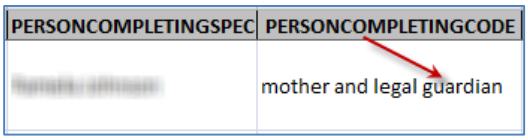
B. If the participant indicates a **corrected date of birth** in the **DOB?** and **DOB** fields of the Updates column (or the CONFIRMDOB and CORRECTDOB fields of the table), see the SOP titled **Updating Date of Birth** for instructions to make the change.

C. If the participant indicates a **corrected gender** in the **Gender** fields of the Updates column, see the SOP titled **Updating Gender** for instructions to make the change.

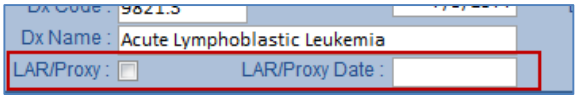


D. Check the **Person Completing** fields (PERSONCOMPLETINGSPEC and PERSONCOMPLETINGCODE fields in the table) for any indication that **someone other than the participant completed the survey**.

i. If someone other than the participant completed the FU5 survey but <u>there is *not* compelling evidence that the participant has an LAR</u>, make a dated note with SI ID in the **Notes** form indicating the circumstances of the survey completion. Click the **Notes** button on the Participant tab to access this form.
Example: 5/14/2015: Mother, Lucy Liu, completed FU5 survey. No indication she is the LAR. [137]



ii. If <u>there is compelling evidence that the participant has an LAR</u> (e.g. if the second **Person Completing** field or PERSONCOMPLETINGCODE field from the table = "mother and legal guardian"), and we do not have a record of this status:
   a. **LAR/Proxy** – Check this checkbox.
   b. **LAR/Proxy Date** – Populate the current date.
   c. **Care of** (Participant tab) – Populate with "C/O" plus the LAR's first and last name.
   Example: C/O VICTORIA ORTIZ
   d. **Notes** (Participant tab) – Make a dated note with SI ID indicating the field changes and the circumstances of the change. Click the **Notes** button on the Participant tab to access this form.
   Example: 7/31/15: Mother, Victoria Ortiz, completed 7/30/15 FU5 survey for adult son and indicated she is his legal guardian. Updated LAR/Proxy status in header and added mother in Care of field. [158]



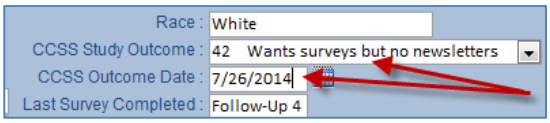
iii. For uncertain or unusual situations, forward the circumstances to the Coordinator, copying the LSI team, for a determination on how to proceed.

E. If the participant requests **no newsletter**:

i. **CCSS Study Outcome** – Update to be 42-Wants Surveys But No Newsletters.

ii. **Outcome Date** – Update to be the current date.

iii. **Notes** (Participant tab) – Enter a dated note with SI ID documenting the data change.



3. Participant Tab

A. **Tracing Code** and **Tracing Date** – Clear any value in the fields, if appropriate.

B. Update all **contact information** for the participant as confirmed in the survey. See the SOP titled **LTFU Participant Database Data Entry** for details on completing the updates.

i. When recording the **confirmation source** for the contact information:

a. Use "Phone Contact With Patient" or "Phone Contact with Family", as appropriate, if the survey WAS completed with an SI.

b. Use "Survey" if the survey WAS NOT completed with an SI.

ii. Check the **Address on File**, **City**, **State**, and **ZIP** fields (ADDRESS, CITY, STATE, and ZIP fields in the table). This is the **address** the participant/parent/proxy has confirmed as correct or incorrect. In the **Address Correct?** field (ADDRCORR field in the table):

a. 1 - Indicates the address is correct

b. 2 - Indicates the address is incorrect. The participant is then able to enter the correct address in the **New Address City**, **State**, and **Zip** fields of the Updates column (UPDATEADDRESS, UPDATECITY, UPDATESTATE, and UPDATEZIP fields in the table).

c. 3 - Indicates the participant plans to move in the next 6 months

1. **Notes** (Participant tab) – Enter the future new address in a dated note with SI ID. Access this field by clicking on the **Notes** button.

2. Do not update the address fields. When 6 months have passed from the date of the survey, the participant will be reported for processing in the address update form. See the section of this document titled *Future Address Updates* for details.

3. Unless there is clarifying information in the survey Comments, do not consider the current address as confirmed.

iii. The **Phone on File** field (PHONECALC in the table) is a preloaded value, not a confirmed number entered by the participant. Use the participant's response in the **Type** field (PHONETYPE in the table) to **update the number displayed in the** Phone on File **field** (PHONECALC in the table). The **Phone on File** (PHONECALC in the table) number is:

a. A confirmed home phone if the **Type** field (PHONETYPE in the table) is 1

b. A confirmed cell phone if the **Type** field (PHONETYPE in the table) is 2

c. A confirmed work phone if the **Type** field (PHONETYPE in the table) is 3

d. An incorrect number if the **Type** field (PHONETYPE in the table) is 4

1. Check to see if the phone number belongs to an associate. It could be an invalid number for the participant but valid for a parent or other party. Consult with the Coordinator if unsure how to proceed.

2. Rank truly incorrect numbers with the 11-Wrong Number rank.

iv. The following fields are populated by the participant and should be used to **update the telephone number fields** in the database.

NOTE: If a participant indicates the same number as two phone types (e.g. home and cell), document the number only once in the LTFU Participant database, and add a note to the **Notes** field documenting the two phone types indicated. Access this field by clicking on the **Notes** button on the Participant tab.

a. **(H)** (HOMEPHONE in the table) – current home number
b. **Moving (H)** (HOMEPHONE_MOVE in the table) – home number after moving and is applicable if the participant indicates with a value of 1 in the **Moving?** field of the Updates column (or MOVING field in the table) a move is planned in the next month
c. **(C)** (CELLPHONE in the table) – current cell number
d. **(W)** (WORKPHONE in the table) – current work number
e. **Moving (W)** (WORKPHONE_MOVE in the table) – work number after moving and is applicable if the participant indicates with a value of 1 in the **Moving?** field of the Updates column (or MOVING field in the table) a move is planned in the next month

v. The **Email?** field in the Updates column (EMAILYN in the table) indicates whether the participant does (value = 1) or does not (value = 2) have an email address. If yes, the confirmed email address is listed in the **Email** field of the Updates column (UPDATEEMAIL in the table) and should be used to **update the email address fields**.

4. Associates Tab - Update all contact information for the participant's associate(s) as confirmed in the survey. The participant's authorized additional contact information will be in the **ADD'L CONTACT**, **Relationship**, **Add'l Contact Addr**, **City**, **State**, **Zip**, **(H)**, **(C)**, and **(W)** (columns whose labels begin with "CONTACT"). See the SOP titled **LTFU Participant Database Data Entry** for details on adding or updating additional contacts.

5. Review the **Comments** field. If any comment needs immediate attention, forward the CCSSID/SIBID and the comment to the Coordinator and/or Research Scientist for review.

6. When all action necessary for the current record has been taken, populate the **Date Reviewed** and **SI ID** fields in the record in the ERC Admin Asst. Database.

Processing DB Change Requests

The forms titled LTFU Pt Db: Contact Log DB Change Requests (DBCR_LTFU on the form tab) and LTFU Pt Db: Trace Log Change Requests (DBCR_LTFUT on the form tab) display records for database change requests entered by SIs. Evaluate each record and take the appropriate action, as described below. When each record's request has been resolved, populate the **Review Date** and **Review SI ID** field for that record.

1. Date of Birth – See the SOP titled **Updating Date of Birth** for instructions.
2. Gender – See the SOP titled **Updating Gender** for instructions.
3. Spanish Survey Completed – Review records in the LTFU Participant and project-specific databases for accuracy and completeness based on the project-specific SOP.
4. Ineligible
   A. Confirm the participant is truly ineligible. If there is any question regarding the ineligibility, consult with the Call Center Coordinator and Research Scientist for a determination.
   B. Review records in the LTFU Participant and, if applicable, project-specific databases for accuracy and completeness based on the project-specific SOP.
   C. Health eHeart (HeH) – In addition to confirmation of ineligibility and the accuracy review, above:

i. Update the Health eHeart database:
   a. **HeH Outcome** – Populate with 7-Ineligible.
   b. **Outcome Date** – Populate with the current date.
ii. Email the Research Scientist and Call Center Coordinator regarding the ineligibility.

D. EQUAL – In addition to the confirmation of ineligibility and accuracy review, above, email the EQUAL project coordinator, Research Scientist, and Call Center Coordinator regarding the participant's ineligibility. The project coordinator will review the record and update the EQUAL database as appropriate.

E. ASK – In addition to the confirmation of ineligibility and accuracy review, above:
   i. On the Tracking tab of the participant's record in the ASK .NET database:
      a. **Skin Cancer Study Outcome**
         1. If currently blank, populate with "Ineligible".
         2. If populated, do not change.
      b. **Skin Cancer Study Outcome Date**
         1. If currently blank, populate with the current date.
         2. If populated, do not change.
      c. **Ineligible Reason** –
         1. If populating the outcome fields, populate with the appropriate reason. NOTE: Get approval before using the value "Other".
         2. If the outcome fields are populated and are not being changed, do not populate this field.
      d. **Notes** – Add a dated note with SI ID documenting any changes made to the outcome and **Ineligible Reason** fields.
   ii. Email – Forward the ineligible email, which should have been sent by the SI, to the project coordinator and Research Scientist indicating that either:
      a. The ASK .NET outcome and **Ineligible Reason** fields have been updated OR
      b. The ASK .NET outcome fields are currently populated and that no changes were made

5. Name Change – See the SOP titled **Updating Database for Name Changes** for instructions.
6. Survival Status
   A. See the SOP titled **Updating Databases with Post-Recruitment Death Notices** for instructions. NOTE: Vital status is not changed in ancillary project databases. These databases reflect the vital status in the LTFU Participant database.
   B. ASK Study
      i. Review records in the LTFU Participant and ASK .NET databases for accuracy and completeness based on the **ASK Study Calls** SOP.
      ii. In the ASK .NET database's Tracking tab:
         a. **Skin Cancer Study Outcome**
            1. If currently blank, populate with "Deceased".
            2. If populated, do not change.
         b. **Skin Cancer Study Outcome Date**
            1. If currently blank, populate with the current date.
            2. If populated, do not change.
         c. **Notes** – Add a dated note with SI ID documenting any changes made to the outcome fields
      iii. Forward the deceased notification email, which should have been sent by the SI, to the Project Coordinator and Research Scientist indicating that either:

a. The ASK .NET outcome fields have been updated OR
b. The ASK .NET outcome fields are currently populated and that no changes were made

7. Partial Surveys – Review and update the LTFU Participant database as follows.
   A. FU5 Surveys
      i. Ensure all post-survey directives in the appropriate project-specific SOP were completed.
      ii. **Interview Status** (FU5 Tracking tab) – Populate with 1-Partially Complete.
   B. ASK Surveys – Ensure all post-survey directives in the SOP titled **ASK Survey Calls** were completed.
8. No Proxy Available Determinations
   A. Confirm that the "no proxy available" determination is appropriate. If there is any question regarding the appropriate status, consult with the Call Center Coordinator and Research Scientist for a determination.
   B. If there is truly no proxy available:
      i. **CCSS Study Outcome** (header) – Populate with 25-unavailable.
      ii. **CCSS Outcome Date** (header) – Populate with the current date.
      iii. **Notes** (on the Participant tab) – Enter a dated note with SI ID documenting the outcome header field changes and the reason for the change.
      iv. If the FU5 process has been initiated (intro letter has been sent), on the FU5 Tracking tab:
         a. **FU5 Outcome Code** – Populate with 11-No Proxy Available.
         b. **FU5 Outcome Date** – Populate with the current date.
         c. **Notes** – Enter a dated note with SI ID documenting the outcome field changes and the reason for the change.
9. Incarcerations Greater than 12 Months – Consult with the Call Center Coordinator and/or Research Scientist to determine if the case should be marked unavailable, placed on consecutive time period holds, etc. Follow up with the appropriate action in the LTFU Participant database.

Future Address Updates

The form titled LTFU PTDB Future Address Updates from DatStat (frm_DR_AddressUpdate_LTFU_PTDB on the form tab) displays records for participants who reported on the FU5 survey that they would be moving within the next 6 months. The records appear in the form 6 months after the date the survey was returned.

Evaluate each record and determine if the participant's record needs to be updated in the LTFU Participant database. Because of the 6-month delay, there may be circumstances that preclude the update. Therefore, these updates must be evaluated on a case-by-case basis. If the update is warranted, use the SOP titled **LTFU Participant Database Data Entry** to make the change.

NOTE: If a participant reported that s/he would be moving but did not provide an updated mailing address, no action or follow-up is required.

When the appropriate action has been taken on each record, populate the **Review Date** and **Review SI ID** field for that record.

Auditing Refusals

The forms titled FU5 Refusals (Ref_LTFU on the form tab) and Ancillary_Refusals (Ref_Anc on the form tab) display records for refusals entered by SIs into the contact log. Evaluate each record and take the appropriate action, as described below.

1. Review records in the LTFU Participant and project-specific databases for accuracy and completeness based on the project-specific SOP.
2. ASK Study Baseline Surveys – In addition to the accuracy review, open the ASK .NET database and access the participant's record.
   A. On the Tracking tab:
      i. **Skin Cancer Study Outcome**
         a. If currently blank, populate with "Refused/Not Interested in ASK".
         b. If populated, do not change.
      ii. **Skin Cancer Study Outcome Date**
         a. If currently blank, populate with the current date.
         b. If populated, do not change.
      iii. **Notes** – Add a dated note with SI ID documenting any changes made to the outcome fields.
   B. Email – Forward the refusal email, which should have been sent by the SI, to the project coordinator and Research Scientist indicating that either:
      i. The ASK .NET fields have been updated OR
      ii. The ASK .NET fields are currently populated and that no changes were made
3. When each record has been audited and all issues with data entry have been resolved, populate the **Review Date** and **LSI ID** field for that record.

Review ASK Consent Forms

These are found in the "Daily Informed Consents" folder in the top drawer of file cabinet A.

1. Review the consent form for accuracy and completeness.
2. If the survey was also completed, review the participant record in the ASK .NET and LTFU Participant databases for accuracy and completeness based on the completed survey directives in the SOP titled **ASK Study Calls**.
3. If a participant copy is needed, process the request using the SOP titled **Sending Participant Copies of the ASK Study Informed Consent**.

File All Forms

When all other processes are completed, file all forms.

1. Reconsent forms:
   A. Participant Copy Needed – Send a request to the Call Center Coordinator or, in the Coordinator's absence, the Research Scientist. A case-by-case letter will be prepared and sent to the participant.
   B. No Participant Copy needed – File numerically in cabinet 2, along with the baseline informed consents, in the appropriate institution folder.
2. ASK consent forms
   A. Partially Completed Surveys – File numerically in cabinet A (bottom drawer) in the folder labeled, "Partially completed surveys".
   B. Completed Surveys – File in cabinet A (top drawer) in the folder labeled, "To Be Filed or Delivered". These will be delivered to the ASK project coordinator.
3. **Expired Participant Information Sheet** – File numerically in cabinet 2 in the database-appropriate folders.

After all daily update data entry is completed (e.g. from this SOP as well as those titled **Daily Expansion Tracking Data Entry – Cases**, **Daily Expansion Tracking Data Entry – Siblings**, etc.), an email should be sent to the applicable CRAs, the Call Center Coordinator, the LSI team, and any other specified designees on weekdays (Monday – Friday).

Example:
Subject: Databases Updated

The databases have been updated from:

- *Surveys completed online (baseline and FU5, cases and siblings)*
- *Baseline DatStat refusals (cases and siblings)*
- Expired Participant Information Sheets
- *DB Change queries (Recruitment, Expansion Tracking, and LTFU Pt databases)*
- *Refusal queries (Recruitment, Expansion Tracking, and LTFU Pt databases)*

Suicidal ideation from baseline surveys and FU5 surveys has also been checked for cases and siblings.

Revision Record
Printed 5/26/2015 11:03 AM

[257] Current Filename:		Daily LTFU Participant and Ancillary Database Updates ver2_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/15/2014	R. Massey, T. Thomas, A. Oyuela, D. Rinehart	Initial Development
1.1	7/26/2014	R. Massey	Add directives for name changes, LARs, incorrect numbers, and add Admin button instructions
1.2	10/15/2014	R. Massey, A. Oyuela	Content Revision: Add directives for new Interview Status field and for surveys completed before iPad letter is mailed
1.3	10/25/2014	R. Massey	Content Revision: Add directives for partial surveys, future addr updates
2.0	5/22/2015	R. Massey, A. Oyuela	Content Revision: Name change from *Database Updates from Online Follow-Up 5 Surveys*, add directives for new projects, filing forms

Dana Farber Cancer Institute (DFCI) Baseline Survey Calls

Background

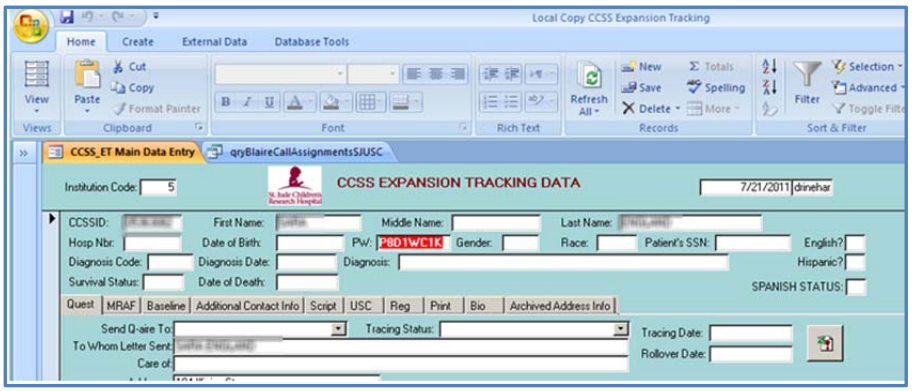
Due to their institutional IRB restrictions, Dana Farber Cancer Institute (DFCI) (institution 05) staff members recruit their own former patients (institution 05) to the expanded cohort. The DFCI staff members send the LTFU Coordinating Center only limited information about the case (i.e., no date of birth, gender, etc.). After receiving the PHI, the Coordinating Center mails the case the baseline questionnaire. The former DFCI patients are not offered the online option. Instead, they can complete the survey via paper or over the phone with an interviewer. The reminder phone calls by Survey Interviewers begin approximately 3-weeks after the survey is mailed.

Procedure

Important reminder - We ***do not*** offer "The Online Option" of completing the survey or send them the web-link.

Completing the Baseline Survey with a Dana Farber participant:

1. Open the Expansion Tracking database.



2. Open the DFCI call assignments file (**qry_DFCI_AgeReferenceList_mm-dd-yyyy**) located at:
   Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls.
   a. This list shows if an Adult or Minor version of the baseline questionnaire was mailed. This will help you to ask for the right person (parent or adult participant) and also know which version of the online survey to access.
   b. It is possible that a person turned 18 after the questionnaire mailing. You will be able to handle this if you begin the survey because you will have the option of going to the adult questionnaire (see process below).

3. Important: After contact is established with the participant, ask them to verify their date of birth by telling us their DOB. Be sure to write down what they give you. You will also give this information to Melanie to update the database (via the Call Outcomes Log described below).

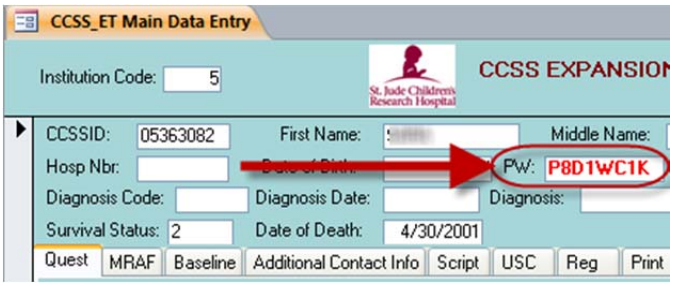
   Be sure to work these questions into the standard script:

> "Hello, my name is…,
> Am I speaking to …?
> For verification purposes, what is your date of birth?"

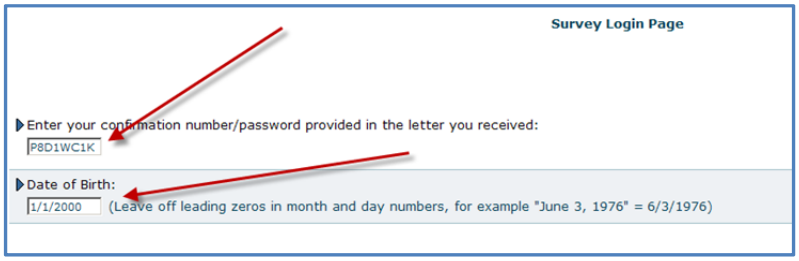
4. If the participant DOES NOT want to complete the survey over the phone, verify their mailing address and order a resend of the paper survey, and **Update the Call Outcomes Log** (see below for steps).

5. If the participant DOES want to complete the survey with you over the phone:
   a. Open the appropriate Baseline Survey web site (based on the information in the excel call reference sheet).

   b. Copy the password (**PW**) from the Expansion Tracking database into the web link for the survey:



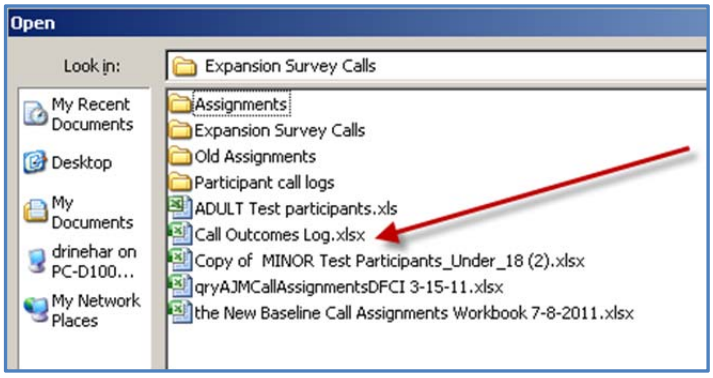
   c. Important: Always enter the "dummy" Date of Birth **1/1/2000** to log into the website.



   d. Early in the survey you will be prompted to answer, "**Is this date of birth correct?**"
      i. Answer"**No**
      ii. You will then be allowed to add the correct date of birth.
   e. ***The rest of the survey completed in the same manner as with other institutions.***

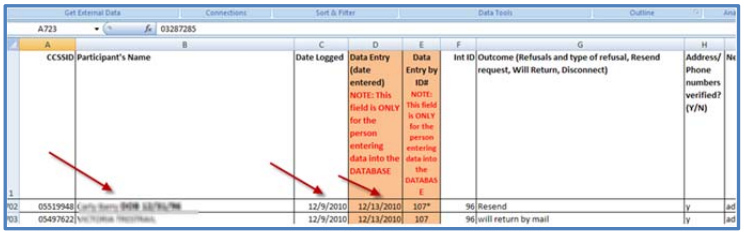
FINAL STEP: Updating the Call Outcomes Log

Melanie will use this information to update the Expansion Tracking database.



1. Find the log in the **Interviewers** folder, in the **Expansion Survey Calls** folder.

2. Enter the **CCSSID**, **Participant's Name**, **Date Logged**, **Int ID**, **Outcome**, and remaining appropriate participant information in the next available row. Melanie will then update the Expansion Tracking database accordingly.



Revision Record

Printed 7/16/2012 9:09 AM

Current Filename:		Dana Farber Baseline Survey Calls ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	7/21/11	D. Rinehart/A. McDonald	Initial Development and refinement
1.1	5/17/12	Procedure Team	Formatting and content editing

Dana Farber Surveys with Incomplete HIPAA

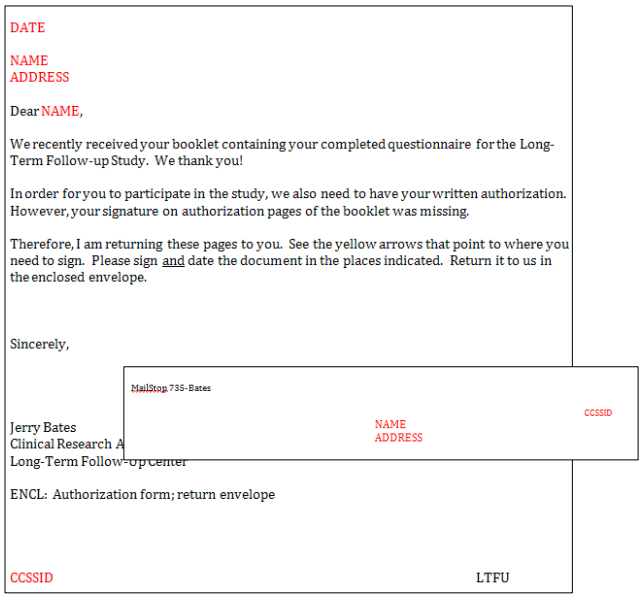
Background

Obtaining a signed LTFU HIPAA (medical release) from Dana Farber study participants is required. When the participant returns the paper survey without having signed the LTFU HIPAA (medical release), we code MR Status with "6" (send medical release). After in-processing the survey, the CRA gives the survey to the lead CRA to send the medical release packet right away. See *Processing LTFU Expansion Baseline Dana Farber*. (To obtain signed HIPAAs for Dana Farber surveys completed with a survey interviewer, we use a monthly automated process; see *Obtaining Signed HIPAA for Dana Farber Cases-Batch Process*).

Procedures

Send Letter with HIPAA form

1. Locate the **model cover letters** and **HIPAA forms** on the server (in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\Consent Resends\DanaFarber 2010 ff\FILL-IN documents**).
2. Cover letter with built-in envelope
   a. Open the appropriate fill-in-the-blank letter (for adult/ minor)
      i. Letter-ADULT DanaFarber for Signature-FillIn
      ii. Letter-MINOR DanaFarber for Signature-FillIn
   b. SAVE the letter with a new name (use SAVE AS), by adding the CCSSID at beginning of file name.
   c. Save the letter in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\Consent Resends\DanaFarber 2010 ff\SENT**.
   d. COMPLETE the fill-in letter and envelope by keying the appropriate information in the RED text areas. Be sure to use the current date.
   e. Use YOUR NAME in the signature block and in the Mail Stop block on the envelope.
   f. Change the text to black, and then save the file again. Remember to save the personalized documents in the "SENT" folder.
   g. Print the cover letter on St Jude letterhead and the envelope on a St Jude envelope. Print a second copy of the letter on plain paper.
   h. Sign the letter


DATE

NAME
ADDRESS

Dear NAME,

We recently received your booklet containing your completed questionnaire for the Long-Term Follow-up Study. We thank you!

In order for you to participate in the study, we also need to have your written authorization. However, your signature on authorization pages of the booklet was missing.

Therefore, I am returning these pages to you. See the yellow arrows that point to where you need to sign. Please sign and date the document in the places indicated. Return it to us in the enclosed envelope.

Sincerely,

Jerry Bates
Clinical Research A
Long-Term Follow-up Center

ENCL: Authorization form; return envelope

CCSSID LTFU

MailStop 735-Bates

NAME
ADDRESS

CCSSID

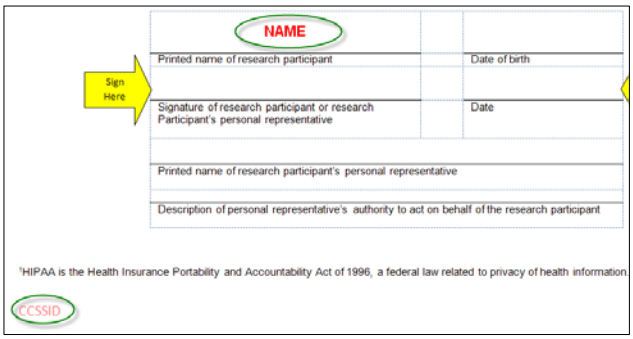
Lead CRA

3. HIPAA/Medical Release

   a. Locate and open the Living LTFU HIPAA Fill-in document from **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\Consent Resends\DanaFarber 2010 ff\FILL-IN documents**)

   b. COMPLETE the HIPAA form, entering name and CCSSID in places indicated. Change the text to black.

   c. SAVE the HIPAA **with a new name (use SAVE AS**), adding the CCSSID at the beginning of the file name. Save the file in **Z:\SJShare\SJCOMMON\ECC\CCSS\ Expansion Baseline\Consent Resends\DanaFarber 2010 ff\SENT**.



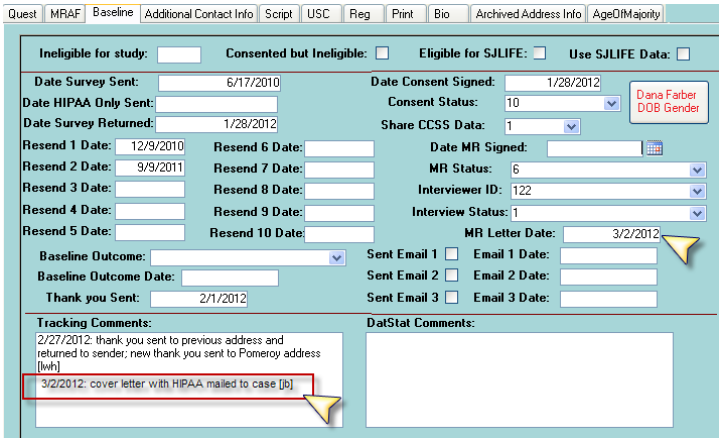
   d. Print the HIPAA in color, then staple the 2 pages together. (Second page is an address update card.)

4. **Document** that material was sent (or resent) using the Baseline tab:

   a. **Tracking Comments** (e.g., *m/d/yy: MR letter sent [inits])*

   b. Letter date in **MR Letter Date** field

   c. If MR Letter Date contains a previous date, make sure the previous letter is documented in Tracking Comments (adding if needed). Then replace MR Letter Date with the date of the resend.



5. **Assemble and mail** the materials.

   a. Be sure to sign the letter.

   b. Insert the signed letter, stapled HIPAA form, and a #9 return envelope with a MailStop sticker into the addressed St Jude envelope.

   c. Seal the package and set out for mail pickup.

6. **File**

   a. Place the copy of the printed letter in the Open Signature Request Letters folder in the DanaFarber standing desk file.

   b. Return the original booklet to the processing queue:

      i. Survey booklet goes to the "to be coded" file drawer.

      ii. Deceased consent booklet goes in the Expansion Deceased drawer.

Processing returned HIPAAs

When the properly signed form is returned (parent or LAR authorized to sign for minors and deceased)

1. Date-stamp and initial in the upper right corner.

2. Photocopy the signed MR and file in the *DF HIPAA Photocopies* folder (where it will be held until being mailed to the data manager).

3. Record in the database
   a. Baseline tab:
      i. Change **MR Status** to 1 (complete)
      ii. Record the signature date in **Date MR Signed**.
      iii. Annotate in **Tracking Comments** (mm/dd/yy: received MR signed by participant/parent/LAR [inits]).

   b. If the person completed the contact update information sheet, update accordingly in the database

4. Retrieve the copy of the request letter from the DanaFarber standing desk file. Shred the letter.

5. File the original signed HIPAA in the Signed HIPAA cabinet, in the Dana Farber HIPAA section.

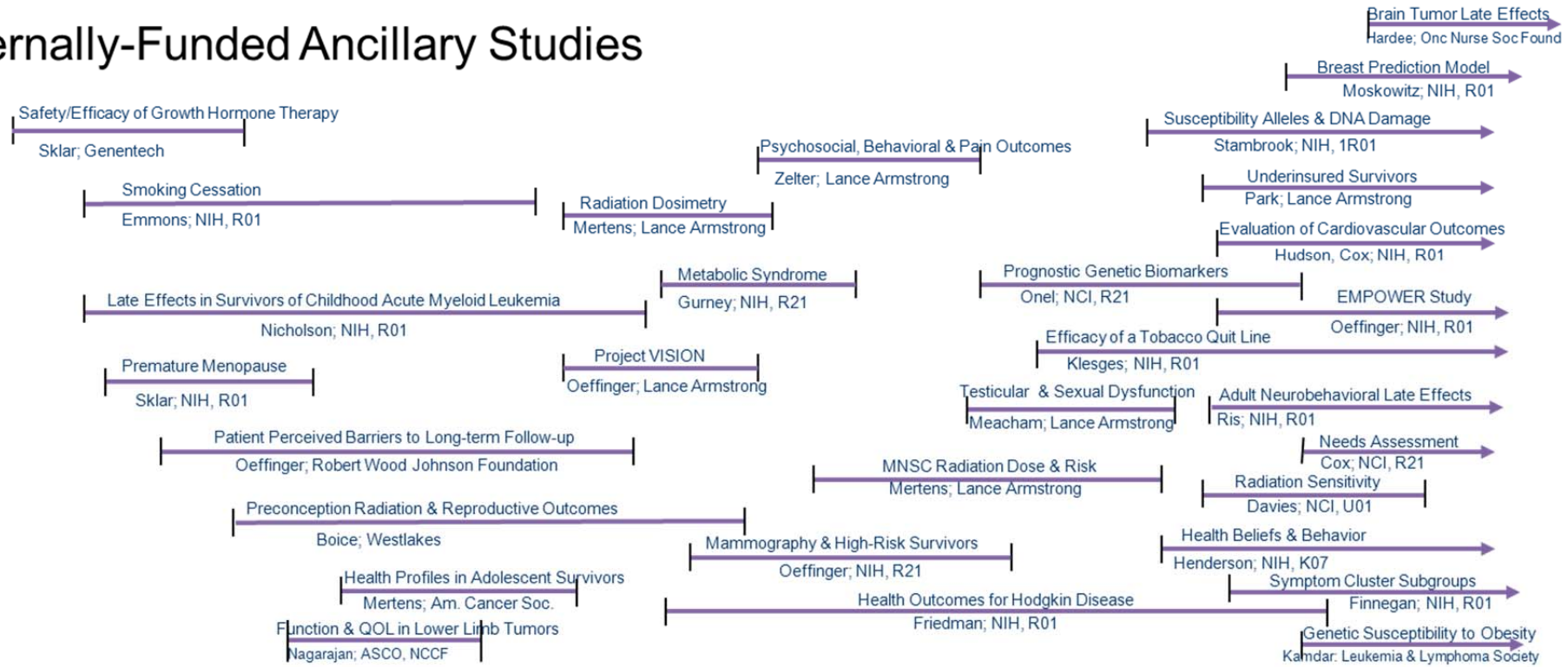
Revision Record Printed 3/7/2013 1:27 PM

(62) Current Filename:		Dana Farber Survey-Incomplete HIPAA 3_3.doc	
Revision No.	Date	Responsible Author	Change Description
1	8/12/10	J.Bates	Initial Development
2	1/25/11	J.Bates	Separate HIPAA document for deceased
3	7/8/11	J.Bates	Combine 2 documents
3.1	7/27/11	J.Bates	Date MR Letter
3.2	8/30/12	J.Bates	Clarify filing; remove mail merge method in lieu of monthly procedure
3.3	3/7/13	J.Bates	Changing dt MR ltr sent on resends; fillin document location correction

Data Collection History

CCSS Cohort Surveys *as of December 2010*

Externally-Funded Ancillary Studies



Data Entry for New Subsequent Neoplasm Reports

Background

The subsequent neoplasm (SN) project seeks to track SNs with which CCSS participants are diagnosed. Data for this project are collected when participants are asked on the baseline and periodic follow-up surveys to report if they have developed an SN since their original diagnosis or since their last Long-Term Follow-Up (LTFU) Study survey. Additionally, the study may learn of SNs when (1) participants and/or their proxies report SNs outside the survey instrument via telephone, written correspondence, or email, (2) tracing information located via online resources (e.g. obituary) indicates an SN, or (3) review of the National Death Index (NDI) reveals a deceased participant had an SN.

This procedure outlines the process for initial documentation of SNs reported to the LTFU Study. After initial documentation, SNs are screened and verified. See the SOP titled **Initial Review of Reported Subsequent Neoplasms** for details on the initial screening process, which follows data entry.

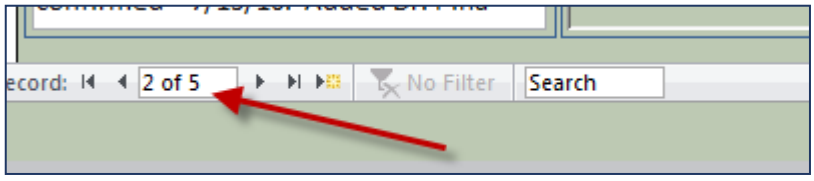
Procedure

Entering SNs Manually

SNs reported via a paper survey instrument, telephone, written correspondence, email, or any mode other than the online survey instrument (DatStat) must be entered manually.

Note that SNs reported in expansion *sibling baseline* surveys, regardless of survey method, must be collected for manual entry on a monthly basis. See the section of this document titled *Expansion Cohort Sibling Baseline Survey* for instructions.

1. Open the SNT database located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Locate the participant in question using the Search Information screen.
3. **Note whether there are reported conditions** already in the database for the participant. If so, navigate through the conditions until a blank form displays. Note how many reported conditions are previously recorded for the participant.



4. **Create a new condition record** by entering the following into the blank form. If the participant did not provide a particular item that requires his/her input, leave the field blank.
   A. **Reported Condition No.**
      i. Cases – Enter "2" if this is the first reported SN for the participant; the original childhood cancer is considered the first neoplasm. If this is not the first reported SN for the participant, review the existing condition numbers to determine the highest recorded number, and enter the next highest number. For example, if the highest recorded condition number for the participant is "4", a new report will be condition number "5".
      ii. Siblings – Enter "1" if this is the first reported neoplasm for the participant. If this is not the first reported neoplasm for the participant, review the existing condition

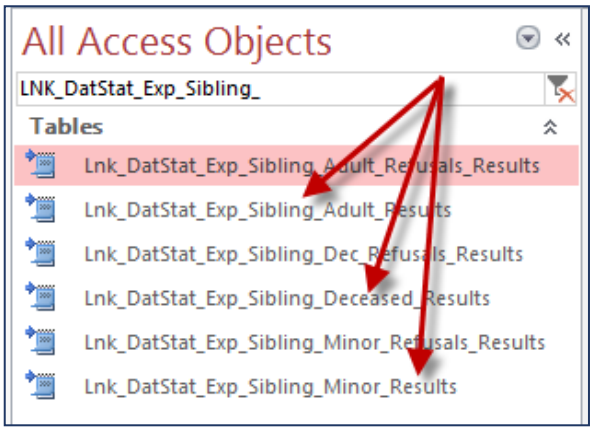
numbers to determine the highest number recorded, and enter the next highest number. For example, if the highest condition number for the participant is "2", a new report will be condition number "3".

B. **Reported Condition** – Enter the name of the disease exactly as the participant reported it.
C. **Reported Body Site** – If the survey has a field for the participant to report the body site (e.g. Expansion Baseline does not provide such a field, but FU6 does), enter the body site exactly as the participant reported it. Otherwise, leave this field blank.
D. **Reported Month/Year of Occurrence** – Enter the month and year of the diagnosis as reported by the participant.
E. **Source** – Use the drop-down menu to select the correct source of the reported condition (e.g. 41-Exp Baseline, 7-FU7, or 87-Other-FU7). See the Senior Coordinator-Clinical Research Operations or Research Scientist if there are questions about the appropriate source.
F. **Reported As** – Use the drop-down menu to record what the participant reported, choosing only from options 1, 2, or 3.
G. **Reported Facility** – Enter the hospital or facility name exactly as the participant reported it.
H. **Reported Address** – Enter the address exactly as the participant reported it.
I. **Reported CSZ** – Enter the city, state, and ZIP code exactly as the participant reported them.
J. **Reported Dr** – Enter the doctor name exactly as the participant reported it.
K. **Condition Notes** – If the participant reported any additional information that may be helpful during pursuit, enter a dated note with initials. Likewise, if the source is anything other than a survey instrument, document how knowledge of the SN was obtained in a dated note with initials.

Expansion Cohort Sibling Baseline Survey

SNs reported in expansion sibling baseline surveys, regardless of survey method, must be collected for manual entry. At least once every month, open the following tables in the CCSS Expansion Tracking database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx, to confirm no new expansion sibling baseline surveys have been returned via DatStat:

- Lnk_DatStat_Exp_Sibling_Adult_Results
- Lnk_DatStat_Exp_Sibling_Deceased_Results
- Lnk_DatStat_Exp_Sibling_Minor_Results



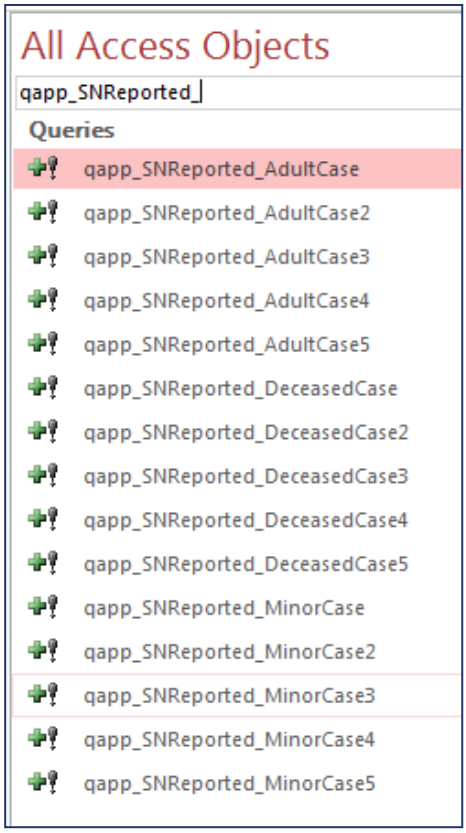
In each table, review the field **DATSTATENDDATETIME** field to determine when the survey was completed. For new surveys, review the **ANOTHERDX1** – **ANOTHERDX5** fields for information related to a reported condition. If a new condition was reported, **enter the reported condition manually** as instructed under the title *Entering SNs Manually*, above.

Entering SNs Automatically – SNs Reported via DatStat

SNs reported via DatStat in the "additional cancers" sections of the Expansion Baseline (cases only) and FU7 surveys can be entered into the appropriate database automatically. These processes should be run monthly.

Expansion Baseline Case Surveys

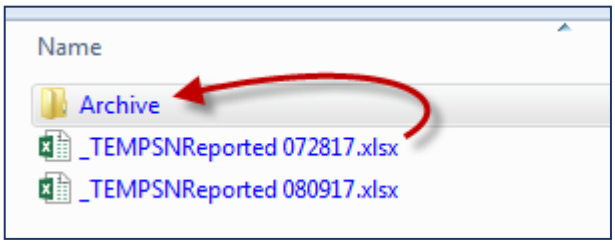
1. Open the CCSS Expansion Tracking database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Open the Access Navigation Pane.
3. Run **qdel_TEMPSNReported** in Expansion Tracking to **delete the previous temporary table**.
4. **Gather information about the newly reported SNs** by (1) adjusting the date range in the expbasereturn column in each of the following queries, (2) running each query, and (3) saving the changes to the query. The new date range should cover all dates since the last run for which survey data has been processed. See the Senior Coordinator or Research Scientist for assistance.
   A. **qapp_SNReported_AdultCase**
   B. **qapp_SNReported_AdultCase2**
   C. **qapp_SNReported_AdultCase3**
   D. **qapp_SNReported_AdultCase4**
   E. **qapp_SNReported_AdultCase5**
   F. **qapp_SNReported_DeceasedCase**
   G. **qapp_SNReported_DeceasedCase2**
   H. **qapp_SNReported_DeceasedCase3**
   I. **qapp_SNReported_DeceasedCase4**
   J. **qapp_SNReported_DeceasedCase5**
   K. **qapp_SNReported_MinorCase**
   L. **qapp_SNReported_MinorCase2**
   M. **qapp_SNReported_MinorCase3**
   N. **qapp_SNReported_MinorCase4**
   O. **qapp_SNReported_MinorCase5**



5. Run **qmk_SNReported_LastCondID** in Expansion Tracking. This query makes a table to store the last condition number for each participant.
6. Run **qupd_SNReported_LastCondID** in Expansion Tracking. This query updates _TEMPSNReported with the last condition number for each participant.
7. Open table _TEMPSNReported.
8. **Export** table _TEMPSNReported as an Excel file to document the table's data prior to the upcoming changes. See the Senior Coordinator or Research Scientist for assistance.
   A. Save the table at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, Expansion Baseline\DatStat Survey, Reported SN*.
   B. Append the current date to the table name when saving the file (e.g. **_TEMPSNReported 111717**).
9. In the database, sort the data by CCSSID.
10. Carefully review the data presented in the database table _TEMPSNReported. This is the information that will be added to the SNT database's condition records. Manually **delete/edit/update fields/records as needed**.

A. If needed, modify the diagnosis month values that are invalid (e.g. 103 for March).
B. Manually enter the ***appropriate*** condition number in the ConditionID column based on (1) the last condition number in the LastConditionID column ***AND*** (2) the number of conditions reported by the individual participant.
C. Note that if a participant reported more than one condition on the baseline survey, not every condition will increment the last condition number by 1.

11. Once satisfied with the data in _TEMPSNReported, run **qapp_SNReported** to **add records to tblSNT** in the SNT database.
12. **Archive** the previous run's file based on the date appended to the file name.



FU6 Surveys

1. Open the CCSS Follow-Up Survey Tracking database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Open the Access Navigation Pane.
3. **Delete the previous temporary table** (_TEMPSNReportedFU7) by running the delete query **qdel_TEMPSNReported_FU7**.
4. **Gather information** about the newly reported SNs and add the new data to _TEMPSNReportedFU7.

A. Open the append query **qapp_SNReported_FU7** in Design View, and proceed as follows:
   i. Update the **DateSurveyReturned** criteria to include all dates from the last run for which survey data have been processed. See the Senior Coordinator or Research Scientist for guidance.
   ii. Save the changes to the query.
   iii. Run the query.
B. Open the append query **qapp_SNReported2_FU7** in Design View, and proceed as follows:
   i. Update the Date Survey Returned criteria to include all dates from the last run for which survey data have been processed. See the Senior Coordinator or Research Scientist for guidance.
   ii. Save the changes to the query.
   iii. Run the query.
C. Open the append query **qapp_SNReported3_FU7** in Design View, and proceed as follows:
   i. Update the Date Survey Returned criteria to include all dates from the last run for which survey data have been processed. See the Senior Coordinator or Research Scientist for guidance.
   ii. Save the changes to the query.
   iii. Run the query.
D. Open the append query **qapp_SNReported4_FU7** in Design View, and proceed as follows:
   i. Update the Date Survey Returned criteria to include all dates from the last run for which survey data have been processed. See the Senior Coordinator or Research Scientist for guidance.

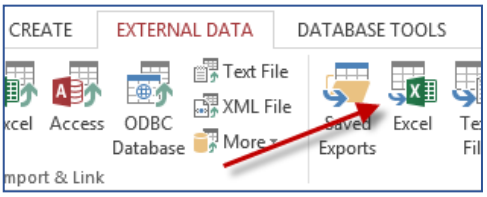
ii. Save the changes to the query.
iii. Run the query.

E. Open the append query **qapp_SNReported5_FU7** in Design View, and proceed as follows:
   i. Update the Date Survey Returned criteria to include all dates from the last run for which survey data have been processed. See the Senior Coordinator or Research Scientist for guidance.
   ii. Save the changes to the query.
   iii. Run the query.

F. Open the append query **qapp_SNReported6_FU7** in Design View, and proceed as follows:
   i. Update the Date Survey Returned criteria to include all dates from the last run for which survey data have been processed. See the Senior Coordinator or Research Scientist for guidance.
   ii. Save the changes to the query.
   iii. Run the query.

G. Open the append query **qapp_SNReported7_FU7** in Design View, and proceed as follows:
   i. Update the Date Survey Returned criteria to include all dates from the last run for which survey data have been processed. See the Senior Coordinator or Research Scientist for guidance.
   ii. Save the changes to the query.
   iii. Run the query.

5. Run the "make table" query **qmk_SNReported_LastConNum**. This creates a temporary table with all participants already in tblSNT and the last ConditionID created for the participant.
6. Run the update query **qupd_SNReportedFU7_LastConNum**, which updates LastN_Cond in _TEMPSNReported_FU7 with the last ConditionID from tblSNT.
7. **Open the table** _TEMPSNReported_FU7.
8. **Export** the table as an Excel file. Seek assistance, if needed. This is a record of the SNs that qualified to be updated.



   A. Save the file at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7*.
   B. Append the date to the file name: **_TEMPSNReported_FU7 mmddyy**.
   C. If the Excel file was opened during the export process, close it.
9. In the database, **sort the table** _TEMPSNReported_FU7 by CCSSID.
10. Carefully review the data presented. This is the information that will be added to the SNT database. **Manually delete/edit/update** fields/records as needed.
   A. If needed, modify diagnosis month values that are invalid (*e.g. 103 for March*).
   B. Manually enter the *appropriate* condition number in the **ConditionID** field based on (1) the last condition number in the **LastN_Cond** field *AND* (2) the number of conditions reported by the individual participant.
      i. Note that the table will include both cases (first reported SN is condition 2) and siblings (first reported SN is condition 1).
      ii. Note that if a participant reported more than one condition on FU6, not every condition will increment the last condition number by 1.
11. When all changes to the table data are finalized:

A. **Export** the table as an Excel file. Seek assistance, if needed. This is a record of the SNs used to update the database.
   i. Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, FU7*.
   ii. Append the date and the word "REVISED" to the file name: **_TEMPSNReported_FU7 mmddyy REVISED**.

B. Run the append query **qapp_SNReported_SNT-FU7** to append the revised records in _TEMPSNReported_FU7 to tblSNT.

12. **Archive** the previous run's files based on the date appended to the file name.

[299]Current Filename:		Data Entry for New Subsequent Neoplasm Reports v1_3.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	7/1/15	L. Harrison	Initial Updated Development
1.1	2/16/16	R. Massey, L. Barnes, A. McDonald, J. Ford	Updated title, merged SOPs for various SN sources, added directives for ASK screening, added directives for exp. sibs.
1.2	8/9/17	R. Massey	Removed FU5 directives (survey closed) and added FU6. Updated directives to indicate SNT db procedures.
1.3	1/14/20	R. Massey	Updated FU6 directives to FU7 directives, updated network paths

Database Key Code Reference

The following keys may be useful in building queries as well as decoding information stored in the LTFU tracking databases. See also *Outcome and Tracing Code Guidelines (in Miscellaneous).*

Survey Return Information

Original Cohort Cases

Quest = Baseline
- Basedate = date sent
- Basereturn = date returned

FollowUpLabels = Follow-up 1
- Fudate = date sent
- Fureturn = date returned

FU2 = Follow-up 2
- FU2date = date sent
- FU2 returned = date returned

FU3 = Follow-up 3
- FU3date = date sent
- FU3return = date returned

FU2007pick = Follow-up 4 (2007)
- 2007Senddate = date sent
- 2007return = date returned

Bone Questionnaire (in FollowUpLabels)

Family History (in Quest table)
- Famdate
- Famreturned

Pregnancy (in Quest table)
- Pregdate
- Pregreturned

Original Cohort Siblings

Sibling = Baseline
- Sbasedate = date sent
- Sbasereturn = date retuned

SibFollowup = Follow-up 1
- Fudate = date sent
- Fureturn = date returned

SiblingFU2 = Follow-up 2
- FU2date = date sent
- FU2returned = date returned

SibFU2007Pick = Follow-up 4 (2007)*
- 2007SenddateSib = date sent
- 2007returnSib = date returned

*Siblings were not included in Follow-up 3

Expansion Cohort Cases

tblBaselineTrackingInfo = Baseline
- expbasedate = date sent
- expbasereturn = date returned

Expansion Cohort Race/Gender Variables

Race	***Hispanic Y/N***	***Gender***
1=White	1=yes	1 = male
2=Black	2=no	2 = female
3=American Indian/Alaska Native	3=unknown	
4=Asian		
5=Pacific Islander		
6=Other/Mixed	Also look at variable called	
7=Unknown	***OtherRace***	

Everyone

Reg Outcome Codes

Refusal Outcome Codes	
7	refused
11	Parental Refusal
12	Completed baseline, refused all else
21	Refused all else after followup
32	Refused all else after FU2
33	Refused all else after FU3
37	Refused all else

Deceased Outcome Codes	
2	died before baseline
14	Died after completing baseline
19	Died after followup questionnaire
29	died after FU2
34	Died after FU3
38	Deceased
	*Alive variable should = 2

Lost to Follow-up (some of these may not apply in some situations)	
6	passive refusal
8	Lost to follow up at baseline
13	Completed baseline, moved out of country
16	Did baseline, no one left to contac
18	Lost since baseline, traced
25	unavailable
26	didn't do FU; in tracing
35	didn't do FU2;in tracing
36	didn't do FU3 pending or in tracing
39	Survey pending or in tracing
	*Also look at tracing status

ALL OUTCOME CODES

2	died before baseline
6	passive refusal
7	refused
8	Lost to follow up at baseline
9	Eligible, but not sending out q'air
10	Ineligible
11	Parental Refusal
12	Completed baseline, refused all els
13	Completed baseline, moved out of country
14	Died after completing baseline
16	Did baseline, no one left to contact
18	Lost since baseline, traced
19	Died after followup questionnaire
21	Refused all else after followup

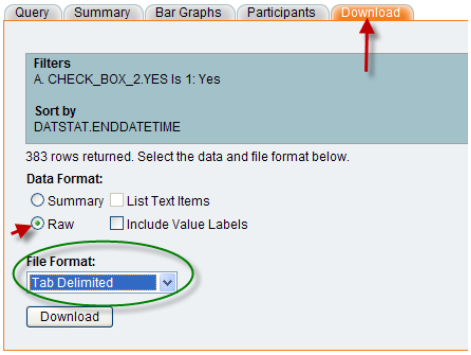
25	unavailable
26	didn't do FU; in tracing
29	died after FU2
31	Language
32	Refused all else after FU2
33	Refused all else after FU3
34	Died after FU3
35	didn't do FU2;in tracing
36	didn't do FU3 pending or in tracing
37	Refused all else
38	Deceased
39	Survey pending or in tracing
40	Wants newsletters but no surveys
41	2nd party completion
82	Resend

Revision Record Printed 7/10/2012 2:28 PM

Current Filename:		Database Key Code Reference ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/29/11	A. McDonald	Initial Development

DatStat Morning Database Procedures

Background



We download online survey activity (including refusals) for several CCSS studies first thing each morning. Each downloaded file is cumulative. The downloads come from queries created in DatStat. We download at least one query from the DatStat console for each survey. Collect all downloads in a central holding location (e.g. your desktop), and then move each download to its respective storage location on the server.

Procedures: DatStat Download

1. Open *_CCSS DatStat Submissions.xlsx* file located here: \\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Databases
    a. Enter the current date on row 1 in the next available blank column
2. Log onto the DatStat console at https://live.datstathost.com/STJUDE/ Username is your full StJude email address; password "download"
3. In upper right section of screen, click on Data Manager
4. Select **CCSS Project** to see the Projects, Published Surveys, and the Cross Survey Views.
5. The default screen is the EQUAL project; Double click on EQUAL link

6. Enter the number of submissions for each EQUAL surveys in *_CCSS DatStat Submissions.xlsx* for current date
7. Compare current number of submissions with number of submissions from previous date
    a. If the current number of submissions **is the same**, then **proceed to step 14** (you do not need to take any further action regarding the EQUAL study).
    b. If the current number of submissions is **greater** than the previous date, then **proceed to next step**.
8. On the screen with the EQUAL Total Submissions, click link of interest
    a. In the new window that opens, double click on the Queries tab
    b. Select the query of interest
9. For each query, select the Download tab
10. Under the Data Format option, select Raw
11. Under the File Format option, select Tab Delimited
12. Click the download button

13. Click the Save As option at the bottom of the screen and save the file in the designated folder on your computer
14. Return to the opening screen (**CCSS Project**) and double click on the Published Surveys tab
15. Enter the number of submissions for each surveys in *_CCSS DatStat Submissions.xlsx* for current date
    a. If the number is the same as the day before, you will NOT need to download that survey's queries
    b. If the number is not the same as the day before, then proceed to step 16
    c. For all surveys**,** you will access the queries from the Published Survey tab
16. For any survey in which there was an increase, click on the survey name and follow the steps outlined in steps 9-13 to run the queries and save them on your desktop. The following is a list of each query that we run with each survey:

Active Survey(s)
CCSS Expansion Baseline
Lnk_DatStat_Expansion_Baseline_Adult
Lnk_DatStat_ExpBase_Adult_Coding1
Lnk_DatStat_ExpBase_Adult_Coding2
Lnk_DatStat_ExpBase_Adult_Refusals
CCSS Expansion Baseline Minor
Lnk_DatStat_Expansion_Baseline_Minor
Lnk_DatStat_ExpBase_Minor_Coding1
Lnk_DatStat_ExpBase_Minor_Coding2
Lnk_DatStat_ExpBase_Minor_Refusals
DECEASED CCSS Expansion Baseline
Lnk_DatStat_Expansion_Baseline_Deceased
Lnk_DatStat_ExpBase_Deceased_Coding1
Lnk_DatStat_ExpBase_Deceased_Coding2
Lnk_DatStat_ExpBase_Deceased_Refusals
LTFU_FU6
Coding
Lnk_DatStat_FU6L
Lnk_DatStat_FU6M
Lnk_DatStat_FU6S
Lnk_DatStat_FU6SibL
Lnk_DatStat_FU6SibM
Lnk_DatStat_FU6SibS
EASE_Breathe
Eligible=No
Updated contact info, online program
EASE_BreatheT2
Completes
EASE_Breathe2Consent
EASE Breathe 2 Consent
EASE_Breathe2
EASE Breathe 2 T2

17. After downloading the queries to the temporary storage location on your desktop**, MOVE** each file into the designated folder (see locations listed below). Use the warning that you are about to replace the existing file as a double-check that you are moving the file to the correct location.

Datstat Query	Server Location [\\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Databases]
Expansion Adult	
Lnk_DatStat_Expansion_Baseline_Adult	\Survey Data - Expansion\DatStat Downloads\Daily Downloads\Completed Surveys
Lnk_DatStat_ExpBase_Adult_Coding1	
Lnk_DatStat_ExpBase_Adult_Coding2	
Lnk_DatStat_ExpBase_Adult_Refusals	
Expansion Minor	
Lnk_DatStat_Expansion_Baseline_Minor	\Survey Data - Expansion Minor\DatStat Downloads\Daily Downloads\Completed Surveys
Lnk_DatStat_ExpBase_Minor_Coding1	
Lnk_DatStat_ExpBase_Minor_Coding2	
Lnk_DatStat_ExpBase_Minor_Refusals	
Expansion Deceased	
Lnk_DatStat_Expansion_Baseline_Deceased	\Survey Data - Expansion Deceased\DatStat Downloads\Daily Downloads\Completed Surveys
Lnk_DatStat_ExpBase_Deceased_Coding1	
Lnk_DatStat_ExpBase_Deceased_Coding2	
Lnk_DatStat_ExpBase_Deceased_Refusals	
FU6 Case	
Coding	\Survey Data - FU6\DatStat Download
Lnk_DatStat_FU6L	
Lnk_DatStat_FU6M	
Lnk_DatStat_FU6S	
FU6 Sibling	
Lnk_DatStat_FU6SibL	\Survey Data - FU6 Sibling\DatStat Download
Lnk_DatStat_FU6SibM	
Lnk_DatStat_FU6SibS	
DatStat Query	V Drive Location [V:\CCSS]
EQUAL	
M12_Completion_Dates_Results	\EQUAL\DatStat Downloads\Month 12
M24_Completion_Dates_Results.txt	\EQUAL\DatStat Downloads\Month 24
EASE_Breathe	
Eligible=No	V:\CCSS\EASE\DatStat downloads
Updated contact info, online program	V:\CCSS\EASE\DatStat downloads
EASE_BreatheT2	
Completes	V:\CCSS\EASE\DatStat downloads
EASE_Breathe2Consent	
EASE Breathe 2 Consent	V:\CCSS\EASE\DatStat downloads
EASE_Breathe2	
EASE Breathe 2 T2	V:\CCSS\EASE\DatStat downloads

18. If there were any surveys submitted for: CCSS Expansion Baseline Adult, Minor, or Deceased,
    a. BEFORE completing the next step and ONLY if there were any recruitment HIPAAs submitted (verify via steps 1-3 in procedure *Import Online Recruits to the Recruitment Database*), complete the following procedures *Import Online Recruits to the Recruitment Database*, *Processing Updated Name and Contact Information*, and *Rolling Over Recruited Cases*.
    b. Open the **Expansion Tracking** database and run **mcrDatStatCompleteDateCommentsUpdate**, **mcrJB_UpdtAOMReconsent** and **mcrPrintTablesUpdate**. Click Yes or OK at each of the macros' messages.
    c. If you receive an error message during any of these procedures, then capture an image of the error message, try to determine what caused the error, fix it, and retry macro.
        i. If you are unable to resolve the issue on your own, then send the info to Chris V.

19. If there were any submissions for a FU6 survey (adults or minors; siblings or cases), then open the **LTFU Participant Database**, run the MACRO **mcrFU6DatStatComplete**, then run **mcrAOMReconsent, mcrtblParticipants,** and **mcrTracingCodeHistory.**
    a. If you receive an error message during any of these procedures, then capture an image of the error message, try to determine what caused the error, fix it, and retry macro.
        i. If you are unable to resolve the issue on your own, then send the info to Chris V.

20. If there were new submissions for EQUAL, email the project manager; copy James and Aaron
21. If there were any submissions for EASE_Breathe, EASE_BreatheT2, EASE_Breathe2, or EASE_Breathe2Consent, then open the **EASE** database and run MACRO **mcr_EASEBreathe**
22. If there were any submission for **HINT_Study**,
    a. Go to **HINT Focus Group** query, **Download** tab, select **Raw** and **Include Value Labels**, and download data in the **Excel** file format
    b. Save file here: Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Ancillary Studies\HINT\Focus Group Survey Data
    c. Email James and Aaron

Revision Record Printed 9/11/2019 2:34 PM

[124]	Current Filename:	DatStat Morning Database Procedures ver 3_6.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/19/11	J.Bates	Initial Development
1.1	5/23/11	J.Bates	Zdrive; specific recruitment queries to run
1.2	7/6/11	J.Bates	Provide greater detail
1.3	7/18/11	J.Bates	Use COPY file, vs MOVE file; desktop location
1.4	8/2/11	J.Bates	Remove highlight on list of queries; need to download ALL of them
1.5	9/20/11	J.Bates	New DatStat URL
1.6	9/27/2011	L.Harrison	Add coding queries and EMPOWER queries to download instructions
1.7	2/22/2012	L Harrison	Add Breast Cancer Calculator query to download instructions
1.8	6/27/12	J.Bates	Add Stroke Proxy
1.9	5/6/13	L.Harrison	Add Sibling and EMPOWER 12 Month FollowUP 1 and 2
1.10	5/22/13	L.Harrison	Add Sibling macro
1.11	6/21/13	J.Bates	Add reference to update print tables function
2.0	7/8/2014	L.Harrison	Updated surveys that are downloaded including new procedures for FU5
3.0	4/6/2015	L.Harrison	Updated procedure to include FU5 sibling, EQUAL and ASK submissions
3.1	8/3/15	J.Ford	Revised flow and added FU5 minor
3.2	5/16/18	J.Ford	Updated server paths; removed references to closed studies; added process for tracking daily submissions
3.3	11/16/18	J.Ford	Rearranged order; updated expansion baseline process
3.4	5/14/19	J.Ford	Added EASE Breathe study info
3.5	8/30/19	J.Ford	Added HINT Study info
3.6	9/11/19	J.Ford	Added EASE Breathe 2 Study info

Death Notifications about St Jude Cases

Background

When we learn from a returned survey or a study interviewer phone call that a CCSS case participant from St Jude has expired, we need to notify the St Jude Life study coordinator within 2 working days. The SJL coordinator will, in turn, notify the St Jude Cancer Registry office. This procedure applies to all cases whose CCSSID starts with "15." (We do *not* need to forward death notifications obtained through MILLI notices.)

Procedure

1. For information obtained by survey interviewer for any study (including ancillary studies), the designated Lead SI will communicate the information to the SJL study coordinator. With the exception of the MRN, this information should be available on the Expired Participant Information Sheet.

2. For information obtained from any returned CCSS (including ancillary) study survey, the project coordinator for that study will provide the information to the SJL study coordinator.

3. Provide the following information:

    a. CCSSID
    b. MRN
    c. Name of Participant
    d. Date of Death
    e. State in which death occurred
    f. Cause of Death
    g. Did case have cancer at time of death?
    h. Source of information (Name of person providing information)
    i. Contact information for information source (address & phone)
    j. Notes

4. If unable to obtain any informational item, please indicate "not provided" or "unable to obtain" and explain in notes.

Revision Record Printed 7/17/2012 2:53 PM

Current Filename:		Death Notifications about St Jude Cases ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	7/17/12	J.Bates	Initial Development

Decoding CCSSID

Background

CCSS participant tracking records are stored in different databases, depending on participation type. Participant types are original cohort, original cohort siblings, and expansion cohort. The databases are Registration (for original cohort and their siblings) and Expansion (for expansion cohort). The 8-digit CCSSID assigned to each participant can be used to identify the database where you can find the participant's tracking record.

Decoding the 8-digit CCSSID to identify appropriate database

- First two digits = institution code (e.g., 15 = St. Jude)
- Next 5 digits = randomly assigned, unique for each participant
  - Greater than 25000 = expansion cohort
  - Less than 25000 = original cohort (reg)
- Last digit = type code, where "9" = Sibling participant
- Sample: "15123459" would be St. Jude, original cohort, and sibling.

Reg Institutions		Expansion Tracking Institutions
University of Minnesota	01	University of Minnesota
The Children's Hospital of Denver	02	The Children's Hospital of Denver
Children's Hospital of Pittsburgh	03	Children's Hospital of Pittsburgh
Children's Hospital at Stanford University	04	Children's Hospital of at Stanford University
Dana-Farber Cancer Institute	05	Dana-Farber Cancer Institute
Emory University	06	Emory University
Children's National Medical Center	07	Children's National Medical Center (DC)
U.T.M.D. Anderson Cancer Center	08	U.T.M.D. Anderson Cancer Center
Memorial Sloan-Kettering Cancer Center	09	Memorial Sloan-Kettering Cancer Center
Texas Children's Hospital	10	N/A (see inst 28)
University of California at San Francisco	11	University of California at San Francisco
Seattle Children's Hospital & Medical Center	12	Seattle Children's Hospital & Medical Center
Toronto Hospital for Sick Children	13	Toronto Hospital for Sick Children
St. Jude Children's Research Hospital	15	St. Jude Children's Research Hospital
Children's Hospital of Columbus	16	Children's Hospital of Columbus
Roswell Park Cancer Institute	17	Roswell Park Cancer Institute
Mayo Clinic	18	N/A
Minneapolis Children's Medical Center	19	Minneapolis Children's Medical Center
Children's Hospital of Philadelphia	20	Children's Hospital of Philadelphia
St. Louis Children's Hospital	21	St. Louis Children's Hospital
Children's Hospital of Los Angeles	22	Children's Hospital of Los Angeles
UCLA Mattel Children's Hospital/Miller/Orange County	23	UCLA Mattel Children's Hospital
Riley Hospital for Children, Indiana University	24	Riley Hospital for Children, Indiana University
UAB/The Children's Hospital of Alabama	25	UAB/The Children's Hospital of Alabama
Univ of Michigan - Mott Children's Hospital	26	Univ. of Michigan-Mott Children's Hospital
Children's Medical Center of Dallas	27	Children's Medical Center of Dallas
	28	Texas Children's Hospital*
	29	City of Hope
	30	Children's Hospital Orange County
	31	University of Chicago
	32	Northwestern Children's Memorial Hospital
	33	Cook Children's Hospital (Fort Worth)
		*TX Children's inst code changed

	Type Code
1	Leukemia
2	Central Nervous System (CNS)
3	Hodgkin's
4	Non-Hodgkin's Lymphoma
5	Kidney
6	Neuroblastoma
7	Soft Tissue Sarcoma
8	Bone
9	***Case Control - Sibling*** *(last digit of CCSSID)*

Revision Record

Printed 7/9/2012 1:42 PM

Current Filename:		Decoding CCSSID ver 1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/5/09	A. McDonald	Initial Development
1.1	10/7/09	J.Bates	Add code reference list
1.2	11/16/10	J.Bates	Add original cohort Inst codes

Documenting Ineligibility

Background

The LTFU Study may learn that persons being recruited to the study or previously recruited to the study are not, in fact, eligible for the study. This can happen when a data manager reviews medical records that had not been retrieved when the initial registration list was compiled or when a participant provides information (e.g. DOB correction) to the study team that affects eligibility.

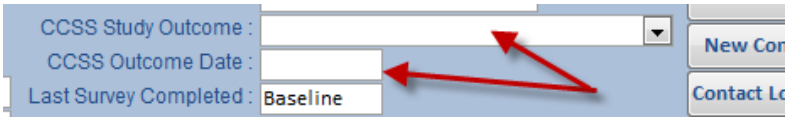
When a Survey Interviewer (SI) believes a case or sibling participant to be ineligible, s/he will notify the LSI team for a determination. The LSI will request an ineligible status determination from the Call Center Coordinator, CRA2, and/or Research Scientist.

When a participant is determined to be ineligible, the appropriate participant record needs to be coded as "ineligible" using this procedure.

Procedure

LTFU Participant Database

1. Locate the participant's record. See the SOP titled **LTFU Participant Database Data Entry** for instructions on using the search features.
2. On the Participant tab, click the **Notes** button to open the Notes form. Document the ineligibility circumstances in a dated note with initials or SI ID, copy the note, then close the Notes form.
   Example: 1/24/15: Sibling participant advised not a full-blooded sibling. [137]
3. On the FU5 Tracking tab, paste the ineligibility note into the **Notes** field.
4. In the header, update the **CCSS Study Outcome** to be 10-Ineligible, and update the **CCSS Outcome Date** field to be the current date.

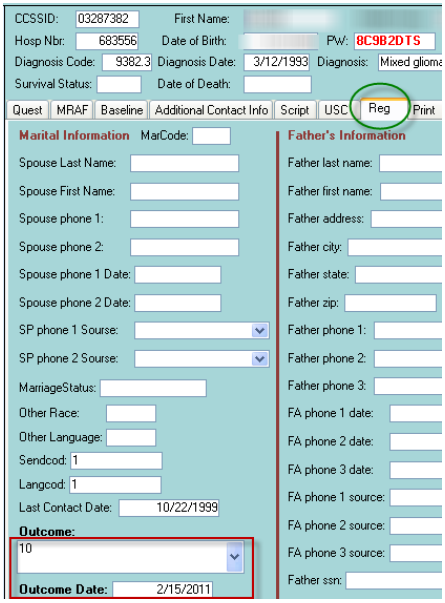


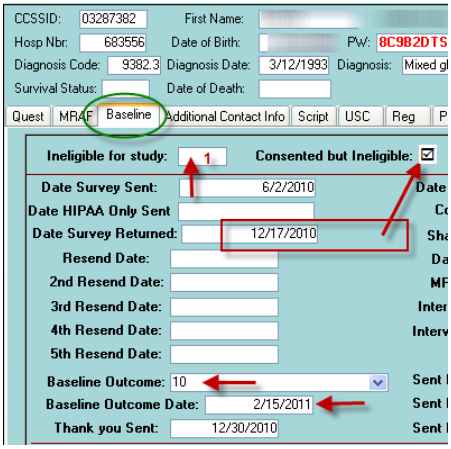
Expansion Tracking Database - Cases

1. Locate the case by CCSSID.
2. On the Quest tab, annotate the ineligibility information with a dated note, including initials or SI ID, in the **Comments** field.
   Example: 3/20/2015: DM indicated pt not eligible; original dx was at Hospital XYZ [jf]
3. On the **Reg** tab:
   a. Populate the **Outcome** field with 10-Ineligible.
   b. Populate the **Outcome Date** field with the date notified.
4. On the **Baseline** tab:
   a. Populate the **Ineligible for study** field with "1". (Do not type the quotation marks.)
   b. Populate the **Baseline Outcome** field with 10-Ineligible.

c. Populate the **Baseline Outcome Date** with the date notified.

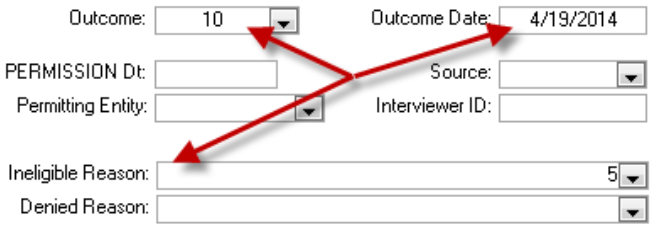
d. If **Date Survey Returned** is *not blank*, also mark the **Consented but Ineligible** checkbox.





Expansion Tracking Database – Siblings

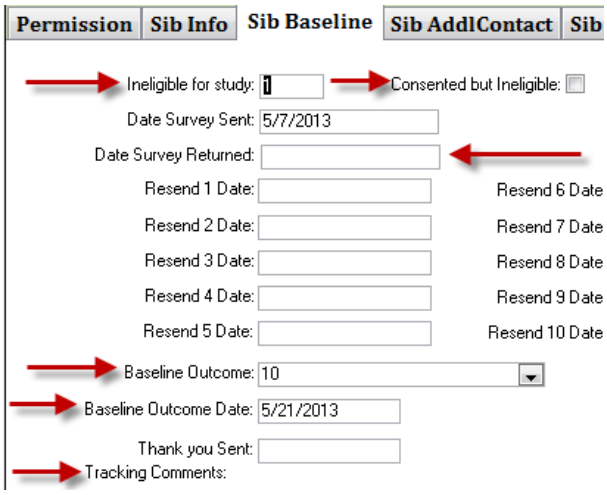
Locate the sibling participant's record, then:



1. For permission-stage ineligibility:
   a. On the green Permission tab's Permission Tracking box:
      i. Populate the **Outcome Code** field with 10-Ineligible.
      ii. Populate the **Outcome Date** field with the current date.
      iii. Populate the **Ineligible Reason** field with the appropriate reason.
   b. In the green Permission tab's **Comments** field, put a dated note with SI ID or initials documenting the ineligibility.
   c. If the case was also determined to be ineligible, document as per the section of this SOP titled *Expansion Tracking Database – Cases* or *LTFU Participant Database*, as appropriate.
2. For survey-stage ineligibility:
   a. On the green Sib Info tab, make a dated note with SI ID or initials in the **Comments** field documenting the ineligibility. Copy this note and paste it into the **Tracking Comments** field on the Sib Baseline tab.
   b. Also on the Sib Baseline tab:
      i. Populate the **Ineligible for study** field with "1". (Do not type the quotation marks.)
      ii. Populate the **Baseline Outcome** field with 10-Ineligible.
      iii. Populate the **Baseline Outcome Date** field with the current date.

iv. Populate the **Baseline Outcome** with 10- Ineligible.

v. If the **Date Survey Returned** field is *not blank*, click the **Consented but Ineligible** checkbox.

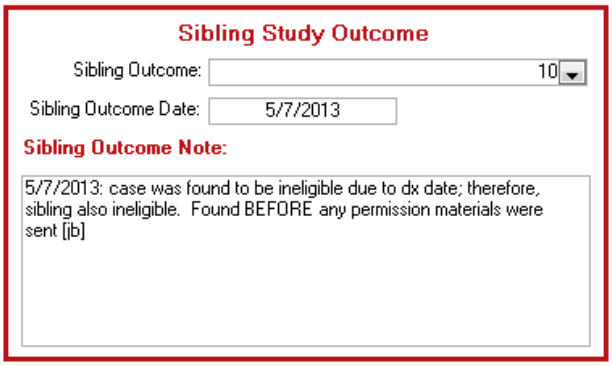


c. On the Sib Reg tab:

i. Populate the **Sibling Outcome** field with 10-Ineligible.

ii. Populate the **Sibling Outcome Date** field with the current date.

iii. Enter a dated note with your SI ID in the **Sibling Outcome Note** field, documenting the ineligibility.



Recruitment Database

1. Locate the case's record.
2. On the Tracking tab:
   a. Check the **Ineligible** box.
   b. Populate the **Ineligible Reason** field.
   c. Make a dated note with SI ID or initials documenting the ineligibility circumstances in the **Recruit Notes** field. Copy the note.
3. On the Quest tab, paste the note into the **Comments** field.

Revision Record
Printed 11/3/2014 9:23 AM

Current Filename:		Documenting Ineligibility ver 2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	3/23/2011	J. Bates	Initial Development
2.0	10/28/2014	R. Massey, J. Ford, L. Harrison	Content Revision: add siblings, Recruitment database, and LTFU Participant database

Duplicate Expansion Baseline Surveys

Background

When we receive a second baseline survey from a participant, only part of the inprocessing occurs as usual. Then the survey is given to the CRA2 for additional processing and determination. Duplicate surveys sometimes occur because the participant completed the survey online and then later mailed in the completed paper survey, or the participant completed two paper-based questionnaires. (The final dataset error checking will identify and subsequently de-duplicate instances where a participant's first baseline survey is the paper survey, and an online baseline survey was subsequently submitted.)

Procedure

When we receive a completed paper baseline survey for a participant from whom we already received a survey, **the CRA** will:

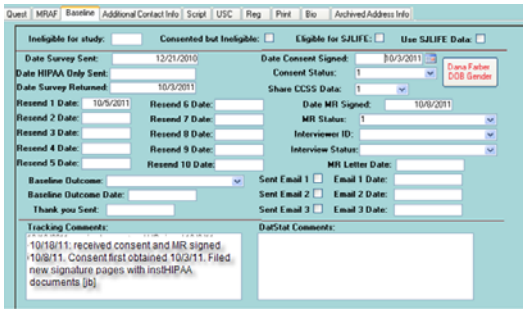
- Date-stamp the survey on the front
- Give the survey to the CRA2 with a post-it note indicating "Duplicate; survey returned mm/dd/yy per database."

The CRA2 will:

1. Process as normal any "actionable" comments on the back page.
2. Determine which survey to keep.
    a. REVIEW
        i. For adult surveys, look at who completed the survey ("self" or someone else).
        ii. Check inprocessing values for second malignancy, suicide ideation, Script items, family history, and comments. If any of these have a response, compare them to values previously received.
            a) Actual data for these fields will be either in DatStat or in scanned data.
            b) SMN and script items are also recorded in the tracking database.
        iii. Additional responses between the surveys may also be compared.
        iv. Determine whether the initial survey has been coded and scanned. If so, ask coder to see if record is already in the TF coding database.
    b. DECIDE
        i. Prefer the adult survey completed by self over one completed by a proxy.
        ii. Prefer the MOST RECENTLY completed survey *when surveys have the **SAME** responses in the SMN, Suicide, and script fields. Note the family history section, including sibling data. The more complete sibling data is preferable.*
            a) This may NOT be the most recently received. Look at survey completion date field on front of survey.
            b) Rationale: the most recently completed may reflect other changes in status that we need to recognize.
            c) If the initial survey was on paper, has already been scanned, and is already in the Teleform Coding database, then all other things being equal, we keep the initial survey so we do not have to purge it from the TF coding database.
        iii. *When surveys **DIFFER** in responses to SMN, Suicide, and script fields*: keep the survey having the MOST indicators of concern. If this is the more recent, and the initial was a paper survey that is already in the teleform coding database, the record will need to be cleared from the TF coding database.

3. DISPOSITION
   a. If we keep the **MORE RECENT SURVEY** (and set aside the initial survey):
      i. Process survey as usual. It may be returned to CRA to resume the in-processing.
      ii. Do not change the date survey received or date consents signed fields on the Expansion Baseline tab. Make a note that a new survey was received, when it was received and that the new information will be used.
      iii. Remove the initial survey:
         a) If initial was ONLINE: un-submit it (notify Christie or follow designated procedure)
         b) If original was on PAPER and…
            1) … has not yet been scanned, retrieve it from the processing queue.
            2) … has already been scanned, delete its records from the data tables in the scanned database. Retrieve it from the paper survey files.
            3) Check with Christie to see if it is in the TFCoding database. This database was created to help clear a backlog in surgery coding; it is not currently being used, but should be checked to see if participant data is there. If so, request to remove its records from the TF Coding database. (Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - Expansion\TF Version Coding Database)

   b. If we keep the **INITIAL SURVEY**: (and set aside the more recent survey):
      i. Check (and harvest) the Consent and MR signature from more recent survey.
         a) If **MR is signed** then UPDATE Date MR Signed and MR status in the tracking database.
         b) If the **paper consent is signed**, do NOT update the date in Date Consent Signed (unless the date consent signed is blank in the database). Instead, include the paper consent signature date in the comment.
         c) If either MR or paper consent is signed, harvest the signed documents:
            1) Use scissors to neatly cut out consent and MR signature pages.
            2) Staple pages together with MR signature page on top.
            3) Date-stamp top of the MR page.
            4) File by CCSSID in instHIPAA documents file.
      ii. Post a comment in the database. E,g. : *"mm /dd/yy: received consent and MR signed m/d/yy; consent first obtained mm/dd/yy; new signature pages filed with instHIPAA documents [inits]"* to explain signature date discrepancies between MR and consent.



   c. Give the rest of the more recent survey or the retrieved initial survey to Aaron, with post-it indicating "duplicate survey."

Revision Record Printed 5/24/2013 8:43 AM

[59] Current Filename:		Duplicate Expansion Baseline Surveys ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/19/11	J.Bates	Initial Development
1.1	10/21/11	J.Bates	Synchronize with previous version: keeping recent ver.
1.2	11/22/11	J.Bates	Teleforms coding as another tie breaker
1.3	5/23/2013	L. Harrison	Family history as another tie breaker; explanation of TF coding database

EASE Breathe Study Follow-Up Calls

Background

The **EASE Breathe** research study (Exploring Aspects of Survivors' Experience of Pain) will examine respiration, emotional health, and pain among adult survivors of childhood cancer with chronic pain.

General Eligibility Criteria

- The study seeks to enroll 100 pts who are 18 years of age or older and experience Chronic pain
- Smartphone owners with cellular data or Wi-Fi connection to the internet
- Can read, write and speak English
- Ability to understand and agree to participate via an informed consent (no LAR or Proxy)

Recruitment Approach

1. Recruitment day one: send EASE Breathe Study recruitment emails
2. Two days after the first recruitment email, follow-up emails are sent to non-responders
3. Six days after the first email, the recruitment email is re-sent to non-responders
4. Five to seven days after the first recruitment email, the paper invitation is mailed to all non-responders who have not enrolled, and have not refused
5. Seven days after the first recruitment email, calls begin to all non-responders who have not registered, and have not refused
6. Thirteen days after the first recruitment email, a non-responder email is sent to those who have not registered, and have not refused
7. Seven days after the first recruitment email, calls begin to all non-responders who have not registered, and have not refused

Tools Needed:

1. **CCSS LTFU Participant Database** (Located in Sharepoint…)
2. **EASE Database** (Located in Sharepoint…)
3. **CCSS SI Assignments Database**, (Located in Sharepoint…)
4. **Pre-Post Call Checklist - EASE Breathe Study** (Located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Breathe Study\Forms, Letters, Brochures)*
5. **EASE Breathe Study Recruitment Calls Script** (Located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Breathe Study)*
6. **EASE Breathe Study Online T1/T2 Survey Links** (Located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Breathe Study\Survey)*
7. **LTFU Participant Database Data Entry SOP**, (Located in Sharepoint…SOP Library)

8. **EASE Breathe Enrollment/T1 Email Template** (Located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\ EASE Breathe Study\Email Templates\Email Templates to send to Pts)*
9. **LTFU Study Mobile App Troubleshooting Tips** (Located at Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Breathe Study\Troubleshooting Tips)

Procedure

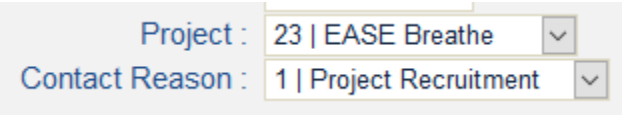
Before the Call

1. Open the **EASE Breathe Call Assignments**, located in the **CCSS Survey Interviewer Ancillary Study Call Assignments Database,** and select a case where the call will be in the participants time zone, between 9am-8:00pm
2. **Check "Spire Invite Outcome" field in EASE Database/Tracking tab to verify field is null. Do Not Call Cases with an Outcome code. Email a screenshot of code to LSI's/Coordinator.**
3. Begin building a profile for the pt, per the corresponding sections of the **Pre-Post Call Checklist – EASE Breathe Study Calls**

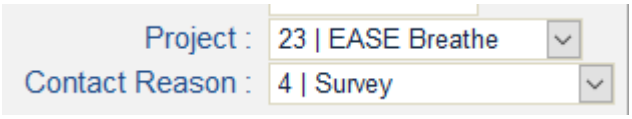
During the call:

Participant Database - See **LTFU Participant Database Data Entry** SOP for full instructions

1. Verify/confirm all **contact information** for the pt and his/her associates. Update the **LTFU Participant Database**
2. Create a new **Contact/Trace Log** in the **LTFU Participant Database**
   A. **Project** field – Populate with **23-EASE Breathe**.
   B. **Contact Reason** field – Populate with
      i. **1- Project Recruitment** for follow-up calls to EASE Breathe Recruitment Invitation Non-Responders (T1 Survey)



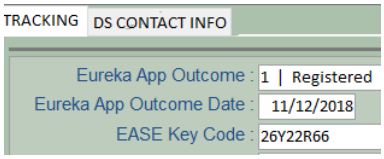
      ii. **4- Survey** for follow-up calls to enrolled pt's in the Control or Intervention Group that have not completed the final survey online (T2 Survey)



   C. Standard Call Outcomes
      i. "**1-Completed"**
      ii. **"2-No Answer"**
      ii. "**3-No answer/left message"**
      iii. "**4-Appt made"**

iv. "**5-Resend"** (*When pt requests a resend of the* EASE Breathe enrollment email use ***EASE Breathe Enrollment/ T1 Email Template****.docx* from this location, *Z... Interviewers\ EASE Breathe Study\Email Templates\Email templates to send to Pts*)
v. "**6-Disconnect"**
vi. **"7-Refused"**
vii. **"8-Deceased"**
viii. "**10-Other"**
ix. "**11-Wrong #"**
x. **"13-Will Enroll"**

3. If the participant **received the invitation**:
   A. Ask if the participant has reviewed the materials. If not, introduce the study.
   B. Answer the participant's questions about the study.
   C. Ask if s/he is willing to participate in the EASE Breathe study.
      i. If yes:
         a. Offer to resend enrollment information via email
            1. Open **EASE Breathe Enrollment/T1 Email Template**
            2. Copy pt.'s EASE Key Code from EASE Database/Tracking tab:



            3. Paste EASE Key Code into email template field:

               Your key code to access the survey is: 26Y22R66

         b. Offer to complete survey via unscheduled phone interview (Open **EASE Breathe Study Online T1/T2 Survey Links)**
         c. Offer to set a phone interview appointment on a day/ time convenient for Pt.
      ii. If no:
         a. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
         b. If it is unclear if the participant is refusing just the EASE Breathe Study or all further participation in the LTFU Study, clarify.
         c. Confirm all contact information.
         d. Thank the participant for his/her involvement in the LTFU Study.
4. If the participant **did not receive the packet**:
   A. Verify the participant's contact information.
   B. Introduce the study, using the **EASE Breathe Study Recruitment Calls Script**
   C. Answer the participant's questions about the study.
   D. Ask if s/he is willing to participate in the EASE Breathe study.
      i. If yes:

a. Offer to resend enrollment information via email (Open **EASE Breathe Enrollment/T1 Email Template**) adding pt.'s EASE Key Code (located in the EASE Breathe Database) to template field

b. Offer to complete survey via unscheduled phone interview (Open **EASE Breathe Study Online T1/T2 Survey Links)**

c. Offer to set a phone interview appointment on a day/ time convenient for Pt.

ii. If no:

a. Reference the bottom of the EASE Breathe Study Recruitment Calls Script to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.

b. If it is unclear if the participant is refusing just the EASE Breathe Study or all further participation in the LTFU Study, clarify.

E. Thank the participant for his/her involvement in the LTFU Study.

F. Refer to the section, After the Call, Refusal, for additional information.

5. If contacting an enrolled participant reporting **Spire Stone device or app issues:**

A. Ask the pt to describe the issue, with as much detail as possible (take copious notes)

I. If unable to assist the participant, say,

a. "I'm sorry for the inconvenience. I will inform the study doctors of the issue you are having."

b. Read the issue back to them for clarity and revise as needed

c. Ask for the best number/time/day for a return call

d. Let them know that someone will get back with them as soon as possible

e. Thank them for their participation and their call

II. Forward all the information to the LSIs, Coordinator via email. The LSIs/Coordinator will research and/or review the question(s) with the study doctors, and return a response

III. A response is made to the pt by one of the following methods:

a. The answer may be emailed back to the SI who took the call, with a request to contact the pt

b. The answer may be sent to one of the SIs assigned to the EASE Breathe study to follow-up with the pt

c. One of the LSIs or Coordinator may contact the pt

d. One of the doctors may contact the pt

After the Call

6. **Resending the EASE Breathe Enrollment Invitation**

A. **Emailing EASE Breathe Invitation** - If the pt requested a resend of the **EASE Breathe** link, send an email using the email template, **EASE Breathe Enrollment/T1 Email Template.docx** (for Remember to send the pt the **EASE Breathe Key Code**, located in the **EASE Database/Tracking tab**.

7. **Ineligible** – All situations of suspected Ineligibility should be documented in the **DB Change** field of the contact or trace log. A member of the LSI team will review the possible ineligibility with the leadership team for a final determination.

8. **Deceased** – If it was discovered that the participant is now expired:
   A. LTFU Participant Database - The deceased outcome should be documented in the **DB Change** field of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
   B. **Expired Participant Information Sheet** – Submit the completed form in file cabinet A.
   C. EASE Breathe Database, Tracking tab:
      i. **Notes** field – Add a dated note with SI ID documenting the deceased outcome.
      ii. **EASE Breathe Outcome** and date – Do NOT populate
   D. Email the project coordinator to advise of the deceased outcome. Copy the Research Scientist, Call Center Coordinator, and LSI team.
9. **No Technology Access** - If the participant indicates they do not have access to either an iPhone or an Android phone:
   A. LTFU Participant Database – Add a dated note to the **Notes** field indicating the participant has "**No Technology Access"**
   B. EASE Breathe Database - Add a dated note to the **Notes** field indicating the participant has "**No Technology Access"**
   C. Email the project coordinator to advise of the **No Technology Access** Outcome. Copy the Research Scientist, Call Center Coordinator, and LSI team.
10. **Refusal** – If the pt refused the **EASE Breathe** or **LTFU** study:
   B. **Update the LTFU Participant Database** –
      i. **Refused EASE Breathe study *ONLY*** – Update **Contact Log** only.
      ii. **Refused All Else** (i.e. the case refused all further participation in the LTFU Study) –
         a. Update the **CCSS Study Outcome** and **CCSS Outcome Date** fields in the header.

         b. Add a dated note with SI ID in the **Notes** field on the Participant tab.
   C. **Update the EASE Breathe Database** –
      i. If the pt **refused all further participation in either the EASE Breathe Study or in the entire LTFU Study**, go to the Tracking tab:
         a. **Notes** – Add a dated note with SI ID documenting the refusal outcome**.**
   D. **Email the Project Coordinator** – to advise of the refusal. Copy the Research Scientist, Call Center Coordinator, and LSI team.

For all other questions, EASE Breathe consult with an LSI, the Coordinator or the Research Scientists.

Revision Record
Printed 12/23/2019 10:40 AM

Current Filename:		EASE Breathe Study Follow-Up Calls ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	05/28/2019	P. Davis, A. Cobble	Initial Development

EASE Study Follow-Up Calls

Background

The **EASE** research study (Exploring Aspects of Survivors' Experience of Pain) will examine emotional health, physical health and chronic pain among adult participants in the Long-Term Follow-Up (LTFU) Study. EASE is an internet-based, mobile platform-enabled study that uses the Eureka Research Platform designed by the University of California at San Francisco (UCSF).

General Eligibility Criteria

- The study seeks to enroll 4,000 CCSS Survivors and 1,000 Sibling who are 18 years of age or older
- Smartphone owners with cellular data or Wi-Fi connection to the internet
- Can read, write and speak English
- Ability to understand and agree to participate via an informed consent (no LAR or Proxy)

Recruitment Approach*

1. EASE Study postcard mailed
2. Recruitment emails are sent to cases with at least one valid email address
3. Two days after the first recruitment email, a follow-up email is sent to non-responders who have not refused
4. Five days after the first email, a follow-up email is sent to non-responders who have not refused
5. Five to seven days after the first recruitment email, the paper invitation is mailed to all non-responders who have not refused
6. Thirteen days after the first recruitment email, a non-responder email is sent to those who have not refused
7. Fourteen days after the first recruitment email, calls begin to all non-responders who have not refused

*For participants who do not have a valid email address, recruitment will consist of postcard mailing, recruitment letter mailing, calls to non-responders who have not refused beginning between 7-14 days of recruitment letter mailing

Tools Needed:

1. **CCSS LTFU Participant Database**
2. **EASE** database
3. **CCSS SI Assignments** database
4. **Pre-Post Call Checklist - EASE Study** located at
   Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Study
5. **EASE Study Recruitment Calls Script** located at
   Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Study
6. **LTFU Participant Database Data Entry** SOP, (Located in Sharepoint…SOP Library)

7. **EASE Enrollment Email Template** (Located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\ EASE Study\Email Templates*
8. **LTFU Study Mobile App Troubleshooting Tips** (Located at Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Study\Troubleshooting Tips)
9. **Eureka App and EASE Study Participant Q and A** (Located at Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Study\Script
10. **Troubleshooting Tips** (Located at Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\EASE Study

Procedure

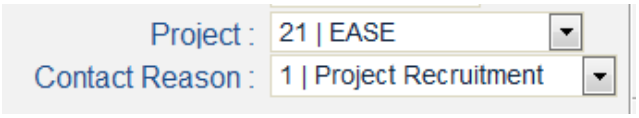
Before the Call

1. Open the **EASE Call Assignments**, located in the **CCSS SI Assignments** database**,** and select a case where the call will be in the participants time zone, between 9am-8:30pm.
2. Begin building a profile for the pt, per the corresponding sections of the **Pre-Post Call Checklist – EASE Study Calls**

During the call:

Participant Database - See **LTFU Participant Database Data Entry** SOP for full instructions

1. Verify/confirm all **contact information** for the pt and his/her associates. Update the **LTFU Participant Database**
2. Create a new **Contact/Trace Log** in the LTFU Participant Database
   A. **Project** field – Populate with **21-EASE**.
   B. **Contact Reason** field – Populate with **1- Project Recruitment**



   C. **Standard Call Outcomes**
      i. "**2-No Answer"**
      ii. "**3-No answer/left message"**
      iii. "**4-Appt made"**
      iv. **"5-Resend"** (*When pt requests a resend of the* EASE enrollment email use ***EASE Enrollment Email Template****.docx* from this location, *Z...Interviewers\ EASE Study\Email Templates\Email templates to send to Pts*)
      v. "**6-Disconnect"**
      vi. "**10-Other"**
      vii. **"11-Wrong #"**
      viii. **"13-Will Enroll"**
3. If the participant **received the invitation**:
   A. Ask if the participant has reviewed the materials. If not, introduce the study.
   B. Answer the participant's questions about the study.

C. Ask if s/he is willing to participate in the EASE study.
   i. If yes:
      a. Advise the participant how to enroll online by accessing the Eureka App via the link, https://eureka.app.link/ease and entering his/her EASE Key Code (located in the EASE tracking database.
      b. Offer to email the link and key code.
   ii. If no:
      a. Reference the bottom of the EASE Study Recruitment Calls Script to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
      b. If it is unclear if the participant is refusing just the EASE Study or all further participation in the LTFU Study, clarify.
      c. Thank the participant for his/her involvement in the LTFU Study.

4. If the participant **did not receive the packet**:
   A. Introduce the study, using the **EASE Study Recruitment Calls Script**.
   B. Answer the participant's questions about the study.
   C. Ask if s/he is willing to participate in the EASE study.
      i. If yes:
         a. Advise the participant how to enroll online by accessing the Eureka App via the link, https://eureka.app.link/ease and entering his/her EASE Key Code (located in the EASE tracking database.
         b. Offer to email the link and key code.
      ii. If no:
         a. Reference the bottom of the EASE Study Recruitment Calls Script to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
         b. If it is unclear if the participant is refusing just the EASE Study or all further participation in the LTFU Study, clarify.
         c. Thank the participant for his/her involvement in the LTFU Study.
         d. Refer to the section, After the Call, Refusal, for additional information.

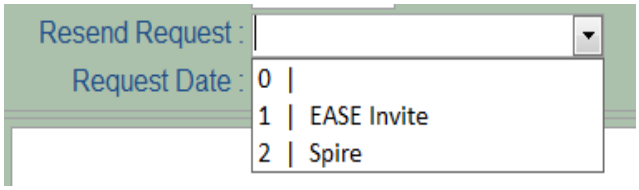
5. If the participant is **experiencing EASE/EUREKA issues:**
   A. Ask the pt to describe the issue, with as much detail as possible (take copious notes)
      i. If unable to assist the participant, say,
         a. "I'm sorry for the inconvenience. I will inform the study doctors of the issue you are having."
         b. Read the issue back to them for clarity and revise as needed.
         c. Ask for the best number/time/day for a return call.
         d. Let them know that someone will get back with them as soon as possible.
         e. Thank them for their participation and their call.
         f. Enter the "**Eureka Issue**" in the New Call Log.
      ii. Forward all the information to the LSIs, Coordinator via email. The LSIs/Coordinator will research and/or review the question(s) with the study doctors, and return a response.

iii. A response is made to the pt by one of the following methods:
   a. The answer may be emailed back to the SI who took the call, with a request to contact the pt.
   b. The answer may be sent to one of the SIs assigned to the EASE study to follow-up with the pt.
   c. One of the LSIs or Coordinator may contact the pt.
   d. One of the doctors may contact the pt.
   e. The Eureka issue is closed when the "**EIR"** and "**EIR ID"** fields on the "APP – TEXT" tab of the CCSS LTFU Participant Database are populated. This data entry process will be completed by the SI, LSI or Coordinator that resolves the issue, along with a dated note explaining how the issue was resolved.

6. If it is determined that the **participant has expired**, offer condolences and, if possible, complete the **Expired Participant Information Sheet**. Do not pursue participation.

After the Call

1. **Resending the EASE Enrollment Invitation**
   A. **Paper EASE Invitation**:
      i. In the **EASE** database, on the **Tracking** tab,
         a. **Request Date** – Populate with the current date.
         b. **Resend Request** – Use the drop-down menu to choose the hardcopy materials to be resent.
         c. **Notes** – Add a dated note with SI ID documenting the resend requested.



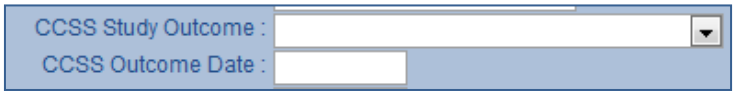
   B. **Emailing EASE Invitation**
      i. If the pt requested a resend of the **EASE** link, send an email using the email template, **EASE Enrollment Email Template.docx** (for those who never received the first recruitment emails), **EASE Resend – Standard Email Template** (for those who received prior emails and are more informed about the study) or **EASE Resend – Tech Issue Email Template**. Remember to send the pt the **EASE Key Code**, located in the **EASE tracking database**.

2. **Ineligible** – All situations of suspected ineligibility should be documented in the **DB Change** field of the contact or trace log. A member of the LSI team will review the possible ineligibility with the leadership team for a final determination.
3. **Deceased** – If it was discovered that the participant is now expired:
   A. LTFU Participant Database - The deceased outcome should be documented in the **DB Change** field of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
   B. **Expired Participant Information Sheet** – Submit the completed form in file cabinet A.
   C. EASE Database, Tracking tab:
      i. **Notes** field – Add a dated note with SI ID documenting the deceased outcome.

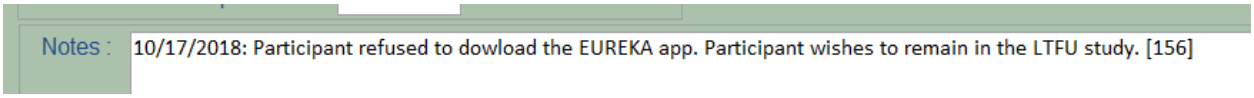
ii. **Eureka App Outcome** and date – Do NOT populate.
iii. **EASE Outcome** and date – Do NOT populate.

D. Email the project coordinator to advise of the deceased outcome. Copy the Research Scientist, Call Center Coordinator, and LSI team.

4. **No Technology Access** - If the participant indicates they do not have access to either an iPhone or an Android phone:
   A. LTFU Participant Database – Add a dated note to the **Notes** field indicating the participant has "**No Technology Access"**
   B. EASE Database - Add a dated note to the **Notes** field indicating the participant has "**No Technology Access"**
   C. Email the project coordinator to advise of the **No Technology Access** Outcome. Copy the Research Scientist, Call Center Coordinator, and LSI team.
5. **Refusal** – If the pt refused the **EASE** or **LTFU** study:
   A. **Update the LTFU Participant Database**
   B. **Refused EASE study *ONLY*** – Update **Contact Log** only.
   C. **Refused All Else** (i.e. the case refused all further participation in the LTFU Study) –
      i. Update the **CCSS Study Outcome** and **CCSS Outcome Date** fields in the header.



      ii. Add a dated note with SI ID in the **Notes** field on the Participant tab.
      iii. If the participant was mailed the FU6 survey and it has not been returned, update the **FU6 Outcome** and **FU6 Outcome Date** fields on the FU6 Tracking tab.
      iv. **Update the EASE Database**
      v. If the pt **refused all further participation in either the EASE Study or in the entire LTFU Study**, go to the Tracking tab:
         a. **Notes** – Add a dated note with SI ID documenting the refusal outcome**.**



         b. **Email the Project Coordinator** – to advise of the refusal. Copy the Research Scientist, Call Center Coordinator, and LSI team.

For all other questions, please consult with an LSI, the Coordinator or the Research Scientists.

Revision Record Printed 11/6/2018 4:18 PM

Current Filename:		EASE Study Follow-Up Calls ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/26/18	P. Davis; D. Rinehart; A. Cobble, R. Daniels	Initial Development

Email Appointment Reminders for Baseline Surveys

Background

In order to reduce the amount of missed appointments and maximize the number of Expansion Baseline surveys completed, the Courtesy Expansion Baseline Survey Appointment Reminder Email template was created. The purpose of this email is to serve as an appointment reminder for participants. The template is located here: Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Baseline Survey Appointment Courtesy Reminder Email. The process for using this email template is as follows:

Procedures

1. The person making the appointment is responsible for sending the email, updating the appointment board, updating the Call Outcome Log.

2. When you verify and/or update the participant's contact information in the database, also verify or ask for the participant's email address.

3. At the end of the call, after the appointment has been set with the participant, thank participant and let them know that you will send them an email reminder with the appointment information (repeat the email address for verification). Example:

   "Thank you for your willingness to participate in this very important study. I will send you an email verifying the appointment to the following email address: (repeat the email address for verification). We look forward to talking with you on (repeat day, date, time of appointment). Have a nice day.

4. Open the template, "Email Survey Appointment Reminder" in the folder listed above.

5. Create a new email in MS. Outlook.

6. Copy and paste the subject line into the subject bar of the email.

7. Copy and paste the template into the body area of the email.

8. Update all applicable fields (participant's/LAR's name; appointment day, date and time; your name and email address.

9. *Carefully proof-read the entire email,* to ensure completeness and correctness.

10. Remove any personalized settings (background colors; special colored or cursive fonts- use fonts that are easy to read, such as Calibri).

11. After determining that everything is correct, looks professional and is complete, send the reminder to the participant.

12. Update the electronic Participant Call Log (MS. Word), indicating the date, time, etc., that you sent the participant a Baseline Survey appointment reminder email. Also include the appointment date/time in the log (for future reference).

13. Unless there are special circumstances that need additional attention or assistance, there are no other actions to take for this process. (other than the usual routine steps of updating the Call Outcome Logs and Appointment Board in the call center, when making appointments with participants).

Please check with your LSI or Coordinator, if you have any questions.

Revision Record Printed 7/18/2012 9:33 AM

Current Filename:		Baseline Survey Email Appointment Reminder ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/28/12	D. Rinehart	Initial Development
1.1	6/26/12	Procedure Team	Content and format revisions

Email Notifications to Data Managers

Background

At the end of each month, we generate an updated list of recruited cases for each institution. We then upload the file to the St Jude Share site and send an email notice to the data managers to alert them that the updated file is ready. Similarly, at the end of every *other* month, we generate an updated list of the status of the surgery and radiotherapy records we have received from each institution. This report gives the record status for each individual in the expansion tracking database. After uploading this file to the St Jude Share site, we notify the data managers via email that the update is available. We document the queries and procedures for producing the lists elsewhere. This procedure outlines an automated method for sending individual email messages.

Procedure

1. Check the currency of the excel file containing the names, institutions, and email addresses. See DataManagerEmailList-ForMerging in **Z:\…\CCSS\Expansion Recruiting\Updated Recruited Lists for Institutions.** Use the ACTIVE column in the sheet "MonthlyRecruitmentLists" to flag individuals who DO receive the email for the HIPAA notifications. Update email addresses as needed. Save and close the file.

2. **Monthly Cumulative HIPAA notice**

   a. Open MonthlyCumulativeHIPAAavailableNotice-MergeDocument. Opening this document also opens the excel file that has the merge fields (see above) and filters the merge to select only records with "Y" in the Active column.

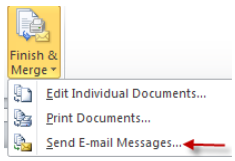
   b. In the Subject line, change the 'mm/dd/yy' to the date used in the file name uploaded to the server. Then copy the updated subject line

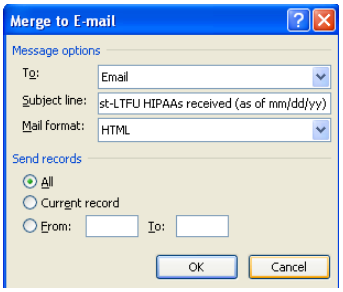
   Subject: Updated cumulative list-LTFU HIPAAs received as of 5/1/2012

   c. Save the merge file

   d. Preview the results to be sure the correct people are included.

   e. On the **Mailings** tab, click the dropdown arrow on the **Finish & Merge** button and then select **Send E-mail Messages….**





   f. The field "Email" should be filled in for the **To** box.

   g. Paste the subject line that you copied from the Word document into the **Subject Line** in the dialog box.

   h. As soon as you click **OK**, the emails are sent.

Subject: Updated cumulative list-LTFU HIPAAs received as of 5/1/2012

Dear «Name» («Email»),

The **Updated cumulative list of HIPAAs received** for your institution (**«Inst»**) is now available for you on the St Jude share site (https://stjudeshare.stjude.org/)

The list shows ALL individuals for whom we've received a HIPAA authorization through the recruitment efforts at the Coordinating Center (St Jude).

(Don't forget to send us the photocopies of their surgery and radiotherapy records. You will find the bi-monthly list of the "sgy_RT" records received on the Share sit as well.)

The list is an Excel file in your respective CCSS\HIPAA folder, and it contains and "as of" date as part of the file name. This means the data are current as of that particular date.

The file is sorted by "outcome date," with the most recent listed first. Outcome date is the date we received the document.

Please let me know if you have any questions….

Jerry

PS:

- Please make note of the last 2 columns in the spreadsheet.
- The column labeled "Alive" provides vital status: 1=alive; 2=deceased.
- I call this to your attention because *when we learn the survivor has since died*, we change the vital status to "2".
- This information may be useful to you in updating your own medical records.

Jerry Bates, M. A., Ed. S., CCRP
Clinical Research Associate II
Epidemiology and Cancer Control
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 735
Memphis TN 38105-2794

3. Bi-Monthly Surgery Radiotherapy Records notice

a. We plan to convert the standard email to a mail merge process similar to the monthly HIPAA notification. The same data file can be used, but the notices will go to ALL the email addresses.

Revision Record

Printed 7/10/2012 12:07 PM

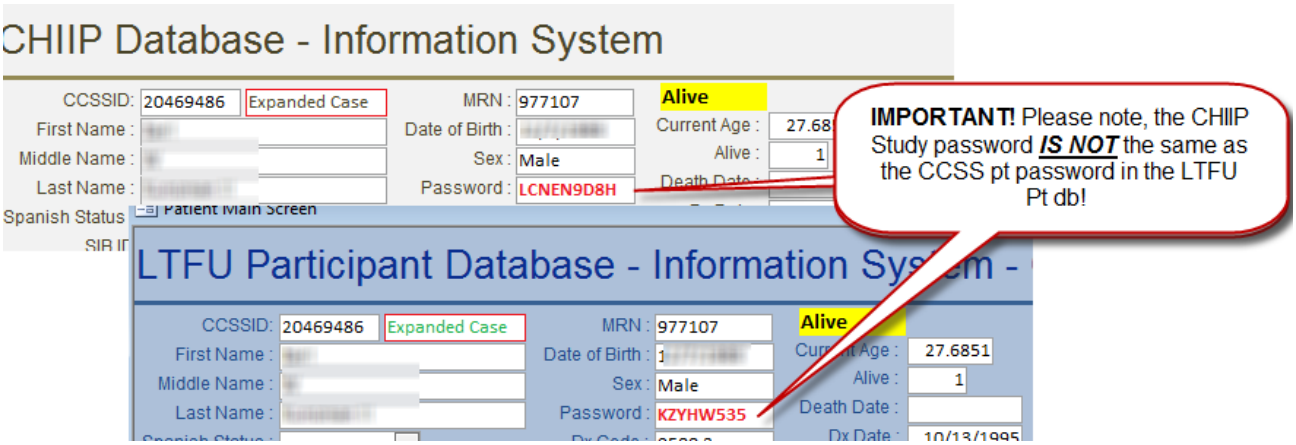
Current Filename:		Email Notifications to Data Managers ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/1/12	J.Bates	Initial Development

Emailing CHIIP Survey Links

Background

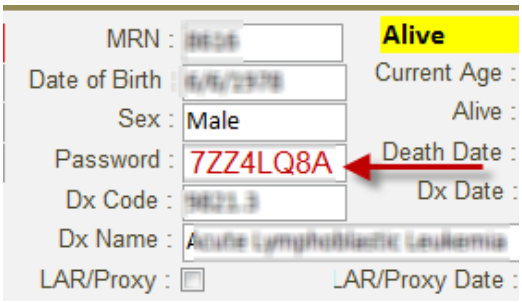
CHIIP Study participants have the option to complete the CHIIP survey via an online form. Using approved verbiage, LTFU Study staff may email the links to study participants to access the online survey form. After sending a CHIIP survey link, staff will make the appropriate documentation of the email communication in the LTFU Participant database.

Important: The CHIIP study password in the CHIIP study tracking database *IS NOT* the same as the CCSS pt password in the LTFU Participant Database. Be careful to send the correct password.



Procedures

1. Locate the participant's record in the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for details on using the search form.
2. Confirm the participant's email address. See the SOP titled **LTFU Participant Database Data Entry** for details on documenting a confirmed email address.
3. Open the email template:
   A. The email template is located at *Z:*\... *Interviewers* *CHIIP**Email templates*.
4. Create a new email in Outlook.
   A. Copy the body of the template, and paste it into the body of the new email using the "Keep Source Formatting" copy option. Clear any automatic Outlook signature in the body of the email and use the signature in the selected template. Without saving changes to the template, close the selected template.
5. Personalize the new email.
   A. In the body of the email, replace "Mr. or Ms. [Participant's Name]" with the appropriate title and name.
   B. In the body of the email, replace "[**from the CHIIP database**]" with the appropriate password. Copy the value in the participant record's **Password** field and paste it using the Match Destination Formatting paste option.



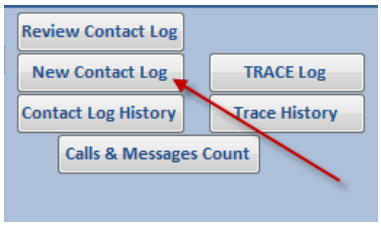
C. In the template's email signature, replace "[Survey Interviewer's Name]" with the first and last name of the interviewer sending the email.

6. Copy the participant's email address from the LTFU Participant database, and paste it into the **To:** bar of the email.

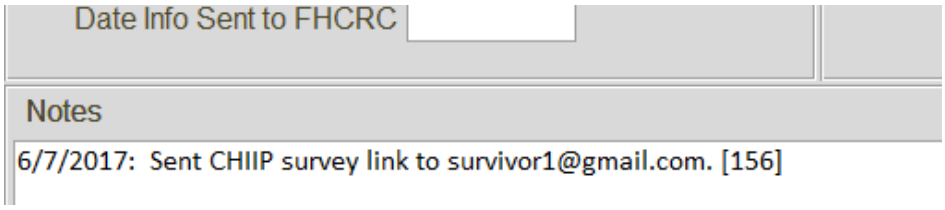
7. Proofread the email to ensure there are no mistakes:
   A. Was the "Long Term Follow-Up Study" note at the top of the page copied into the **Subject:** line and deleted from the body of the email?
   B. Was the appropriate title and name typed into the salutation?
   C. Was the appropriate password pasted into the body of the email?
   D. Was the Survey Interviewer's name typed into the email signature?

8. **Send** the email.

9. Document the sent link in the LTFU Participant database:
   A. Make an email entry in the participant record's contact log specifying which template was used. See the SOP titled **LTFU Participant Database Data Entry** for detailed instructions on documenting an email message.



   B. Add a dated comment with SI ID in the **Notes** field of the CHIIP Tracking tab indicating that a survey link was sent via email. *Example: 6/7/2017: Sent CHIIP survey link to survivor1@gmail.com. [156]*



Revision Record Printed

Current Filename:		Emailing CHIIP Survey Links ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	7/17/2017	A. Cobble, D. Rinehart, R. Daniels	Initial Development

Emailing Expansion Baseline Survey Links

Background

Expanded cohort participants for the Long-Term Follow-Up (LTFU) Study, including both case/survivor and sibling participants, finish the enrollment process by completing the baseline survey.

For most participants, the baseline survey can be completed using a paper copy, via telephone with a Survey Interviewer (SI), or by using the online survey form. During baseline phone calls, a qualifying participant or his/her legally authorized representative may ask the SI to email the link to the online baseline survey form.

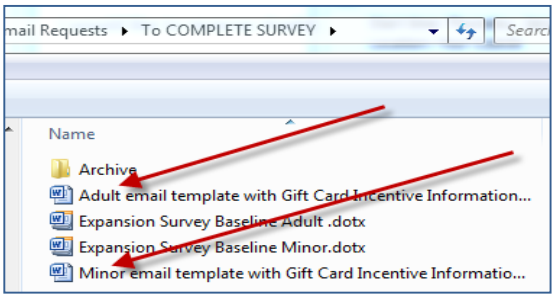
Proxies for deceased participants and participants requiring Spanish must complete the baseline survey via telephone with an SI. Survivors from Dana Farber Cancer Institute (DFCI, institution 05) must complete the baseline survey either via telephone or using a paper copy. These participants should not be emailed the baseline survey link.

Procedures

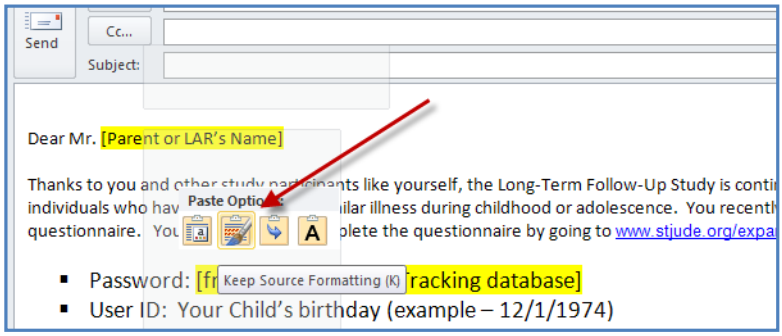
***CASE/SURVIVOR* Baseline Survey Link**

The online survey option is NOT AVAILABLE for Dana Farber cases, cases requiring Spanish, or proxies of deceased cases. Do NOT send survey links to these cases or their representatives. Otherwise, for someone who has completed the institutional HIPAA and would like to complete the baseline survey online:

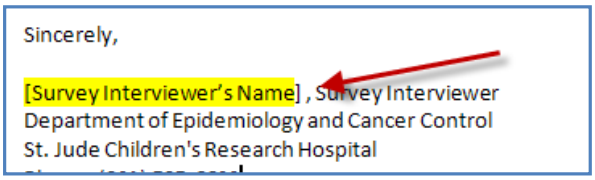
1. Locate the case's record in the CCSS Recruitment database (if sending the link at the time of a verbal HIPAA) or the CCSS Expansion Tracking database (if sending the link after the case has rolled over to Expansion Tracking).
2. **Open** the appropriate file:
   A. Go to *Z:\Departments\ECC\common\Interviewers\Expansion Survey Calls\Email\To COMPLETE SURVEY*.
   B. Open the appropriate email template. IMPORTANT: CHOOSE THE CORRECT TEMPLATE. ADULT AND MINOR SURVEYS HAVE DIFFERENT LINKS.
      i. Use "**Minor email template with Gift Card Incentive Information**" if sending the email to the parent or legal guardian of a case that is less than 18 years old.
      ii. Use "**Adult email template with Gift Card Incentive Information**" if sending the email to a case that is 18 years old or older or the legal guardian of such a case.



3. **Create a new email** in Outlook.
   A. Copy the body of the selected template and paste it into the body of the new email using the "Keep Source Formatting (K)" paste option.
      i. Do not copy the subject line from the Word template into the body of the email.



      ii. Replace any automatic Outlook signature with the template signature.
   B. Copy the subject line from the selected template and paste it into the subject line of the email. Do not copy and paste the words "Subject line:" from the Word file.
   C. Close the selected template. Do not save changes to the Word template file.
4. **Individualize the email** as follows:
   A. Replace "Mr. or Ms. [Participant's Name]" in the body of the email with the appropriate **title and name**.
   B. Replace "[from the Expansion Tracking database]" with the appropriate **password**.
      i. Copy the password from the Expansion Tracking database (or from the Recruitment database if sending the survey link at the time of a verbal HIPAA).
      ii. Paste the password into the email using the "Match Destination Formatting" paste option.
   C. Replace "[Survey Interviewer's Name]" in the **email signature** with your name.



5. Copy and paste the **email address** from the database into the **To:** field of the email.
6. **Proofread the email** to ensure that there are no mistakes:
   A. Selected the correct template (adult or minor)?
   B. Used the appropriate name and title (Mr., Ms., Mrs., Dr., etc.)?
   C. Updated the password to the one that belongs to this recipient?
   D. Entered your name in the email signature?
7. **Send the email**.
8. **Document** the sent link:
   A. If the survey link is sent at the time of the verbal HIPAA (i.e., the case is only found in the Recruitment database), populate the **Outcome** field of the **New Contact Log** with 12-Completed VH-Sent Link to document the survey link was sent at the time of the HIPAA.
   B. If the case is found in the Expansion Tracking database, on the Baseline tab:

      i. Enter a dated note with your SI ID in the **Tracking Comments** field indicating that the survey link was sent and the email address to which it was sent.

ii. Check the next available **Sent Email #** box, and enter the date the email was sent in the corresponding **Email # Date** field. (NOTE: If all 3 **Sent Email #** boxes are already populated, skip this step.)

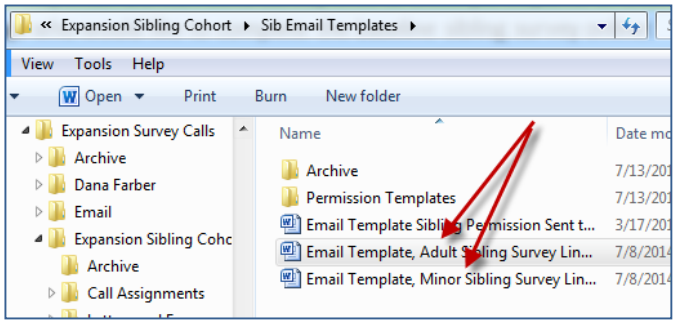
C. In the contact log of the appropriate database, document the email in a new contact record.
   i. **Project** – Populate with 3-Case Baseline.
   ii. **Project Reason** – Populate with 4-Survey.

9. For questions, consult the Call Center Coordinator or a member of the Lead Survey Interviewer (LSI) team.

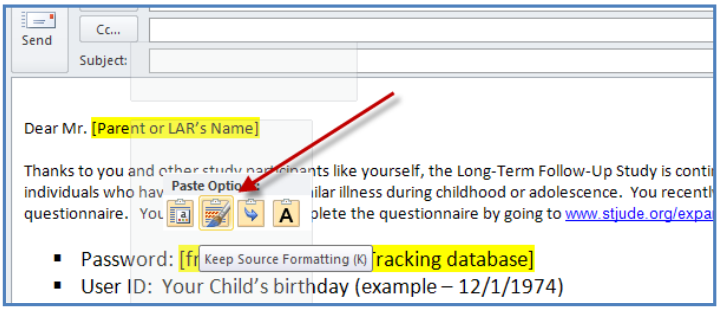
***SIBLING* Baseline Survey Link**

The online survey option is NOT AVAILABLE for participants who require Spanish or proxies of deceased sibling participants. Do NOT send survey links to these participants or their representatives. Otherwise, for siblings who would like to complete the baseline sibling survey online:

1. Locate the sibling's record in the CCSS Expansion Tracking database.
2. Check email history for the most recent sibling DatStat upload. Compare this to the date of the permission to be sure the sibling's DatStat record is active before sending the survey link.
3. **Open** the appropriate file:
   A. Go to *Z:\Departments\ECC\common\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Sib Email Templates*.
   B. Open the appropriate email template. IMPORTANT: CHOOSE THE CORRECT TEMPLATE. ADULT AND MINOR SURVEYS HAVE DIFFERENT LINKS.
      i. Use "**Email Template, Minor Sibling Survey Link**" if sending the email to the parent or legal guardian of a sibling that is less than 18 years old.
      ii. Use "**Email Template, Adult Sibling Survey Link**" if sending the email to a sibling that is 18 years old or older or the legal guardian of such a sibling participant.

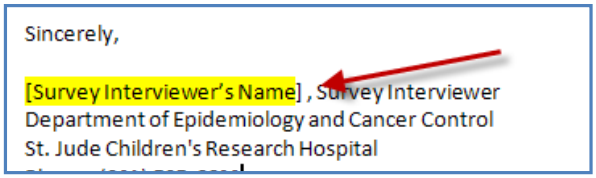


4. **Create a new email** in Outlook.
   A. Copy the body of the selected template and paste it into the body of the new email using the "Keep Source Formatting (K)" paste option.
      i. Do not copy the subject line from the Word template into the body of the email.
      ii. Replace any automatic Outlook signature with the template signature



B. Copy the subject line from the selected template and paste it into the subject line of the email. Do not copy and paste the words "Subject line:" from the Word file.
C. Close the selected template. Do not save changes to the Word template file.

5. **Individualize the email** as follows:
   A. Replace "[Participant Name]" in the body of the email with the appropriate **title and name**.
   B. Replace "[from the Expansion Tracking database]" with the appropriate **password**.
      i. Copy the password from the Expansion Tracking database.
      ii. Paste the password into the email using the "Match Destination Formatting" paste option.
   C. Replace "[Survey Interviewer's Name]" in the **email signature** with your name.



6. Copy and paste the **email address** from the database into the **To:** field of the email.
7. **Proofread the email** to ensure that there are no mistakes:
   A. Selected the correct template (adult or minor)?
   B. Used the appropriate name and title (Mr., Ms., Mrs., Dr., etc.)?
   C. Updated the password to the one that belongs to this recipient?
   D. Entered your name in the email signature?
8. **Send the email**.
9. **Document** the sent link. In the Expansion Tracking database:
   A. Enter a dated note with SI ID in the **Comments** field of the Sib Info tab indicating that the survey link was sent and the email address to which it was sent.
   B. Copy the note from the **Comments** field in the Sib Info tab and paste it into the **Tracking Comments** field of the Sib Baseline tab.
   C. Also on the Sib Baseline tab, check the next available **Sent Email #** box, and enter the date the email was sent in the corresponding **Email # Date** field. (NOTE: If all 3 **Sent Email #** boxes are already populated, skip this step.)
10. For questions, consult the Call Center Coordinator or a member of the LSI team.

Revision Record Printed 9/20/2016 9:20 AM

[292]Current Filename:		Emailing Expansion Baseline Survey Links ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	3/13/15	R. Massey	Replacing "Emailing LTFU Internet Links to Expanded Cohort Participants" with new title, content revision, separation of recruitment procedure
1.1	9/2/2016	A. Cobble	Content Revision

Emailing Expansion Recruitment HIPAA Links

Background

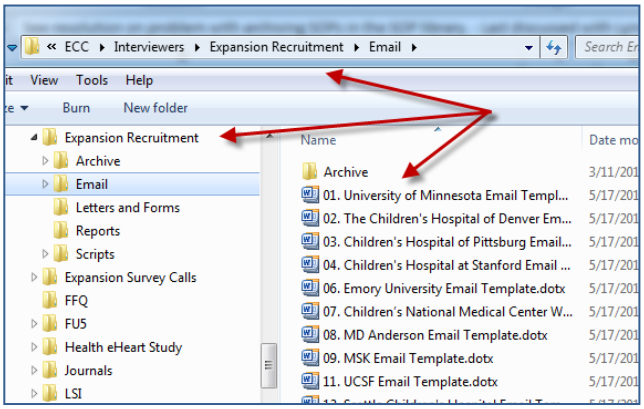
Expanded cohort potential participants for the Long-Term Follow-Up (LTFU) Study initiate the enrollment process by completing the institutional HIPAA during recruitment. This HIPAA releases the records of their treatment for the qualifying childhood illness from the participating treating institution to the LTFU Study.

The institutional HIPAA may be completed by signing a paper copy, by completing the HIPAA agreement verbally with a Survey Interviewer (SI), or by completing the form online. During recruitment phone calls, a survivor/case or his/her legal representative may request that the SI email the link to the online institutional HIPAA.

Procedures

For potential participants that would like to complete the recruitment (treating institution) HIPAA online:

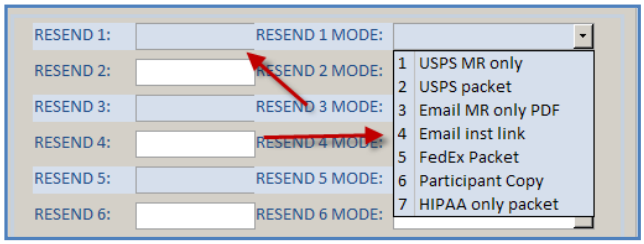
1. Use the Find feature to locate the case's record in the CCSS Recruitment database.
2. **Open** the appropriate **[Institution] Email Template.dotx** file, located at *Z:\Departments\ECC\common\Interviewers\Expansion Recruitment\Email*, <u>for the institution where the person was treated</u>.
   A. See the SOP titled **Decoding CCSSID** for details on determining the treating institution.
   B. If there is no file listed for the institution in question, please consult the Call Center Coordinator or a Lead Survey Interviewer (LSI).



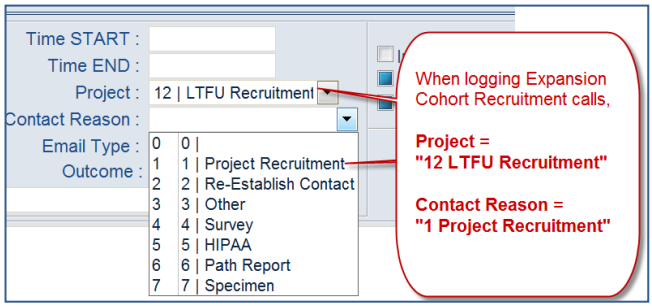
3. **Create a new email** in Outlook.
   A. Copy the body of the appropriate **[Institution] Email Template.dotx** and paste it into the body of the new email using the "Keep Source Formatting (K)" paste option.
      i. <u>Do not copy and paste the subject line</u> from the template.
      ii. Replace any automatic Outlook signature with the template signature.
   B. Copy the subject line from **[Institution] Email Template.dotx** and paste into the subject line of the email. Do not copy and paste the words "Subject line:" from the template.
   C. Close **[Institution] Email Template.dotx**. Do not save changes to the Word template file.
4. **Individualize the email** as follows:
   A. Replace "[Mr./Mrs. Participant's Name]" in the body of the email with the appropriate **title and name**.

B. If **sending to a parent or guardian**, change the line that reads, "Your login ID is your four digit year of birth" to "Your login ID is *[participant name]*'s four digit year of birth".
C. Replace "["PASSWORD" from Recruitment Database Quest Tab here]" with the appropriate **password**.
   i. Copy the password from the Recruitment database.
   ii. Paste the password into the email using the "Match Destination Formatting" paste option.
D. Replace "[Survey Interviewer Name]" in the **email signature** with your name.

5. Copy and paste the **email address** from the CCSS Recruitment database into the **To:** field of the email.
6. **Proofread the email** to ensure that there are no mistakes:
   A. Selected the template for the correct institution?
   B. Used the appropriate name and title (Mr., Ms., Mrs., Dr., etc.)?
   C. If sending to a parent or guardian, changed the line that reads, "Your login ID is your four digit year of birth" to "Your login ID is *[participant name]*'s four digit year of birth"?
   D. Updated the password to the one that belongs to this recipient?
   E. Entered your name in the email signature?
7. **Send the email**.
8. In the Recruitment database, go to the case's record.
   A. On the **Tracking tab**:
      i. **Resend #:** - In the next available field, enter the date the email was sent.
      ii. **Resend # Mode:** - Select option 4-Email inst link in the corresponding field.
      iii. **Recruit Notes** – Add a dated note with SI ID indicating the HIPAA link was sent and to what email address it was sent.



   B. In the contact log, document the email in a new contact record.
      i. **Project** – Populate with 12-LTFU Recruitment.
      ii. **Contact Reason** – Populate with 1-Project Recruitment.
9. For questions, consult the Call Center Coordinator or a member of the LSI team.



Revision Record
Printed 9/20/2016 9:18 AM

[291]Current Filename:		Emailing Expansion Recruitment HIPAA Links ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	3/13/15	R. Massey, D. Rinehart	Replacing "Emailing LTFU Internet Links to Expanded Cohort Participants" with new title, content revision, separation of baseline procedure
1.1	9/2/16	A. Cobble	Content Revision

Emailing Follow-Up 5 Survey Links

Background

English-speaking LTFU Study participants have the option to complete the Follow-Up 5 (FU5) survey via an online DatStat form. Using approved verbiage, LTFU Study staff may email links to study participants to access the online survey form. After sending a FU5 survey link, staff will make the appropriate documentation of the email communication in the LTFU Participant database.

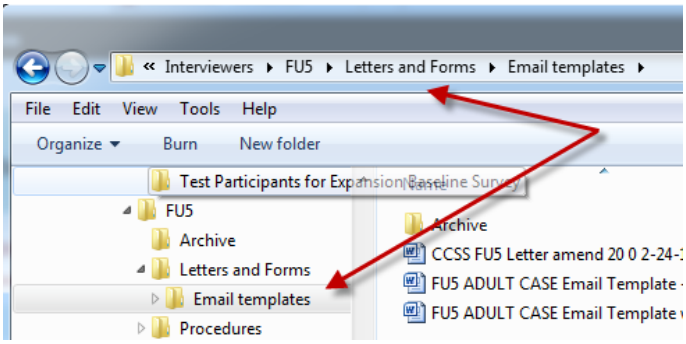
Procedures

Spanish-speaking participants must complete the FU5 survey on the telephone with a Spanish-speaking interviewer and should not be emailed the survey link. For English-speaking LTFU participants:

1. Locate the participant's record in the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for details on using the search form.

2. Confirm the participant's email address. See the SOP titled **LTFU Participant Database Data Entry** for details on documenting a confirmed email address.

3. Open the appropriate email template:
   A. The email templates are located at *Z:\SJShare\SJCOMMON\ECC\Interviewers \FU5\Letters and Forms\Email templates*.
   B. Choose the template based on the participant's status *to ensure the correct survey link is sent*:
      i. Incentive vs. NO Incentive –
         a. Choose the "incentive" template if:
            1) The participant is still within the iPad incentive period. See the SOP titled **Follow-Up 5 Survey – Incoming Calls** for information about determining the incentive period expiration.
            2) The participant was mailed the iPad letter, the letter was returned to sender, and no other notice of the iPad incentive has previously reached the participant.
         b. Choose the "NO Incentive" template if the participant's iPad incentive period has expired, and the iPad letter was not returned to sender.
      ii. Choose the ADULT CASE template when the participant is a survivor who is 18 years old and older.

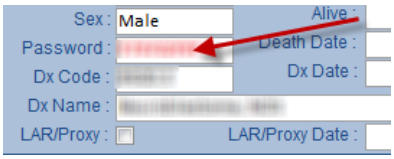


iii. Choose the MINOR CASE template when the participant is a survivor who is less than 18 years old.
iv. Choose the ADULT SIBLING template when the sibling participant is 18 years old or older.
v. Choose the MINOR SIBLING template when the sibling participant is less than 18 years old.

4. Create a new email in Outlook.
   A. Copy the body of the selected template, above, and paste it into the body of the new email using the "Keep Source Formatting" copy option. Clear any automatic Outlook signature in the body of the email and use the signature in the selected template. *DO NOT copy and paste the subject line* from the template to the body of the email.
   B. Copy the subject line from the selected template (NOT the words "subject line"), and paste it into the **Subject:** bar of the new email.

   C. Without saving changes to the template, close the selected template.

5. Personalize the new email.
   A. In the body of the email, replace "Mr. or Ms. [Participant's Name]" with the appropriate title and name.
   B. In the body of the email, replace "[from the LTFU Participant database]" with the appropriate password. Copy the value in the participant record's **Password** field and paste it using the Match Destination Formatting paste option.



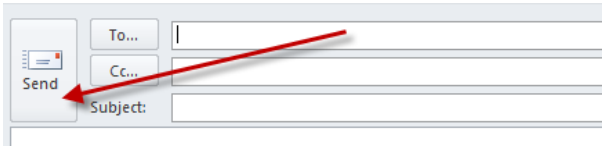
   C. For incentive templates:
      i. If the intro letter was not returned to sender, replace "[iPad cutoff date]" in the body of the email with the value in the **IPad Due Date** field.
      ii. If the intro letter was returned to sender and the link being emailed is the first written notice of the incentive that the participant is receiving, replace "[iPad cutoff date]" with the date 30 days from the date of the email.
      iii. If the intro letter was never mailed (i.e. the **IPad Due Date** field is not populated), replace "[iPad cutoff date]" with the date 30 days from the date of the email.
   D. In the template's email signature, replace "[Survey Interviewer's Name]" with the first and last name of the interviewer sending the email.

6. Copy the participant's email address from the LTFU Participant database, and paste it into the **To:** bar of the email.

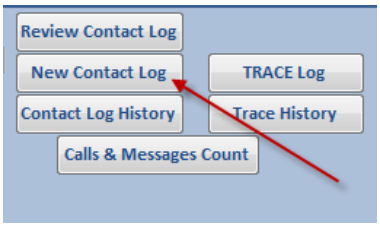
7. Proofread the email to ensure there are no mistakes:

A. Was the correct template selected (adult vs. minor, case vs. sibling, incentive vs. NO incentive)?
B. Was the appropriate title and name typed into the salutation?
C. Was the appropriate password pasted into the body of the email?
D. For incentive templates, was the correct due date typed into the template?
E. Was the Survey Interviewer's name typed into the email signature?

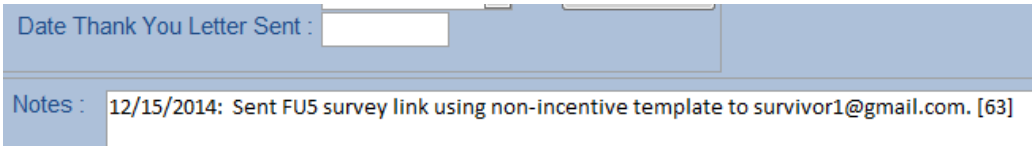
8. Click the **Send** button to send the email.



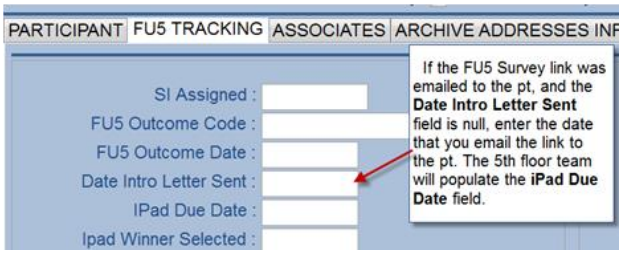
9. Document the sent link in the LTFU Participant database:
   A. Make an email entry in the participant record's contact log specifying which template was used (incentive vs. NO incentive). See the SOP titled **LTFU Participant Database Data Entry** for detailed instructions on documenting an email message.



   B. Add a dated comment with SI ID in the **Notes** field of the FU5 Tracking tab indicating that a survey link was sent via email. Specify whether an incentive or non-incentive template was used.
   Example: 12/15/2014: Sent FU5 survey link using non-incentive template to survivor1@gmail.com. [63]



   C. For emails successfully sent using the incentive template:
      i. If the **Date Intro Letter Sent** field is blank:
         a. Populate the **Date Intro Letter Sent** field with the date of the email.
         b. Do not populate the **Request Date** or **Resend Request** fields except in the rare event that participant wants a paper copy of the iPad letter in addition to the email link.
         c. Do not populate the **IPad Due Date** field. The 5th floor team will populate this field.

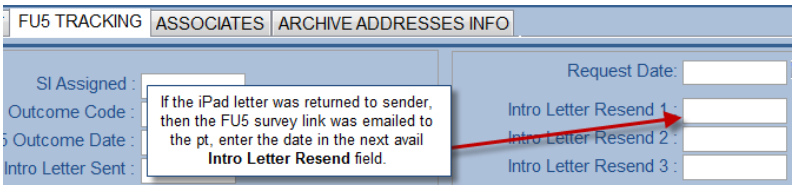


      ii. If the **Date Intro Letter Sent** field is populated and the most recent letter was NOT returned to sender (i.e. the incentive deadline does NOT need to be extended):

a. DO NOT overwrite the date in the **Date Intro Letter Sent** field.
b. Do not populate the **Request Date** or **Resend Request** fields except in the rare event that the participant wants a paper copy of the iPad letter in addition to the email link.

iii. If the **Date Intro Letter Sent** field is populated, the most recent letter was documented as **returned to sender**, *and* the successfully sent link is the first written notice the participant has received regarding the iPad incentive (i.e. the incentive deadline needs to be extended):

a. Do not overwrite the date in the **Date Intro Letter Sent** field.



b. Enter the date of the email in the next available **Intro Letter Resend** field.
c. Do not populate the **Request Date** or **Resend Request** fields except in the rare event that the participant wants a paper copy of the iPad letter in addition to the email link.
d. Do not re-populate the **IPad Due Date** field. The 5th floor team will re-populate this field.

Revision Record — Printed 9/26/2014 1:38 PM

Current Filename:		Emailing Follow Up 5 Survey Links ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	7/25/14	R. Massey	Initial Development
1.1	9/25/14	J. Ford, R. Massey, D. Rinehart	Content Revision: Revised directives for documenting links sent

Emailing Follow-Up 6 Survey Links

Background

English-speaking LTFU Study participants have the option to complete the Follow-Up 6 (FU6) survey via an online DatStat form. Using approved verbiage, LTFU Study staff may email links to study participants to access the online survey form. After sending a FU6 survey link, staff will make the appropriate documentation of the email communication in the LTFU Participant database.

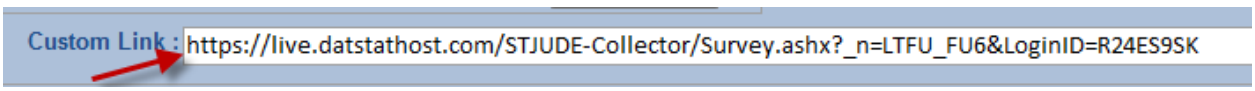
Tools needed: (located at *Z…Interviewers\FU6\Email Template*)

1. **FU6 Survey Email Template_Custom.docx** – to send pt "Custom Link", which takes the pt directly to the survey and only requires pt to enter DOB (no password required)
2. **FU6 Survey Email Template_Standard.docx** – for sending instructions for pt to visit www.stjude.org/LTFUsurvey, and log in, using ***Password*** and ***DOB***

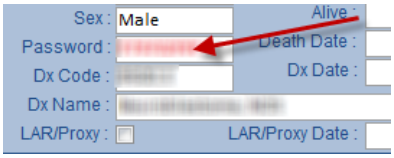
Procedures

Spanish-speaking participants must complete the FU6 survey on the telephone with a Spanish-speaking interviewer and should not be emailed the survey link. For English-speaking LTFU participants:

1. Locate the participant's record in the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for details on using the search form.
2. Confirm the participant's email address. See the SOP titled **LTFU Participant Database Data Entry** for details on documenting a confirmed email address.
3. Open the appropriate email template.
    - Please use the template, **FU6 Survey Email Template_Custom.docx**, unless otherwise instructed or if encountering an unforeseen issue with the link.
4. Create a new email in Outlook.
    - Copy the body of the template, and paste it into the body of the new email using the "Keep Source Formatting" copy option. Clear any automatic Outlook signature in the body of the email and use the signature in the selected template. Without saving changes to the template, close the selected template.
5. Personalize the new email.
    A. In the body of the email, replace "Mr. or Ms. [Participant's Name]" with the appropriate title and name.
    B. if using the template, **FU6 Survey Email Template_Custom.docx**, in the body of the email, replace "[Insert pt's Custom Link here]" with the personalized link in the field, **Custom Link**, on the **FU6 Tracking tab.**



C. If using the template, **FU6 Survey Email Template_Standard.docx**, in the body of the email, replace "[from the LTFU Participant database]" with the appropriate password. Copy the value in the participant record's **Password** field (in the header section) and paste it using the Match Destination Formatting paste option.



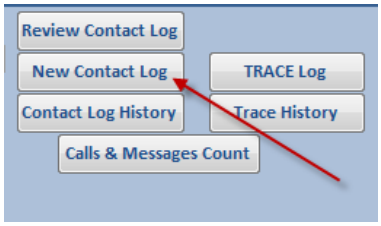
D. In the template's email signature, replace "[Survey Interviewer's Name]" with the first and last name of the interviewer sending the email.

6. Copy the participant's email address from the LTFU Participant database, and paste it into the **To:** bar of the email.

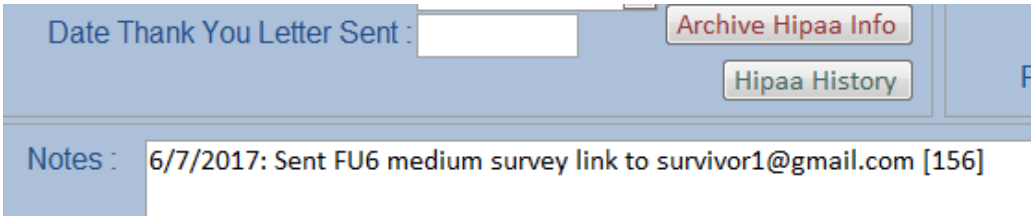
7. Proofread the email to ensure there are no mistakes:
   - Was the "Long Term Follow-Up Study" note at the top of the page copied into the **Subject:** line and deleted from the body of the email?
   - Was the appropriate title and name typed into the salutation?
   - Was the appropriate password pasted into the body of the email?
   - Was the Survey Interviewer's name typed into the email signature?

8. **Send** the email.

9. Document the sent link in the LTFU Participant database:
   - Make an email entry in the participant record's contact log specifying which template was used. See the SOP titled **LTFU Participant Database Data Entry** for detailed instructions on documenting an email message.



   - Add a dated comment with SI ID in the **Notes** field of the FU6 Tracking tab indicating that a survey link was sent via email. *Example: 6/7/2017: Sent FU6 medium survey link to survivor1@gmail.com. [156]*



Revision Record — Printed

[321] Current Filename:		Emailing Follow-Up 6 Survey Links v1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/14/2017	A. Cobble, D. Rinehart, R. Daniels	Initial Development

Emailing pdf from Color Copier

Background

The Epi Color Copier 2 can be used to output a pdf file from a paper document and send it via email to an individual having access to this feature.

Procedure

1. Position the document pages in the feed tray.
2. On the console of the EPI ColorCopier 2, select Fax/Scan
    a. Select the individual (or individuals) from the list of available email addresses/
3. In Scan Settings
    a. choose pdf multi page
    b. Press OK
4. In Document name
    a. Clear the default
    b. Type in the file name you want applied to the pdf document
    c. Press OK
5. Press the Start button

Revision Record Printed 7/9/2012 3:10 PM

Current Filename:		Emailing pdf copies from Color Copier ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/24/10	J.Ford	Initial Development

Empower Study for Survey Interviewers

Background

The Empower study involves Survey Interviewers in a variety of tasks. This document outlines tasks that specific to Survey Interviewers, and provides additional background information.

Procedures

Call Log Information

The "**QUEST**" tab is where you record your Call Log information (use the Call Log information *just like you do for the Recruitment database*.)

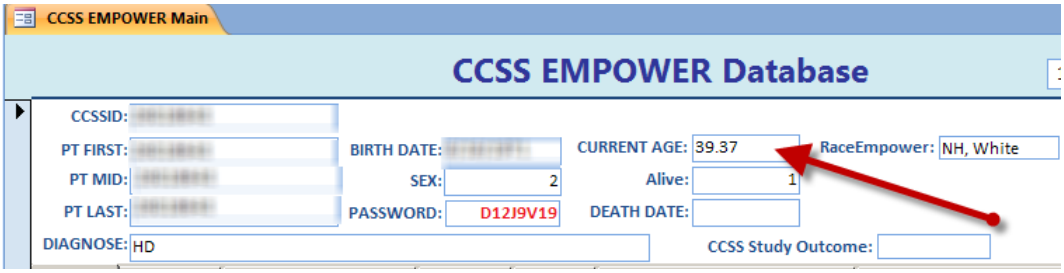
1. Record **Date Last Phone Call** (QUEST tab)
2. On the line with the phone number you actually called, click the **Call Log pencil icon.** Key in your notes and call outcome on that screen. If the number turns out to be dead, change that number's rank to a '9'. Manually increase the # of Calls/# messages. Similarly, use a rank of "1" for the participant's preferred number, then a 2 for the next best number, etc.
    a. NOTE: People being recruited for Empower are ALREADY in the LTFU study. No firewall exists.
    b. Copy and paste the call notes onto the **Comments** space on the QUEST tab.
3. If there is a **NAME CHANGE**: you cannot enter name changes directly. Therefore:
    a. Enter a note in recruit notes using the standard note format.
    b. Email James/Jerry and cc Dayton giving CCSSID, name-on-file, new name. We will then manually update the appropriate tables, which will eventually get reflected on the Empower database.
4. If person you are talking to tells you the *patient* is **DECEASED** or **OUT OF THE COUNTRY**, then
    a. Enter a note in recruit notes, and indicate WHO is telling you this information. For example, "m/d/yy: Mother Mary Smith reports Jane Smith died on m/d/yy. [##]"; "m/d/yy: Husband John Jones reports Nancy Jones is in Afghanistan for the next 6 months. [##]"
    b. Report the situation to Dayton via email, including CCSSID and name.
    c. (Dayton will notify James/Jerry so they can update the database). (We will not complete a survey for deceased or out of country individuals.)
5. Verify the **address** we have on file.
    a. If the address we show IS correct, then
        i. Enter today's date in the **Address Date** box, and select "Phone contact w/ Pt" from the dropdown box for **Address Source**
    b. If the address we show is NOT correct, then
        i. Click the **Archive Address** button
        ii. Key in the new address, date, and source
        iii. Click the **Update Empower Print table ADDRESS** button

6. Confirm current **phone number**: identify phone **TYPE**, select "relationship", key in TODAY'S date in **phone date**, and identify **phone source**.
    a. NOTE that in EMPOWER, we look for 3 phone numbers: Home, Cell, and WORK. *Get all 3 if you can (and if they have all 3)*
7. Confirm **current email address**. If the address is already listed on the screen, key in today's date in that email's Date, and select the appropriate source. If multiple email addresses are shown on the screen, confirm each one. Delete any that are NO LONGER ACTIVE. IF the person has NO EMAIL, make a note in the comments section. For example: "mm/dd/yy: has no email address [##]" (put today's date instead of mm/dd/yy; put your interviewer # instead of ##)

COMPLETING Recruitment Baseline Survey ("Baseline Q'naire") by Phone

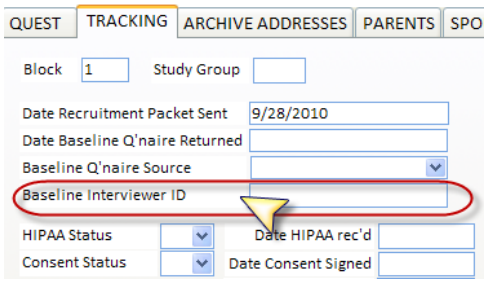
When you complete the Recruitment Baseline survey with the participant by phone, you (a) log into the online survey system, (b) key in information, and (c) submit the survey on the person's behalf. In addition, you need to enter the following information into the Empower database:

1. Before you administer the survey, check the participant's age in the Empower database.
    a. If the participant's Current Age is **40 or older**, she is NOT currently eligible for the study. Do NOT complete the survey. Follow the script for informing the participant of her ineligibility. Then STOP!



    b. If the person IS **under the age of 40**, then continue as follows:

2. On the **TRACKING** tab,
    a. In **Recruit notes**: enter "mm/dd/yy: completed informed consent and baseline survey by phone [##]"
    b. Enter YOUR interviewer ID # in "**Baseline Interviewer ID**" NOTE: Record Interviewer ID here ONLY when completing BASELINE questionnaire by phone.



    c. If the person answers "YES" or "UNSURE" to any one of the three initial eligibility questions, note this in **Recruit notes**: For example: "m/d/yy: Q1 and Q3 unsure [##]".

d. If the individual answered "YES" or "Unsure" to any one of the 3 eligibility questions, the online survey STOPS after those questions. Follow the script for what to say at that point.
    a. *For your information only:* if the person marked YES or Unsure to any of the questions then it is *possible* they may be eligible. But you will not know this at the time you are doing the survey. Their eligibility will be confirmed by the researchers conducting this study.
        i. Once Dr. Oeffinger makes a determination, James/Jerry will notify Dayton so proper phone follow-up can be done.
        ii. If Dr. Oeffinger says they ARE eligible, then the follow-up phone call can go through the survey process again.

REQUESTS to RESEND materials

1. When we need to resend the recruitment packet, then the person who learns of this resend need will enter the Resend Request on the TRACKING tab. Enter the **Date of Request** and then select *100-Baseline Packet* from the **Resend Request** dropdown list.
2. When do resend requests happen?
    a. When you are talking to the person on the phone and she does NOT want to complete the survey over the phone, but has misplaced the survey and wants to have a new one sent.
        i. NOTE: If the baseline questionnaire has not been returned 4 weeks after the recruitment packet has been sent, the person will be put into call rotation.
    b. When the materials we mailed out were "Returned to Sender", and James/Jerry recorded the "Undeliverable" Tracing Code, and then the Tracing Division locates and corrected address, then the Tracing person will enter the Resend Request (and clear the Tracing Code)

RECORDING "Interim Contact Date(s)"

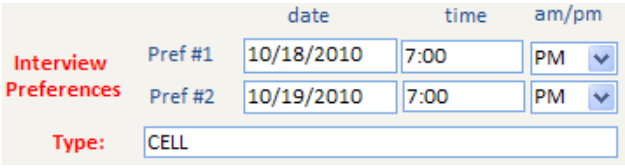
When any "unscheduled" phone contact is made with the person, then enter the date (using m/d/yy format) in the **Interim contact date(s)** space (in the Yellow area). For additional interim contacts, string the dates together separated by semicolons. Put the NOTES from the contact in the Recruit notes area. For example:

1. In **Interim contact date(s)**: 10/1/10; 10/15/10
2. In **Recruit notes**:
   10/1/10: pt called asking what the survey was for [##]
   10/15/10: pt called to say she could not use the website [##]

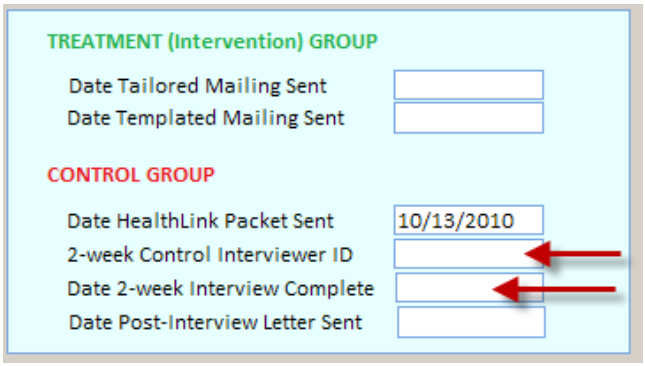
RECORDING Control Group Interview

After a participant has completed the baseline survey and it is determined she is eligible to participate in the study, she is randomly placed into either the intervention or the control group. The HealthLink Packet is sent to control group participants. (A copy of these materials can be found in your EMPOWER notebook.)

From two to four weeks after this HealthLink packet is mailed to a person in the **CONTROL** group, the survey interviewer will conduct a phone interview. The database provides you with dates and times the individual preferred you to contact her, as well as the way she preferred you to contact her. Use these preferences as a guide in scheduling the interview.



After the interview has been conducted,



1. Locate the participant in the Empower database
2. Open the **TRACKING** tab,
   a. Enter ***2-week Control Interviewer ID number***. Note: record Interviewer ID *here* only when completing 2-week control interview. Do NOT confuse the 2-week Control Interviewer ID field with Baseline Interviewer ID field; they are for *totally separate, distinct, events.*)
   b. Enter ***Date 2-week Interview Complete***
3. Notify James Ford via email when interview is complete
   a. Indicate individual's CCSSID
   b. If the participant indicates she has not yet received the packet, please note this in the *Recruit Notes* field, and include this information in your email to James.

As we proceed through the EMPOWER protocol, we will have MORE information for interviewers and the tracing division.

Revision Record
Printed 7/13/2012 9:46 AM

Current Filename:		Empower Study for Interviewers v1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/19/10	J.Bates	Initial Development
1.1	10/22/10	J.Bates	Clarification on interviewer ID locations

EMPOWER Study Phone Calls

Background

The EMPOWER Study, which stands for Encouraging Mammography/MRI and Preventive Opportunities for Women Exposed to Radiation, examines different methods to inform female childhood cancer survivors of breast and heart health issues. The study includes original and expanded cohort participants who had therapeutic chest radiation for their childhood illness. Three institutions are partnering on the study: Memorial Sloan Kettering, Colorado Children's Hospital, and the Coordinating Center at St. Jude.

Eligible female participants will be recruited in blocks and then randomly assigned to either an intervention-treatment group or a control group. The assignments are made at Memorial Sloan Kettering, and a motivational interview intervention is conducted by Colorado Children's staff members.

Survey Interviewers (SIs) call participants at different points in the study and for different reasons. In brief:

- Prospective participants are mailed study information including a consent form and eligibility checklist. Three weeks following the mailing, non-responders are assigned to an SI for recruitment.
- After enrollment, participants are mailed a baseline questionnaire. SIs call non-responders.
- After baseline, SIs call all control group participants to complete a phone-based interview.
- 12-months after enrollment, all participants are mailed a survey. SIs call non-responders.

Tools

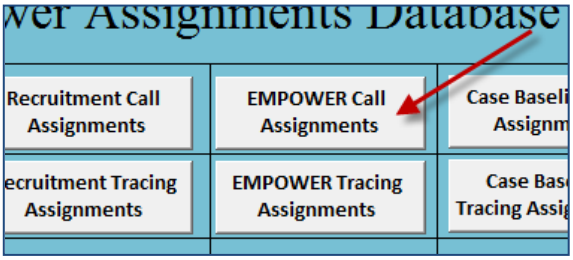
1. CCSS SI Assignments database, located at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
2. CCSS LTFU Participants database, located at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
3. CCSS EMPOWER database , located: *http://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
4. **EMPOWER Study Phone Calls** SOP, located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
5. Original and Expanded Cohort **Phone Contact Logs**
    A. Original, located: *Z…\Interviewers\Original Cohort Call Logs - Reg db*
    B. Expanded, located: *Z…\Interviewers\Expansion Survey Calls\Participant call logs*
6. **Phone Message Guidance_Rev 5-30-2014** (located at *Z:\SJShare\SJCOMMON\ECC \Interviewers\Calling Tools*)
7. **EMPOWER SI Scripts**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\EMPOWER\Procedures*

8. **EMPOWER Eligibility Checklist_SI Copy** located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\EMPOWER\Forms*
9. Informed consent document, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\EMPOWER\Procedures*
10. **LTFU Participant Database Data Entry** SOP, located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx

Procedure

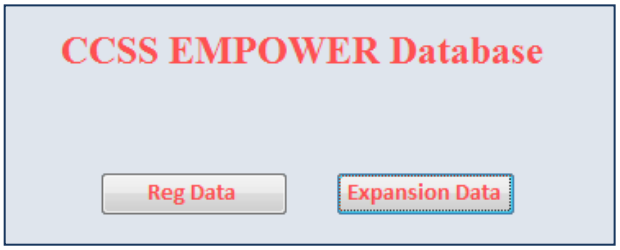
Before the Call

1. Open CCSS SI Assignments database. Click the **EMPOWER Call Assignments** button, enter the SI ID at the prompt, and click **OK**. Note the first participant in the list. If she is in multiple studies, as indicated in the "# of Studies" column, prepare to address the EMPOWER study and the other studies in the same call. Coordination with another SI may be needed.



2. Open the CCSS LTFU Participants database and locate the first participant's record. See the SOP titled **LTFU Participant Database Data Entry** for instructions on using the Search Information screen.

3. Open the CCSS EMPOWER database:
   A. Click on the **Reg Data** and **Expansion Data** buttons on the EMPOWER switchboard. – Participants are found in one form or the other depending on the cohort (Original or Expansion) of which they are a member.



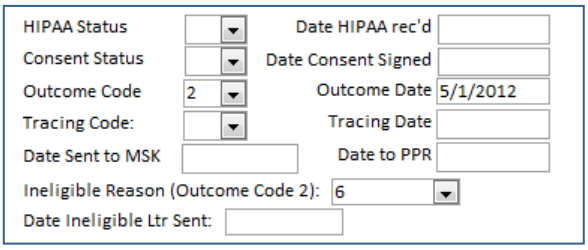
      i. If the third and fourth numbers in the CCSSID are under 25, the participant is in the Original cohort and will be found in the Reg Data form.
      ii. If the third and fourth numbers of the CCSSID are over 25, the participant is in the Expansion cohort and will be found in the Expansion Data form.
   B. Find the participant's record:
      i. Click in the **CCSSID** field, then click **Find** in the Find group of the Home tab in Access.
      ii. In the Find and Replace dialog box, enter the CCSSID number in the **Find What** field.
      iii. Click the **Find Next** button.

4. Review all available data as indicated in the SOP titled **Pre-Post Call Checklist - EMPOWER Study**.

Making Calls – Use the **EMPOWER SI Scripts** when making calls. See also specified call events, below.

Completing the EMPOWER Eligibility Checklist

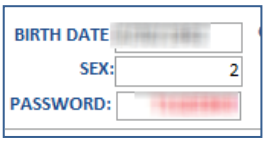
1. Reference the **EMPOWER Eligibility Checklist_SI Copy** document.
2. Ask the participant each of the four questions and circle her response.
   A. If the participant answers "Yes" to any of the questions 1 through 3, she is *ineligible* for the study. The SI should, however, continue to ask all four questions.
   B. If the participant answers "No" to *all* of the questions 1 through 3, she is *eligible* for the study. The SI should:
      i. Continue to ask all four questions
      ii. Read the informed consent statement
      iii. Answer any questions the participant may have
   C. Responses to question four do not affect eligibility.
   D. If the participant answers "Unsure" to any question, email the study coordinator.
3. On the Tracking tab in the EMPOWER database:
   A. **Date Eligibility Received** – Enter the current date.
   B. **Eligibility Checklist Source** – Choose option 3-Interviewer.
   C. **Eligibility Checklist Interviewer ID** – Enter your SI ID.
   D. If the participant was consented during the call:
      i. **Consent Status** – Choose 1-Complete
      ii. **Date Consent Signed** – Enter the current date.
   E. If the participant is ineligible for the study:
      i. **Outcome Code** – Choose 2-Ineligible.
      ii. **Outcome Date** – Populate with the current date.
      iii. **Ineligible Reason (Outcome Code=2)** – Populate with the appropriate reason.
      Note: If the participant's Current Age is 50 or older, she is *ineligible* for the study. Choose 6-Age from dropdown menu.



      iv. **Recruit Notes** – Document the ineligibility with a dated note and SI ID.

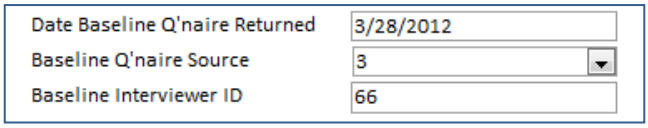
Baseline Questionnaire – Completed for both the Control group and the Intervention/Treatment group

1. Login to the baseline survey at https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name =EMPOWER using the birthdate and password in the database header.



2. If the consent form was not previously signed (See the **Consent Status** and **Date Consent Signed** fields on the Tracking tab of the EMPOWER database.), read the informed consent statement and answer any questions the participant may have.
3. Proceed with the questionnaire using standard interview procedures.
4. When the survey is complete:
   A. Press the **Submit** button in the survey.
   B. On the Tracking tab in the EMPOWER database:

i. **Recruit Notes** – Document the survey information in a dated note with SI ID.
Example: 03/28/2012: Pt completed informed consent and baseline survey by phone. [66]



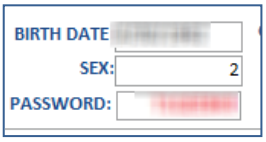
ii. **Date Baseline Q'naire Returned** – Enter the current date.
iii. **Baseline Q'naire Source** – Choose 3-Interviewer.
iv. **Baseline Interviewer ID** – Enter your SI ID.
v. If the participant was consented during the call:
   a. **Consent Status** – Choose 1-Complete.
   b. **Date Consent Signed** – Enter the current date.

Control Group 2-Week Interview – Completed for the Control group only

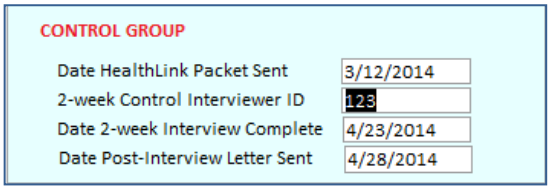
After a participant has completed the eligibility checklist, she will be randomly assigned to either the Control or Treatment Intervention group.

The HealthLink packet is mailed to the Control group participants. Two weeks after the HealthLink packet is mailed to a Control group participant, the SI will call to conduct the 2-Week Control Interview.

1. Login to the 2-Week Control Interview at https://live.datstathost.com/stjude-Collector/Survey.ashx?Name=EMPOWER_ControlGroup_2-Week_Interview using the birthdate and password in the database header.



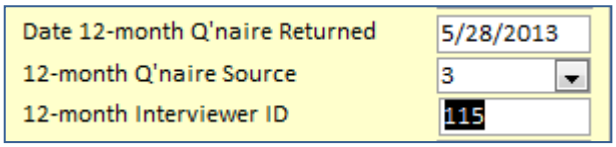
   NOTE: This interview usually lasts about 20-30 minutes. No informed consent statement is needed before completing the 2-Week Control Interview.
2. Proceed with the questionnaire using standard interview procedures.
3. When the survey is complete:
   A. Press the **Submit** button in the survey.
   B. On the Tracking tab in the EMPOWER database:
      i. **2-Week Control Interviewer ID** – Enter your SI ID.
      ii. **Date 2-week Interview Complete** – Enter the current date.
      iii. **Recruit Notes** – Document the survey information in a dated note with SI ID.



12-Month Interview – Completed for both the Control group and the Intervention/Treatment group

1. Login to the appropriate (control or treatment group) 12-Month Survey using the birthdate and password in the database header.
   A. 12-Month Control Group = www.stjude.org/EMPOWER2
   B. 12-Month Treatment Group = www.stjude.org/EMPOWER1

   NOTE: No informed consent statement is needed before completing the 12-Month Interview.
1. Proceed with the questionnaire using standard interview procedures.
2. When the survey is complete:
   A. Press the **Submit** button in the survey.
   B. On the Tracking tab of the EMPOWER



database:

i. **Date 12-month Q'naire Returned** – Enter the current date.
ii. **12-month Q'naire Source** – Choose 3-Interviewer.
iii. **12-month Interviewer ID** – Enter your SI ID.
iv. **Recruit Notes** – Document the survey information in a dated note with SI ID.

Resend Requests

If a participant requests a resend of study materials in lieu of participating by phone, on the Tracking tab of the EMPOWER database:

1. **Date of Request** – Enter the current date.
2. **Resend Request** - Specify which materials should be mailed to the participant.

Refusals

If a participant states that she does not want to participate in EMPOWER at any point of the study:

1. During the call:
   A. Try to capture a reason why the participant has decided to refuse. If there are concerns that can be addressed, do so. Offer a hold, if appropriate.
   B. If it is unclear whether the participant is refusing just the EMPOWER study or all further participation in the LTFU Study, clarify this.
2. LTFU Participant database
   A. Document the refusal in the **Outcome** and **Notes** fields of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for details.
   B. For Refused All Else outcomes, document the refusal in the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for details.
3. In the EMPOWER database:
   A. **Comments** (Quest tab) – Document the refusal in a dated note with SI ID. Copy the note.
   B. **Recruit Notes** (Tracking tab) – Paste the note from the Quest tab.
   C. If the participant refuses the baseline survey or 2-Week interview:
      i. **Outcome Code** (Tracking tab) – Choose 1- Refused/not interested in EMPOWER.

      ii. **Outcome Date** (Tracking tab) – Enter the current date.
   D. If the participant refuses the **12-Month Survey**:
      i. **12-month outcome** (Tracking tab) – Choose 1-Refused/not interested in EMPOWER.
      ii. **12-month outcome date** (Tracking tab) – Enter the current date.
4. Email the Clinical Research Associate (CRA).

After Every Call

1. Document each call, email, or other communication in the LTFU Participant database's contact or trace log as appropriate. See the SOP titled **LTFU Participant Database Data Entry** for details.
2. Document all confirmed or updated contact information in the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for details.

3. Proof-read all notes and data entry in all locations for accuracy and completeness.
4. File completed eligibility checklists and informed consent documents in the hanging file labeled "Completed Empower Eligibility forms" located in the top drawer of file cabinet A.
5. Consult with the study coordinator, Call Center Coordinator, or a Lead Survey Interviewer (LSI) with questions.

Revision Record Printed 3/3/2015 12:58 PM

Current Filename:		EMPOWER Study Phone Calls ver1_5.doc	
Revision No.	Date	Responsible Author	Change Description
1		D. Rinehart/J. Ford	Initial Development
1.1	5/9/12	Procedure Team	Format and content revisions
1.2	5/11/12	D. Rinehart/J. Ford	Email process clarification/blurred PHI/updated color legend
1.3	5/18/12	J. Ford / D. Rinehart	Added script guidance, location and screenshot to page 4, "Making Calls"
1.4	8/19/13	E. Moore, D. Rinehart, T. Thomas, R. Massey, J. Ford	Content Revision and Formatting
1.5	2/14/15	R. Massey, T. Thomas	Content Revision: Remove references to workbook and add directives for SI Assignments db and LTFU Pt db

EMSI Home Visit Pilot Study Follow-Up Calls

Summary

The EMSI Home Visit Pilot Study is a feasibility study to determine if it is possible and practical to obtain direct measures of important health outcomes from CCSS participants. Participation in the study involves a one-time visit by an EMSI technician to collect a blood sample, some physical measurements (height, weight, blood pressure and waist circumference), and a brief questionnaire. After completion of the study (blood sample, physical measurements, and survey), the participant will get results of their blood lab work and a $50 gift card.

Two weeks following the mailing of the introductory packet, which contains a consent form, Survey Interviewers (SIs) begin calling participants who have not returned the consent form. The purpose of the call is to:

1. Verify contact information.
2. Explain the EMSI Home Visit Pilot Study.
3. Determine if the CCSS participant is willing to participate. If yes, obtain permission to have a representative from EMSI contact the participant.
4. Determine if a resend is applicable.
5. Determine the best time for EMSI to call in order to set up the appointment for the study visit.

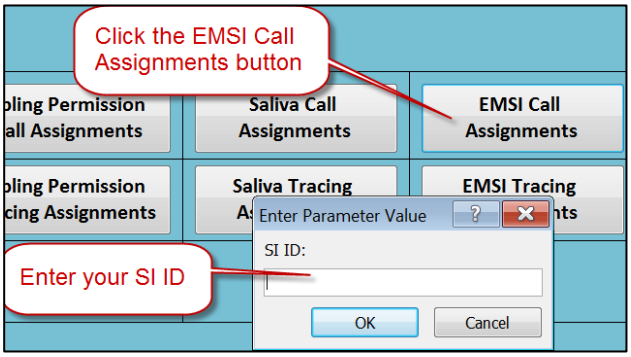
Tools:

1. **EMSI Home Visit Pilot Study Follow-Up Calls** (located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
2. CCSS SI Assignments database (located on the Sharepoint database site at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
3. EMSI study database (located on the Sharepoint database site at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
4. LTFU Participant database (located on the Sharepoint database site at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
5. **EMSI Home Visit Pilot Study Call Worksheet** (located at Z:\SJShare\SJCOMMON\ECC\Interviewers\EMSI Home Visit Study\Call Assignments)
6. **LTFU Participant Database Data Entry** (located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)

Procedures

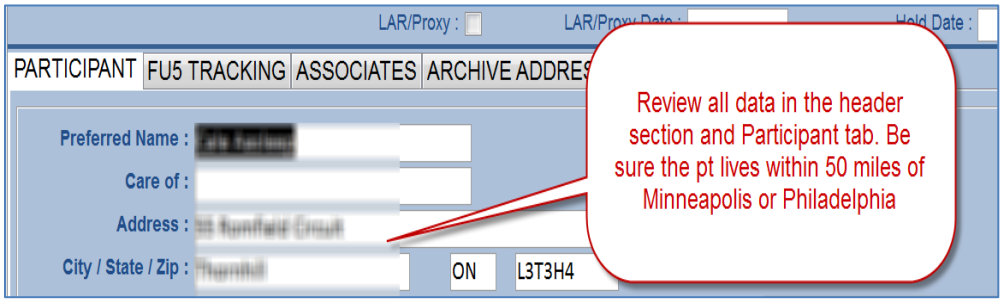
Before the Call - Create a Profile

1. Open the CCSS SI Assignments database. Select the **EMSI Call Assignments** button, enter the SI ID at the prompt, and click **OK**.



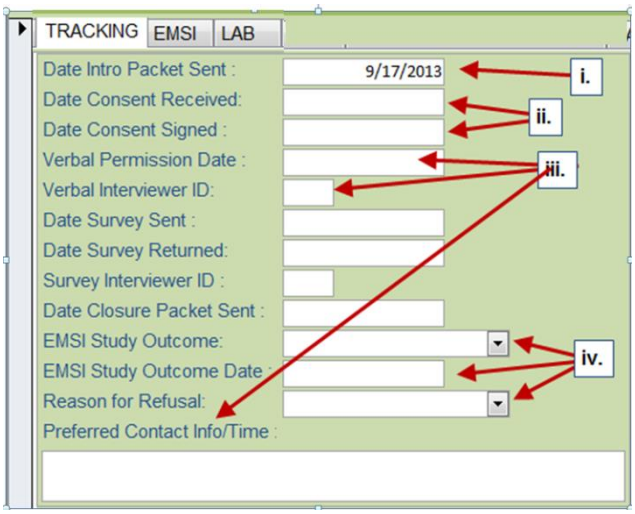
2. Open both the LTFU Participant database and the EMSI database. Find the first participant from the CCSS SI Assignments database in both the LTFU Participant and EMSI databases.

3. Review the following data in the participant's record:
   A. LTFU Participant database
      i. **Header section**: name, **Spanish Status**, **Date of Birth**, **Sex**, **Current Age**, **Alive**, **LAR/Proxy** status, **CCSS Study Outcome** (NOTE: If the **CCSS Study Outcome** field is populated, *DO NOT CALL* this participant. Check with an LSI on how to proceed.), **CCSS Hold**, **CCSS Hold Date**, **Contact Log/History**, and **Trace Log/History**



      ii. **PARTICIPANT tab**: **Preferred Name**, **Care of**, **Address**, **Address Date/Source**, **Date Last Phone Call**, time zone, **Phone Numbers**, **Ranks**, **Phone Types**, **Phone Dates**, **Phone Sources**, **Email**, **Email Dates**, **Email Sources**, **Notes**, **Tracing Code**, and **Tracing Date**
      NOTE: If the **Tracing Code** and **Tracing Date** fields are populated, check the **Trace History** in the header section and/or with the assigned Tracer to see if any progress has been made. If the fields are blank and the contact numbers are invalid, populate these fields as directed in the SOP titled **LTFU Participant Database Data Entry**.
   B. EMSI database - TRACKING tab

Note: Any changes made to fields on the Tracking tab require a dated comment in the **Notes** field and an email sent to the CRA.



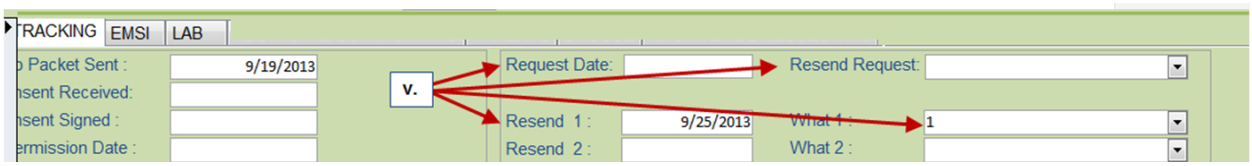
i. **Date Intro Packet Sent** and **Resend** dates – Determine *if* and *when* a packet was mailed. Calls should begin 14 days after the most recent date in these fields.

ii. **Date Consent Received** and **Date Consent Signed** – If these fields are populated, move to the next case in the assignments list.

iii. **Verbal Permission Date**, **Verbal Interviewer ID**, and **Preferred Contact Info/Time** –These fields are populated when a Survey Interviewer gains permission for EMSI to contact the participant.

iv. **EMSI Study Outcome**, **EMSI Study Outcome Date** and **Reason for Refusal** – These fields are populated if the participant refuses EMSI or refuses all else.

v. **Resend Request** and **Request Date** – These fields are populated if the participant requests a resend of the introductory packet. When the resend is processed, the CRA (Koko Kochar) will clear these fields and enter the date of the resend in the **Resend #** and **What #** fields.



During the Call - Gaining Permission and Information

Using a blank copy of the **EMSI Home Visit Pilot Study Call Worksheet**, contact the participant, follow the script, and complete the worksheet.

1. If the participant **received the packet**:
    A. Ask if the participant has reviewed the materials. If not, introduce the study.
    B. Ask if the participant is willing to participate.
        i. If there are **concerns** about an unknown technician visiting their home or other designated location, advise that:
            a. When EMSI receives the participant names from the LTFU Study Coordinating Center, their clinical study coordinators will call the participant to determine when the participant is available for testing.
            b. The coordinator will contact the branch office to set up the appointment, and then contact the participant again to (1) confirm the

date and time for the appointment and (2) provide the participant with the name of the examiner that will visit him/her.

c. Standard procedure requires the examiner to call the participant 24 hours prior to the appointment to confirm the appointment and introduce themselves to the participant.

d. Each technician is required to wear an EMSI identification badge when they are conducting the on-site visit.

ii. If the participant is **willing to participate**:

a. Thank the participant and gain permission for EMSI to contact him/her to set up an appointment.

b. Verify the participant's contact information including their preferred contact number and the best day and time for EMSI to call. If the participant's address is not the address we have on file:

1) Advise the participant that this study is recruiting only those that live within 50 miles of Minneapolis or Philadelphia.
2) Ask if the participant lives within the defined study range.
3) If the participant is outside the range by only 5 – 15 miles but is still interested in participating, take their information and advise that the study will call again after determining their eligibility.

NOTE: Participants are pre-selected to live within the eligible radius of 50 miles from Minneapolis or Philadelphia.

c. Ask for an additional contact number.

iii. If the participant is **undecided**, remind them to return the signed consent form if they decide to participate; otherwise, we will follow up with them periodically.

iv. If the participant **refuses to participate**:

a. Try to capture a reason for the refusal. If the participant has concerns that can be addressed, do so.

b. Clarify if the participant wants to refuse participation in the EMSI Home Visit Pilot Study only or all further participation.

2. If the participant **did not receive the packet**:

A. Verify the participant's contact information.

B. Introduce the study. If the participant's address is not the address we have on file:

i. Advise the participant that this study is recruiting only those that live within 50 miles of Minneapolis or Philadelphia.

ii. Determine if the participant lives within the defined study range.

iii. If the participant is outside the range by only 5 – 15 miles but is still interested in participating, take their information and advise that the study will call again after determining their eligibility.

C. Ask if the participant is willing to participate.

i. If there are **concerns** about an unknown technician visiting their home or other designated location, advise as indicated in the "received packet" instructions, above.

ii. If the participant is **willing to participate**:

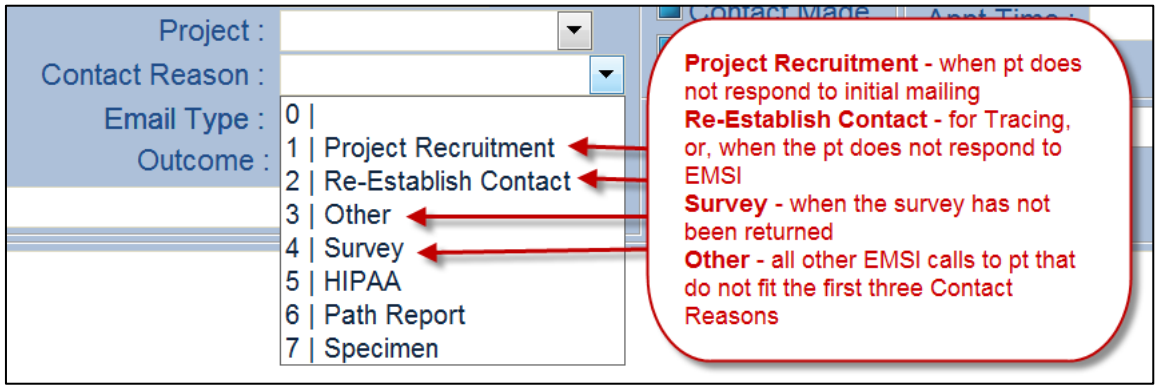
a. Thank the participant and gain permission for EMSI to contact him/her to set up an appointment.
b. Verify the participant's preferred contact number and the best day and time for EMSI to call.
c. Ask for an additional contact number.

iii. If the participant is **undecided**, offer to resend the packet and let them know we will follow up to see if they have questions.
iv. If the participant **refuses to participate**:
a. Try to capture a reason for the refusal. If the participant has concerns that can be addressed, do so.
b. Clarify if the participant wants to refuse participation in the EMSI study only or all further participation.

3. If the participant **does not speak English**, or if s/he prefers a Spanish-speaking interviewer:
A. And a Spanish-speaking interviewer is available, tell the participant, "Uno momento, por favor," and transfer the call to the Spanish-speaking interviewer.
B. And a Spanish-speaking interviewer is not available but the potential participant can understand, ask the best time for a Spanish-speaking interviewer to call back.
4. If it is determined that the potential participant has **expired**, offer condolences and (if possible) complete the **Expired Participant Information Sheet**.

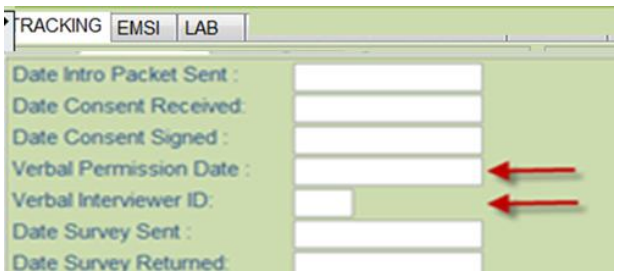
After the Call - Update, Email, File

1. Create a new **Contact Log** record in the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
A. **Project** – Use the drop-down menu to select EMSI.
B. **Contact Reason** – Use the drop-down menu to select the purpose of the call.



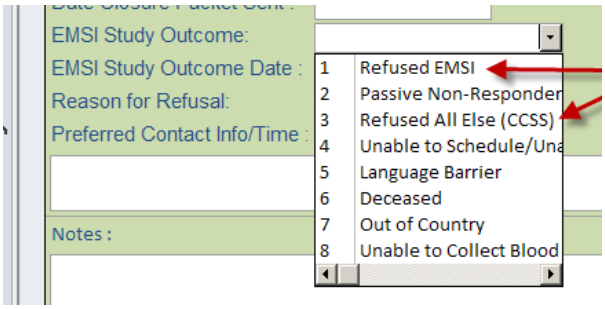
2. Update the LTFU Participant database with all confirmed contact information for the participant and his/her associates. See the SOP titled **LTFU Participant Database Data Entry** for detailed instructions.
3. **Permission Gained**
A. In the EMSI database's Tracking tab:

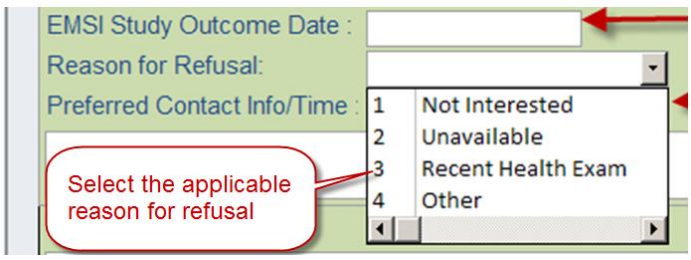
i. Enter the date in the **Verbal Permission Date** field.
ii. Enter your SI ID in the **Verbal Interviewer ID** field.
iii. Enter the participant's preferred day of the week and time to receive a call from EMSI in the **Preferred Contact Info/Time** field.
iv. Move to a new field, then click the Save icon in the Records section of the Home tab on the Access Ribbon.



B. Email the CRA and copy the Call Center Coordinator and Lead Survey Interviewer (LSI) team indicating the permission gained.
C. File the completed **EMSI Home Visit Pilot Study Call Worksheet** in the file folder labeled "Completed EMSI Worksheets", located in top drawer of the file cabinet A. (Retain and secure incomplete forms at your workstation until complete.)

4. **Permission Refused**
   A. In the LTFU Participant database:
      i. Populate the **Outcome** field in the contact log with 7-Refused. See the SOP titled **LTFU Participant Database Data Entry** for instructions on creating a contact log record.
      ii. If the participant **refuses all else**, update the **CCSS Study Outcome**, **CCSS Outcome Date**, and any other appropriate fields. See the SOP titled **LTFU Participant Database Data Entry** for detailed instructions on documenting "refused all else".
   B. In the EMSI database:
      i. Populate the **EMSI Study Outcome** field with:
         a. 1-Refused EMSI if the participant **refuses EMSI only**.
         b. 3-Refused All Else (CCSS) if the participant **refuses all else**.
      ii. Populate the **EMSI Study Outcome Date** with the current date.





iii. Populate the **Reason for Refusal** field by selecting from the drop-down menu.
iv. Enter additional explanatory information in the **Notes** field, if necessary.

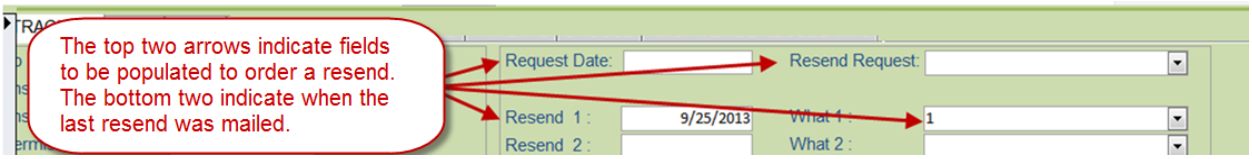
C. Email the CRA and copy the Call Center Coordinator and Lead Survey Interviewer (LSI) team indicating the refusal.

D. File the completed **EMSI Home Visit Pilot Study Call Worksheet** in the file folder labeled "Completed EMSI Worksheets", located in top drawer of the file cabinet A. (Retain and secure incomplete forms at your workstation until complete.)

5. **Resend Request**

A. In the EMSI database:

i. Populate the **Resend Request** and **Request Date** fields.
ii. Do not populate the **Resend #** and **What #** fields. When the resend is processed, the CRA will clear the **Resend Request** and **Request Date** fields and enter the date of the resend in the **Resend #** and **What #** fields.



B. Email the CRA and copy the Call Center Coordinator and Lead Survey Interviewer (LSI) team indicating the resend request.

6. **Needs Tracing** – In the LTFU Participant database, enter the appropriate tracing code in the **Tracing Code** field and the current date in the **Tracing Date** field. See the SOP titled **LTFU Participant Database Data Entry** for detailed instructions.
7. Log any **name change requests, vital status updates, etc.** in the **DB Change** field in the LTFU Participant database contact log. See the SOP titled **LTFU Participant Database Data Entry** for detailed instructions.

Re-Establishing Contact

On occasion, EMSI is unable to reach a participant that has agreed to participate in the EMSI Home Visit Pilot Study. After the maximum number of contact attempts, as established by EMSI, the study coordinator will request that an SI re-establish contact with the participant.

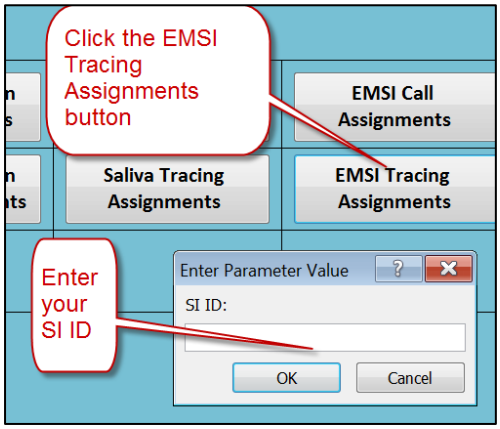
When the participant is reached, the SI should:

1. **Explain** to the participant that EMSI has been unable to reach him/her to arrange the home visit.
2. **Verify** the participant's preferred contact number and the best day and time for EMSI to call.
3. For participants reached via an **outgoing call**:

A. Provide the toll free EMSI Clinical Services Hotline number at 866-202-5310 to the participant.
B. Let the participant know that we will also relay his/her contact information to EMSI.
C. Call the toll free EMSI Clinical Services Hotline number at 866-202-5310 and provide them with the participant's information.

4. For participants reached via an **incoming call**, transfer the participant to the EMSI Clinical Services Hotline at 866-202-5310 using the standard transfer process as described in the document titled **Transferring Calls 101**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers \Calling Tools*.
    A. If an EMSI representative is reached, introduce the call to the representative before completing the transfer (i.e. "warm transfer" the call).
    B. If an EMSI representative does not answer during the transfer process:
        i. Leave a message asking EMSI to call the participant at the preferred contact number and on the best day and time, as gathered above. Do not complete the transfer.
        ii. Provide the EMSI Clinical Services Hotline number at 866-202-5310 to the participant, and ask him/her to call again later to schedule the EMSI visit.
5. **Send an email** to the EMSI Home Visit Pilot study coordinator regarding the outcome of the call.

The Tracing Process



1. The Tracer will open the CCSS SI Assignments database, click on the **EMSI Tracing Assignments** button, enter his/her SI ID, and click **OK**.
2. The Tracer will trace the participant and:
    a. If contact is made, the Tracer will use a blank **EMSI Home Visit Pilot Study Call Worksheet** and the section of this document titled *During the Call - Gaining Permission and Information* to:
        i. Introduce the study.
        ii. Attempt to gain permission for EMSI to contact the participant and obtain the best phone number, time of day, and day of the week for EMSI to contact the participant.
        iii. Verify or gain contact information.
        iv. Obtain additional contact information.
        v. Document the reason for refusal, if applicable.
    b. If commitment is gained or refused, the Tracer will use the section of this document titled *After the Call - Update, Email, File* to:
        i. Update the LTFU Participant database and EMSI database.
        ii. Email the CRA and copy the Call Center Coordinator, the LSI team, and the entire EMSI interviewer team.
        iii. File the completed worksheet in the "Completed EMSI Worksheets" file folder.

Revision Record Printed 2/10/2015 7:39 AM

Current Filename [261]:		EMSI Home Visit Pilot Study Follow-Up Calls ver 2_2.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/10/13	R. Massey	Initial Development
1.1	7/22/13	R. Massey, D. Rinehart	Content and format revision
1.2	7/25/13	D. Rinehart, R. Massey, A. McDonald, K. Kochar	Content Revision
1.3	7/31/13	R. Massey	Add Purpose Reason field instructions for call log
1.4	8/20/13	K. Kochar, D. Rinehart, R. Massey	Content Revision: Updated database screenshots
1.5	9/26/2013	D. Rinehart, R. Massey, T. Thomas	Content Revision: Added Tracing Process, updated screen shots
1.6	10/21/2013	R. Massey	Content Revision: add verbiage regarding EMSI procedures.
2.0	10/1/2014	T. Thomas, D. Rinehart, R. Massey	Content Revision: expanded background, updated assignments and db refs, added directive for pts to reside in study radius
2.1	11/18/2014	D. Rinehart, R. Massey	Content Revision: Add directives for re-establishing contact
2.2	1/28/2015	D. Rinehart, R. Massey	Content Revision: Updated directives for re-establishing contact

Envelope Guidelines – Bulk and First Class

Background

We package questionnaire materials in white 10x13 mailing envelopes. We include a blue self-addressed return envelope with questionnaire materials so the participant can return the completed questionnaire to us. The types of envelopes utilized depend on two factors:

1. U.S. vs. International Resident
2. Bulk vs. First Class Mailing

Note - See the Bulk and First Class Mailing Guideline/Procedure for additional information on when to use Bulk vs. First Class mailing.

Bulk Mailing (200 pieces or more AND 50 lbs or more)

- U.S. Participants
  - White mailing envelope **with** indicia
  - Blue return envelope **with** indicia
  - NOTE: Place the address label on the BULK MAIL envelope in the lower right quadrant. Otherwise, the post office will refused to send by bulk mail.
- Canadian Participants
  - White mailing envelope **without** indicia
  - Blue return envelope **without** indicia (place two Canadian stamps in the upper right hand corner of the envelope)
- Other International Participants
  - White mailing envelope **without** indicia
  - Blue return envelope **without** indicia

First-class Mailing

- U.S. Participants
  - White mailing envelope **without** indicia
  - Blue return envelope **with** indicia
- Canadian Participants
  - White mailing envelope **without** indicia
  - Blue return envelope **without** indicia (place two Canadian stamps in the upper right hand corner of the envelope)
- Other International Participants
  - White mailing envelope **without** indicia
  - Blue return envelope **without** indicia

Revision Record Printed 7/6/2012 11:33 AM

Current Filename:		Envelope Guidelines-Bulk and First Class ver 2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	2/19/09	G. Garner	Initial Development
2	7/7/11	J.Bates	Address label placement-bulk mail

EQUAL Daily Procedures

Background

This document summarizes the daily procedures to follow after EQUAL submissions are downloaded from Datstat. The procedure includes running queries, identifying participant eligibility, updating contact information and responses in databases, completing EQUAL eligibility checklist form and consent, and emailing enrolled participant data to Memorial Sloan Kettering Cancer Center team.

Procedures

1. In EQUAL database, run mcrEQUALDatStatUpdate
    a. Select "Yes" for each prompt
2. Run qry_Ineligible_UpdateReason
    a. This query identifies anyone who started or completed the EQUAL baseline survey, is ineligible, and we haven't updated the Ineligible Reason in the database
    b. For each participant, view the eligibility question responses and select the best Ineligible Reason in the database
3. Run qry_EligConsentNo_AdrsPhnInfo
    a. This query identifies anyone who completed the EQUAL baseline survey, is eligible, but refused to participate
    b. For each participant, see if the participant provided any address and phone info and update the LTFU database accordingly
4. Run qry_PPRList
    a. This query identifies anyone who completed the EQUAL baseline survey, is eligible, consented to EQUAL, and has not been sent to PPR for randomization
    b. For each participant, see if the participant provided any address, phone, and email info and update the LTFU database accordingly (Archiving Addresses as needed)
    c. In EQUAL, go to participant record and click DatStat Data
    d. Open EQUAL ECL 2-26-16.pdf
        i. Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\EQUAL (Tonorezos)\PPR Registration
        ii. Update form using data from EQUAL database
        iii. Save as *EQUAL Study Eligibility Checklist_[CCSSID] [Current Date].pdf* here:
            1. Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\EQUAL (Tonorezos)\PPR Registration
    e. Open CCSS EQUAL Consent (3).doc
        i. In header, update CCSSID and Name
        ii. Print to PDF and save as "*EQUAL Consent_[CCSSID] [Current Date].pdf* here:
            1. Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\EQUAL
    f. Send Checklist and Consent forms to MSKCC via encrypted email (type "[ENCRYPT]" as the first word in the "Subject" line of your email)
        i. Send to adsuarr@mskcc.org, mudbin@mskcc.org, and anderson@mskcc.org

ii. Copy Aaron McDonald

g. Enter current date in Date Information Sent to PPR field in EQUAL database

5. Update LTFU Participant Database
    a. Click DatStat Data in the EQUAL Database
    b. Check the Updated Address (the last 4 rows) in the EQUAL database against the LTFU Database.
    c. Update the new address and date in the LTFU using the date of consent. Note: If the participant did not provide a new address or confirm the listed address, do not update.
    d. Update the email address and use the date of consent.
    e. Update the phone number and use the date of consent.
6. Update the study group in EQUAL Database
    a. MSK will send an email classifying participants in a group (control or intervention).
    b. Click the drop down menu in the EQUAL database and select the appropriate group.
    c. Add a note with today's date "Per [name], participant has been randomized in the [insert group]. [initials]

Revision Record Printed 5/19/2016 3:27 PM

[311] Current Filename:		EQUAL Daily Procedure ver 1.docx	
Revision No.	Date	Responsible Author	Change Description
1	5/19/16	L. Bonner	Initial Development

EQUAL Study Calls

Background

The Exercise and Quality Diet after Leukemia (EQUAL) Study, which began in 2015, seeks to enroll 400 adult Long-Term Follow-Up (LTFU) Study participants who are survivors of childhood acute lymphoblastic leukemia (ALL) and who are obese. The purpose of the study is to determine if diet and exercise can help participants lose weight and improve other health issues. The Principal Investigator (PI) is Dr. Emily Tonorezos at Memorial Sloan Kettering (MSK) Cancer Center. Johns Hopkins University is also an EQUAL Study partner.

The EQUAL Study is a two-year study that will compare two methods of informing participants about ways to lose weight. Participants will be randomized into one of two groups. Group A participants will be assigned a health coach offering internet-based weight loss support. Group B participants will receive written materials that include lists of resources for a self-directed program.

Each group will be asked to complete 3 online questionnaires and 3 in-home visits where representatives from Examination Management Services, Inc. (EMSI), will draw blood and take height, weight, and blood pressure measurements. The questionnaires and in-home visits will occur upon enrollment, 12 months post-enrollment, and 24 months post-enrollment. Participants will receive a $50 gift card after completion of each survey plus in-home visit but will not receive individual results.

Introductory packets will be mailed by the LTFU Coordinating Center to the selected participants. One week following the mailing, a reminder email will be sent to the participants. Survey Interviewers (SIs) will begin calls to non-responders one week following the reminder email. Calls are made to confirm receipt of the study materials, answer questions, and direct the participants to the website for survey completion.

Tools

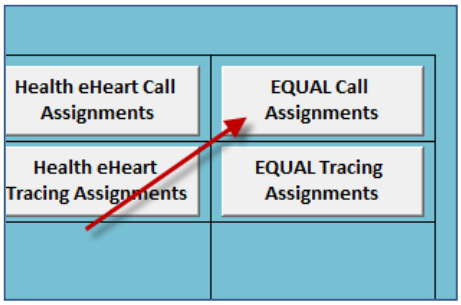
1. CCSS SI Assignments database, located at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
2. CCSS LTFU Participants database, located at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
3. EQUAL database, located at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
4. **Pre-Post Call Checklist – EQUAL Study Calls**, located in the SOP library at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
5. **EQUAL Study Calls**, located in the SOP library at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
6. **LTFU Participant Database Data Entry**, located in the SOP library at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*

7. **Phone Message Guidance_Rev 5-30-2014**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools*
8. **EQUAL Study Baseline Calls Script**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\EQUAL Study\Scripts*
9. **EQUAL Baseline Email Template**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\EQUAL Study\Email*

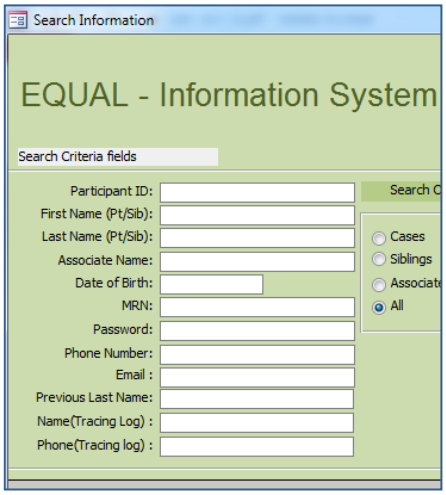
Procedures

Before the Call

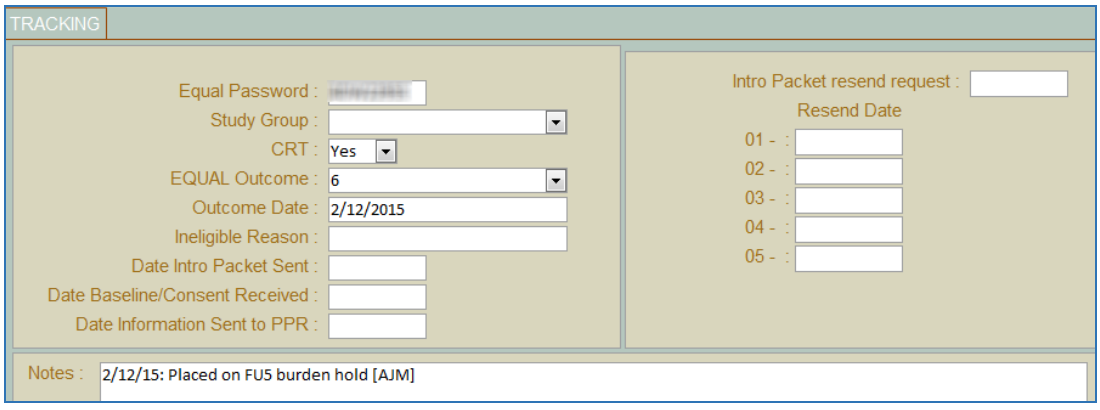
1. Locate the first participant to be called.
   A. Open the CCSS SI Assignments database. Click the **EQUAL Call Assignments** button, enter the SI ID at the prompt, and click **OK**.
   B. Note the first participant in the assignment list. If s/he is in multiple studies, as indicated in the "# of Studies" column, prepare to address the EQUAL study and the other studies in the same call. Coordination with another SI may be necessary.



2. Open both the CCSS LTFU Participants and the EQUAL databases, and locate the participant in each database using the participant ID from the assignments list, above. See the SOP titled **LTFU Participants Database Data Entry** for instructions on using the Search Information screen in both databases.



3. Review the following data in the participant's record:
   A. CCSS LTFU Participants database – Review all fields indicated in the **Pre-Post Call Checklist – EQUAL Study Calls** to create a pre-call profile.
   B. EQUAL Database



i. **EQUAL Outcome** field – If this field is populated, do not call the participant. S/he has already consented, refused, been determined to be deceased or ineligible, or been placed on a burden hold.
ii. **Notes**
iii. **Date Intro Packet Sent** and **Resend Dates**

During the Call:

Use the **EQUAL Study Baseline Calls Script** and **Phone Message Guidance_Rev 5-30-2014** to make calls to assigned participants.

1. If the participant **received the packet**:
   A. Ask if the participant has reviewed the materials. If not, introduce the EQUAL study.
   B. Answer the participant's questions about the study.
   C. Ask if s/he is willing to participate in the EQUAL Study.
      i. **If yes**:
         a. Advise the participant to access the website www.stjude.org/ltfu-EQUAL and use his/her password to enroll. Offer to email the link.
         b. SIs will not complete the survey via telephone. If the participant requests to complete the survey via telephone, politely explain that the EQUAL Study is a technology-based study in which all surveys are completed online. However, special cases can be evaluated by the Research Scientist.
      ii. **If no**:
         a. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
         b. If it is unclear if the participant is refusing just the EQUAL Study or all further participation in the LTFU Study, clarify.
      iii. If the participant **does not have a personal email address and/or access to the internet**:
         a. Thank the case for making us aware of this.
         b. Advise that because the EQUAL Study is technology-based, the case is not eligible.
         c. Email the Research Scientist, Project Coordinator, Call Center Coordinator and the LSI Team about this outcome. Please include the participant's CCSSID in the subject line and in the email body.
      iv. If the participant **does not want to participate because they do not want the EMSI team to come to their home**:
         a. Thank the case for making us aware of this inconvenience.
         b. Advise that you will ask your supervisor if there is any possibility for the case to meet the EMSI tech at an agreed upon location, somewhere other than the case's home.
         c. Email the Research Scientist, Call Center Coordinator, Study CRA1 and the LSI team to inform of the situation.
   D. Confirm all contact information.

E. Thank the case for his/her participation in the LTFU Study.

2. If the participant **did not receive the packet**:
   A. Verify the participant's contact information.
   B. Introduce the EQUAL Study.
   C. Answer the participant's questions about the study.
   D. Ask if s/he is willing to participate in the EQUAL Study.
      i. **If yes**:
         a. Advise the participant how to enroll online at www.stjude.org/ltfu-EQUAL using his/her password. Offer to email the link.
         b. SIs will not complete the survey via telephone. If the participant requests to complete the survey via telephone, politely explain that the EQUAL Study is a technology-based study in which all surveys are completed online. However, special cases can be evaluated by the Research Scientist.
      ii. **If no**:
         a. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
         b. If it is unclear if the participant is refusing just the EQUAL Study or all further participation in the LTFU Study, clarify.
      iii. If the participant **does not have a personal email address and/or access to the internet**:
         a. Thank the case for making us aware of this.
         b. Advise that because the EQUAL study is technology-based, the case is not eligible.
         c. Email the Research Scientist, Project Coordinator, Call Center Coordinator and the LSI Team about this outcome. Please include the participant's CCSSID in the subject line and in the email body.
      iv. If the participant **does not want to participate because they do not want the EMSI team to come to their home**:
         a. Thank the case for making us aware of this inconvenience.
         b. Advise that you will ask your supervisor if there is any possibility for the case to meet the EMSI tech at an agreed upon location, somewhere other than the case's home.
         c. Email the Research Scientist, Call Center Coordinator, Study CRA1 and the LSI team to inform of the situation.
   E. Thank the case for his/her participation in the LTFU Study.

3. If the participant **requires or prefers a Spanish-speaking SI**:
   A. And a Spanish-speaking SI is available, tell the participant, "*Un momento, por favor*," and transfer the call to the Spanish-speaking SI.
   B. And a Spanish-speaking SI is not available but the participant can understand, ask the best time for a Spanish-speaking interviewer to call back.

4. If it is determined that the participant is **deceased**, offer condolences and, if possible, complete the **Expired Participant Information Sheet**. Do not pursue participation.

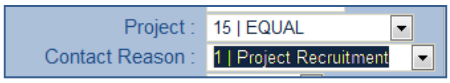
5. If the case is **disabled** (cognitively or physically):
   A. Obtain as much information as possible regarding the disability and the case's physical limitations, if any.
   B. Advise that the researchers will make a determination on the case's participation eligibility.
   C. Cases with LAR's are **not** eligible for the EQUAL study.
   D. Email the Research Scientist, Project Coordinator, Call Center Coordinator and the LSI Team to notify of the case's ineligibility.

After the Call:

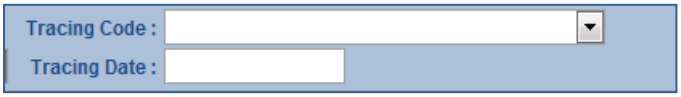
1. **Send the enrollment email**, if requested by the participant.
   A. Open the **EQUAL Baseline Email Template**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\EQUAL Study\Letters and emails*.
   B. Create a new email in Outlook.
      i. Copy the body of the template, and paste it into the body of the new email using the "Keep Source Formatting" paste option.
         a. Replace any automatic Outlook signature in the body of the email with the signature in the template.
         b. *Do NOT copy and paste the subject line* from the template to the body of the email.
      ii. Copy the subject line from the template (NOT the words "Subject Line:"), and paste it into the **Subject:** bar of the new email.
      iii. Without saving changes to the template, close the template.
   C. Personalize the new email.
      i. Update the greeting in the email with the correct salutation and name.
      ii. Replace "[from the EQUAL database]" in the body of the email with the correct password. Copy the value from the participant's EQUAL database record, and paste it using the "Match Destination Formatting" option.
      iii. In the signature of the email, replace "[Survey Interviewer's Name]" with the first and last name of the SI sending the email.
   D. Copy the participant's email address from the LTFU Participant database, and paste it into the **To…** bar of the email.
   E. Proofread the email to ensure there are no mistakes.
   F. Send the email.
   G. Document the email in the LTFU Participant database's contact log. See the "Update the LTFU Participant database" instructions, below, for details.
   H. EQUAL Study database, **Notes** field – Log a dated note with your SI ID documenting that the enrollment link was sent.

2. Request **participation determination for disabled cases** – If the case is disabled, and does NOT have an LAR, email the Research Scientist and Project Coordinator for a determination on the case's EQUAL Study participation eligibility. In the email:
   A. **To…** bar – Populate with the email addresses for the Research Scientist and the Project Coordinator.
   B. **Cc…** bar – Populate with the email addresses of the Call Center Coordinator and LSI team members.
   C. **Subject:** bar – Type "EQUAL: Request Participation Eligibility Determination – CCSSID" followed by the case's CCSSID.
   D. Email body – Request that an eligibility determination be returned for the case's participation.
      i. Include a clear, concise, and complete summary of the participant's disability and physical limitations.
      ii. Include the case's CCSSID in the email body.

3. **Update the CCSS LTFU Participant database**:
   A. Contact/Trace Log – Create a new contact or trace log record for each communication (call, email, etc.). See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
      i. **Project** – Choose 15-EQUAL.
      ii. **Contact Reason** – Choose 1-Project Recruitment.



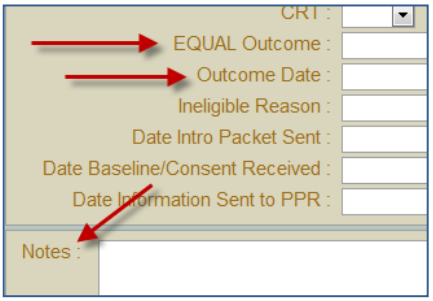
   B. Update the LTFU Participant database with all confirmed contact information for the participant and his/her associates. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
   C. Hold – Update the **CCSS Hold** and **Hold Date** fields if the participant requested or agreed to a hold. See the SOP titled **LTFU Participant Database Data Entry** for full instructions. Holds are documented in the LTFU Participant database only.
   D. Needs Tracing – Update the **Tracing Code** and **Tracing Date** fields on the Participant tab. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.



4. **Refusals** – If the participant refused participation in the EQUAL Study or refused all further participation in the LTFU Study:
   A. LTFU Participant database
      i. Contact Log or Trace Log:
         a. **Project** – Choose 15-EQUAL.
         b. **Contact Reason** – Choose 1-Project Recruitment.
         c. **Outcome** field of the contact or trace log – Populate with 7-Refused.
      ii. Refused EQUAL Study *ONLY* – Do NOT update the **CCSS Study Outcome** or **CCSS Outcome Date** fields.

iii. Refused All Else (i.e. the case refused all further participation in the LTFU Study) – Update the **CCSS Study Outcome** or **CCSS Outcome Date** fields in the header. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.

B. EQUAL database



i. **EQUAL Outcome** – Populate with the appropriate outcome.
   a. 2-Refused – Use this code if the participant refused the EQUAL Study ONLY.
   b. 3-Refused all else – Use this code if the participant refused all further participation in the LTFU Study.

ii. **Outcome Date** – Populate with the current date.

iii. **Notes** – Enter a dated note with SI ID documenting the refusal and the changes to the outcome fields. Indicate if the participant refused the EQUAL Study only or refused all else.

C. Email the Research Scientist, Project Coordinator, Call Center Coordinator and the LSIs to inform of the refusal. Include the participant's CCSSID in the subject line and in the email body.

5. **Ineligible** – If the participant is suspected to be ineligible, including ineligibility due to lack of access to technology (e.g. no personal email address):

A. LTFU Participant database – In the Contact Log or Trace Log:
   i. **Project** – Choose 15-EQUAL.
   ii. **Contact Reason** – Choose 1-Project Recruitment.
   iii. **Outcome** – Populate with 10-Other.
   iv. **Notes** – Document the circumstances of the suspected ineligibility.
   v. **DB Change** – Populate with 4-Ineligible.

B. EQUAL database
   i. **Notes** field – Enter a dated note with your SI ID explaining the suspected ineligibility.
   ii. No other fields are updated in the EQUAL database. The LSI team will follow up.

C. Email the Research Scientist, the Project Coordinator, Call Center Coordinator and the LSIs to inform of the participant's ineligibility. Include the participant's CCSSID in the subject line and in the email body.

6. **Deceased** – If it was discovered that the participant is now deceased:

A. LTFU Participant database
   i. In the Contact Log or Trace Log:
      a. **Project** – Choose 15-EQUAL.
      b. **Contact Reason** – Choose 1-Project Recruitment.
      c. **Outcome** – 8-Deceased
      d. **DB Change** – 6-Survival Status
   ii. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.

B. EQUAL database
   i. **EQUAL Outcome** – Populate with 4-Deceased.
   ii. **Outcome Date** – Populate with the current date.
   iii. **Notes** – Enter a dated note with SI ID documenting the newly discovered deceased status and the changes to the outcome fields.

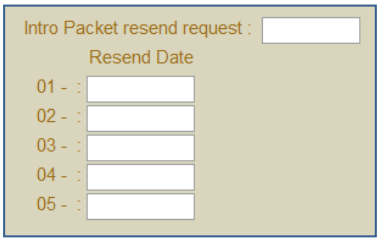
C. **Expired Participant Information Sheet** – Submit the completed form in the "Refusals and Deceased" folder in file cabinet A.

D. Email the Research Scientist, Project Coordinator, Call Center Coordinator and the LSIs notifying about this outcome. Include the participant's CCSSID in the subject line and in the email body.

7. **Resend Requests** – If the participant requested a resend of the paper introductory packet:

A. LTFU Participant database – In the Contact Log or Trace Log:
   i. **Project** – Choose 15-EQUAL.
   ii. **Contact Reason** – Choose 1-Project Recruitment.
   iii. **Outcome** – 5-Resend

B. EQUAL database – On the Tracking Tab:
   i. **Intro Packet resend request** – Populate with the current date.
   ii. **Notes** – Add a dated comment with SI ID documenting the resend request, as instructed below.



Revision Record — Printed 10/13/2015 1:34 PM

[288] Current Filename:		EQUAL Study Calls ver1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	3/10/2015	R. Massey, A. Oyuela, D. Rinehart	Initial Development
1.1	5/9/2015	R. Massey	Content Revision
1.2	9/23/2015	A. Stock, R. Daniels, C. Cantú-Voyles, A. DiScenza	Content Revision – Ineligibility due to LAR, pt does not want EMSI in the home, contact/trace log fields

Evaluations of Cardiovascular Health Outcomes among Survivors (ECHOS) Study Calls

Background

The purpose of this study is to find out how we can inform cancer survivors about possible heart-related health risks. Participants are invited to participate in this study by completing a survey, and are then randomized into two groups. One of the groups will receive two 15 minute phone calls from a nurse practitioner. Participating in this study takes approximately 2 hours of your time over a 1-year period. To thank the participant for their time and information, they receive a $50 check after each questionnaire is completed.

Principal Investigators: Melissa Hudson, MD and Cheryl Cox, PhD, and Brenda Steen is coordinator (St. Jude)

SRC Interview Role

Current SI's assigned: Demetrius Jackson, Justin Currie and Carol Lee

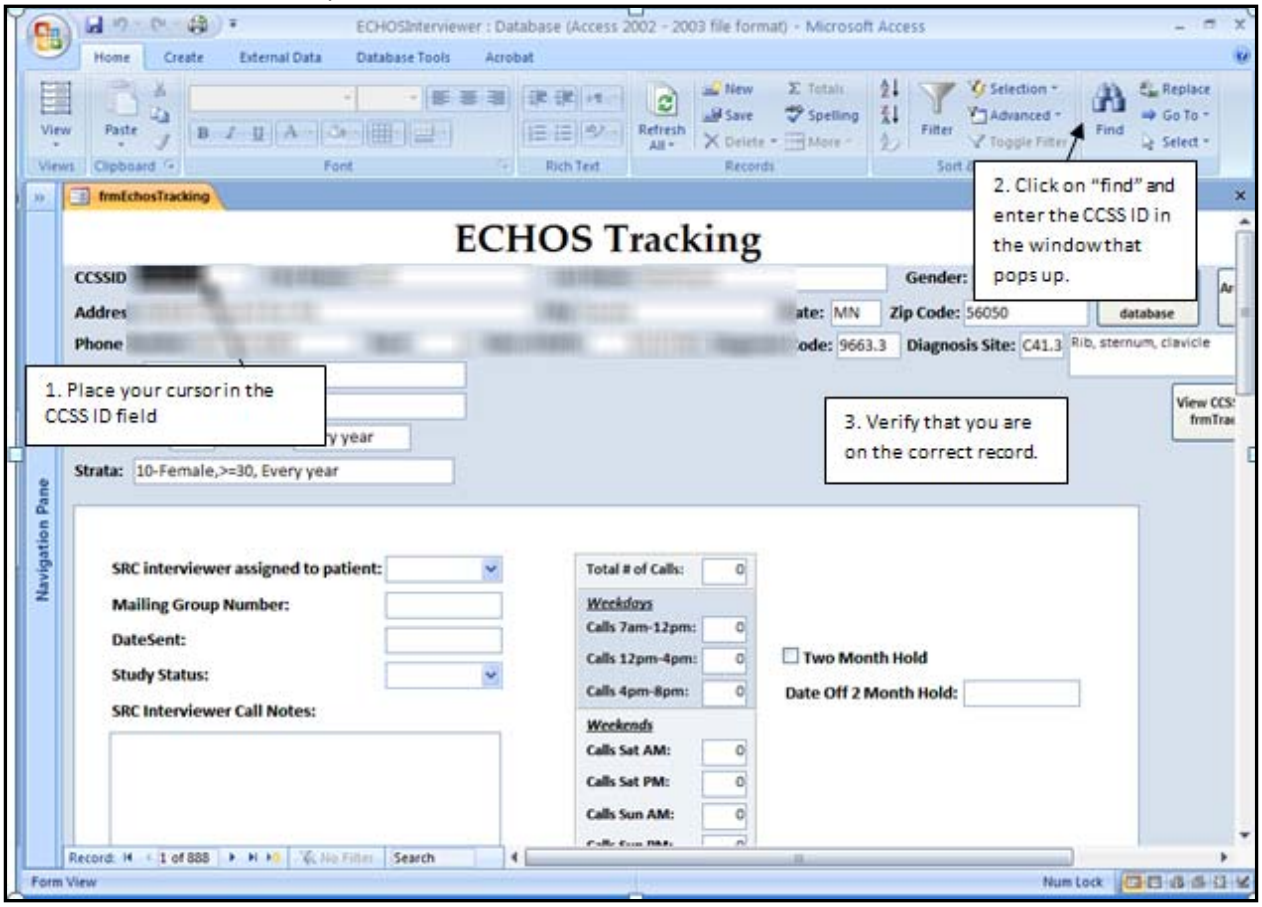
- Your main role will be to contact the participant and remind them about the enrollment packet, document which participants are not interested, need a call from a study nurse, or a new enrollment packet. You will also update participant contact information as needed.
- All interactions with potential participants will be noted in the ECHOS SRC database (see below).
- Your calls will begin with the 99 participants who we currently have not been able to contact (i.e., passive non-responders). You will be provided with a list. These participants are from mailings 1, 2, 3, 4 and currently are assigned study status 13 (on hold). We may not have the correct phone or address for some of these individuals, although many have been sent to tracing.
- Phone calls may continue until the participant is enrolled or declines study participation. (IRB revision 0.2, not yet approved), but see additional notes below.
- Enrollment packets will be returned to Aimee Santucci.
- Subsequent mailings will target potential participants who have not yet received an enrollment packet. We anticipate sending 100 packets per mailing.

Procedures

ECHOS SRC Database:

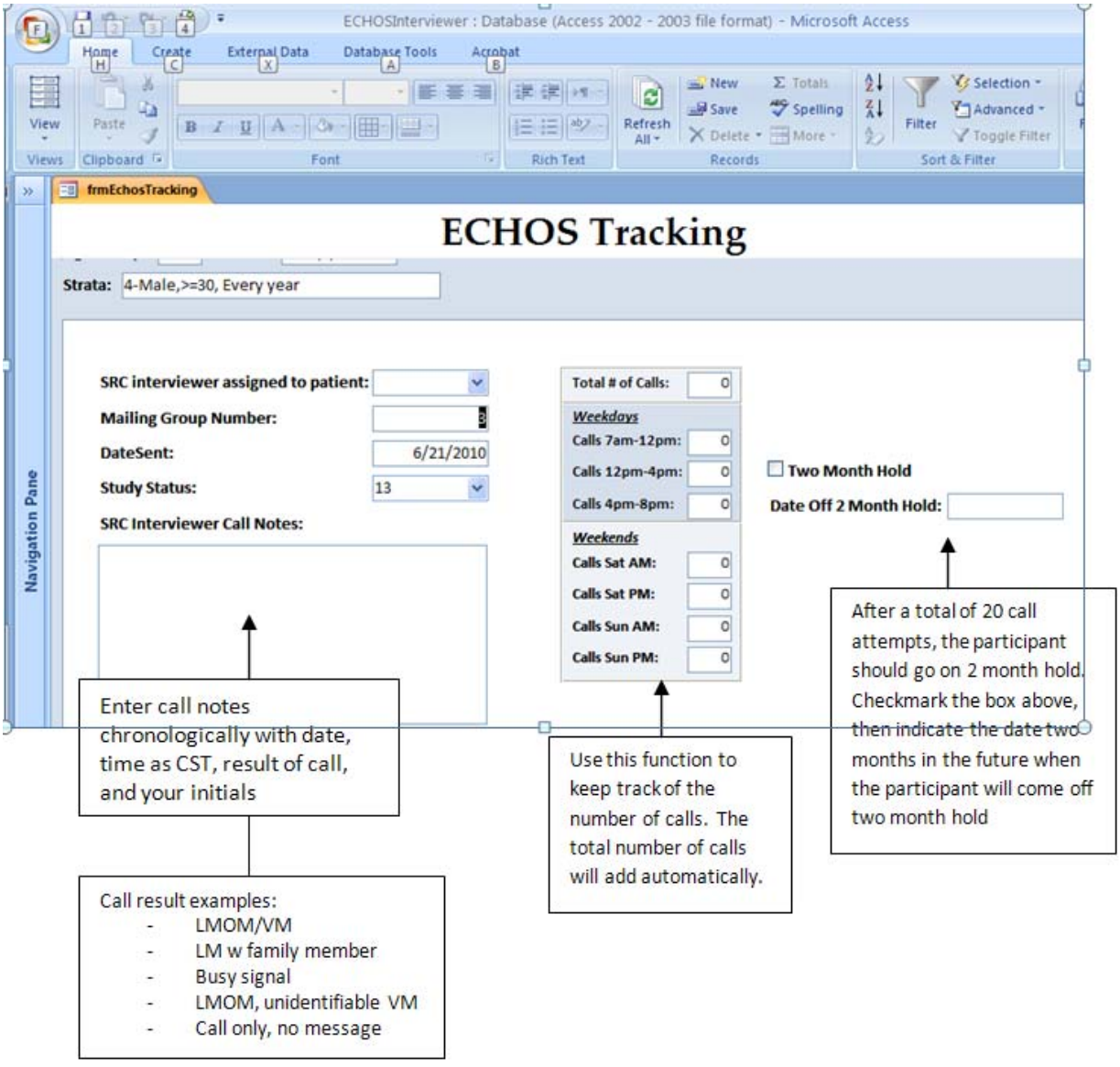
- This database is stored in the following path: "Z:\Archive\ECC\ECHOS\Databases\SRCInterviewer". You should have access to this; if not please contact the ECHOS coordinator (Brenda Steen).

- Every potential ECHOS participant is in the database. You will receive a list of CCSS IDs/Names who need follow-up calls. To find a new record:



- The SRC ECHOS database is linked to the main ECHOS db. If a change in study status is made on either end, this change will be reflected in both databases.
- **<u>The SRC will utilize the following statuses. If new statuses need to be created, please contact the ECHOS study coordinator.</u>**
    1. 0 = new enrollment packet sent: When a NEW mailing is sent, the mailing number will be reflected in the tracking db, and the participant will receive an initial study status of 0.
    2. 4 = Death
    3. 9 = interested (the participant received the packet and intends to return it)
    4. 10 = declined
    5. 14 = in tracing
    6. 15 = interested/pending enrollment packet and consent (use this when the participant indicates interest and will return the packet to us)
    7. 17 = send new enrollment packet (ECHOS team will send)
    8. 18 = study nurse follow-up with patient (e.g., participant interested but wants to discuss previous heart screening)

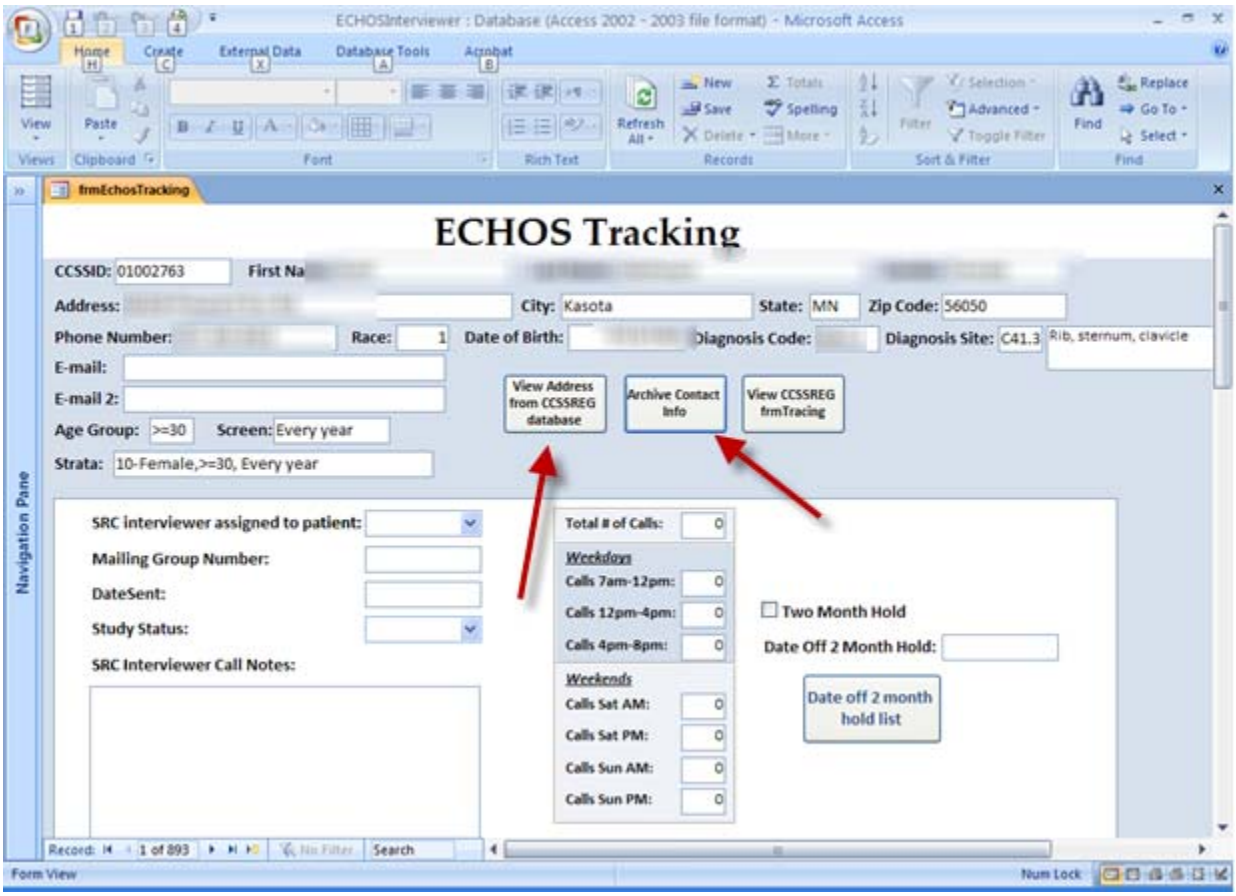
- If a participant requires a new enrollment packet, the ECHOS study team will change the "date sent" field and reset the study status to 0. Those participants will need a follow-up call to determine whether they received the new packet.
- You can also update the status dropdown with vital status information and overall outcomes information in REG (e.g., declined participation in all CCSS studies). Assign status "declined" (10) and indicate in notes that this applies to all CCSS studies.
- All calls and call notes should be tracked in the fields below:



- The ECHOS study team will be receiving packets, so you periodically may see the study status changed (e.g., enrolled, declined, ineligible) when you are due to make additional calls for a participant. This means we have received an enrollment packet, or a participant talked with a study

nurse and was found ineligible or not interested. If this occurs that participant is taken off your call list.

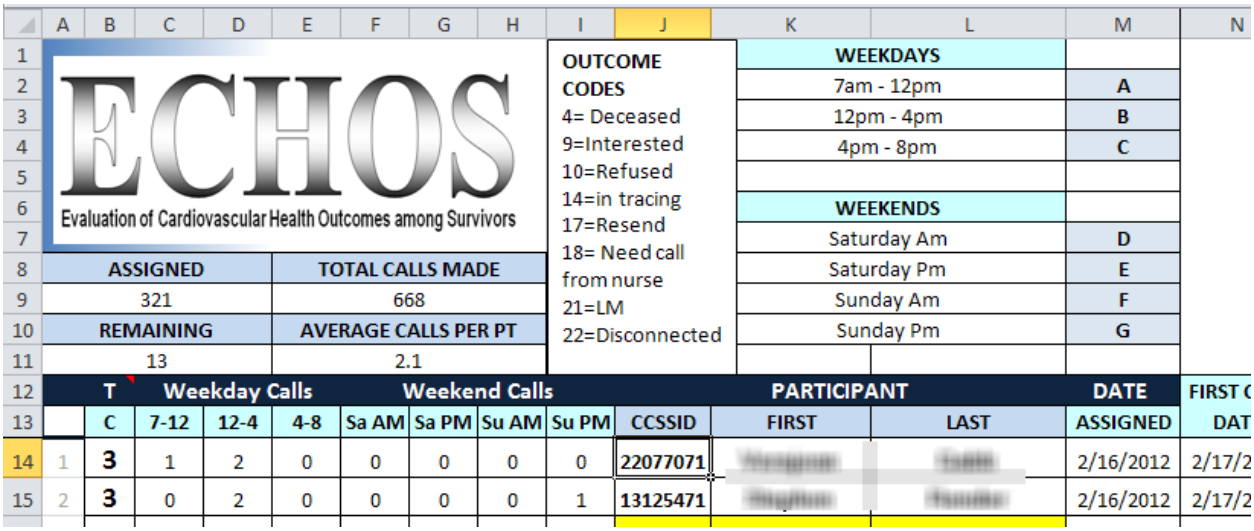
- You may use any additional contacts you have in CCSS Reg to track a potential participant.
- If a participant provides a new address, phone, or email, press the "archive contact info" button, then delete the old information and enter the new information. Indicate the source of the new information in call notes (e.g., participant, spouse, parent, tracing info).
    - Also send the Lead SI (Melanie) an email with the new contact information (address, phone, email, etc) so she can update the CCSS Reg Database.



In order to access the CCSSREG database to determine whether a new address, phone or email are available, you can press the CCSS REG button. This will bring up a window with CCSSREG information.

ECHOS Call Assignments:

- Brenda Steen will assign the participants who need calls. The list of these participants will be sent to Dayton Rinehart, Coordinator, who will update "The New ECHOS Workbook mm-dd-yyyy.xlsx," located: "Z…Interviewers\ECHOS



ECHOS
Evaluation of Cardiovascular Health Outcomes among Survivors

ASSIGNED	TOTAL CALLS MADE
321	668
REMAINING	**AVERAGE CALLS PER PT**
13	2.1

OUTCOME CODES
4= Deceased
9=Interested
10=Refused
14=in tracing
17=Resend
18= Need call from nurse
21=LM
22=Disconnected

WEEKDAYS	
7am - 12pm	A
12pm - 4pm	B
4pm - 8pm	C
WEEKENDS	
Saturday Am	D
Saturday Pm	E
Sunday Am	F
Sunday Pm	G

	T	Weekday Calls			Weekend Calls					PARTICIPANT		DATE	FIRST C
	C	7-12	12-4	4-8	Sa AM	Sa PM	Su AM	Su PM	CCSID	FIRST	LAST	ASSIGNED	DAT
1	3	1	2	0	0	0	0	0	22077071	[redacted]	[redacted]	2/16/2012	2/17/2
2	3	0	2	0	0	0	0	1	13125471	[redacted]	[redacted]	2/16/2012	2/17/2

Before making the call:

- See "Pre-Post Procedure - ECHOS Calls ver1_1.docx," located: Z…Interviewers\Calling Tools\Pre and Post Call Check Lists, review all data in the database and the Participant Call Log, located: "Z…Interviewers\Original Cohort Call Logs - Reg db"

Review the Script:

For leaving voice messages:

1. If you are 100% confident that you've reached the voicemail of the participant (or their legal representative), then you can leave a message similar to:
    a. "Hello, this is <interviewer name> calling from the Long Term Follow-Up study. I am calling for <participant name> regarding some information we recently mailed. Please call me at <number>. Thank you very much."
2. If you speak with a live person (not the participant) who indicates we've reached the right number, then you can say something similar to "I am trying to reach <participant name> regarding some materials that we sent from the Long Term Follow-Up study."
    a. Still be very cautious.
3. If you reach a generic voicemail, then say something similar to the following:
    a. "Hello, this is <interviewer name>. I am trying reach <participant name>. Please call me at <phone number>. Thank you."

4. If the person who answers doesn't appear to know the participant, then let them know we have the wrong number and thank them for their time. Do not mention the Long Term Follow-Up study (or St. Jude).
5. If you call someone's workplace and they are not available, then you can leave a generic message (or no message), similar to "Please call <interviewer name> at <phone number>.
6. If you are calling someone other than the participant during tracing, then you should leave a generic message, or no message at all, similar to:
    a. Hello, this is <interviewer name>. I am trying reach <participant name>. I can be reached at <phone number>. Thank you."
    b. Do not mention the Long Term Follow-Up study or St. Jude
7. If you are calling an "additional point of contact" who the participant gave us permission to contact *and* you are 100% sure you have the correct person, then you can leave a message similar to:
    a. "Hello, this is <interviewer name> calling from the Long Term Follow-Up study. You were listed as a point of contact for <participant name>. We have been trying to reach <him/her> regarding some information we recently mailed. Please call me at <number>. Thank you very much."
8. If the voicemail is generic or you are not 100% sure you have the correct person, then leave a generic message (just your name and number) or no message at all.

If the person answers the phone:

Hello, my name is _____ and I'm calling from Long-Term Follow-Up study. A few weeks ago, we sent you some information regarding the ECHOS study. . I am calling to provide you with more information about this study. Is this a good time to tell you about the study? If not, when would be a more convenient time for me to call back? (set-up call back time if needed)
Did you receive this packet?

RECEIVED PACKET –

(If interested)

Great. In your packet are two consent forms, a HIPAA wavier form, and a form where you list current physicians. Please sign and date one consent form, sign the HIPAA waiver, and list all your current doctors and send all materials in the prepaid envelope. These instructions are also located on the first page of the letter in your packet. Once we receive these a study nurse will be in contact regarding any heart tests you may have had in the past and describe the next steps.

(If has questions for the nurse)

Great. I will send your contact information to one of the nurses working on this project. One of them will call you to answer any questions you have and to also discuss the next steps in the process. I show your address (x) and your phone number as (x). Are these correct? Is there an alternate phone number where we may reach you? Do you preferred days or times for the nurse to call you? You may also call 1-866-278-5833 (ext 3271) and ask for Kristine or Brenda,

(If not interested)

I understand. Can you tell me why you are not interested? Thank you very much for your time. Have a great day.

DID NOT RECEIVE PACKET

That's OK. I can tell you about the study and then also send you an additional packet in the mail if you'd like. The goal of this study is to study is find out how we can inform cancer survivors about heart-related risks that they may face. There will be two groups of participants in this study. Both groups will receive information about heart health. Also, both groups will be asked to complete 2 questionnaires over a 1 year period. One of the groups, however, will also receive 2 phone calls from an Advanced Practice Nurse, to answer any questions about heart health. These calls would last approximately 15-20 minutes each.

Everybody who decides to participate in this study will be randomly assigned to one of these two groups (like flipping a coin). No matter what group you are in, participating in this study would only take approximately 2 hours of your time over a 1-year period. To thank you for your time and information, you will also receive a $50 check after each questionnaire you complete. Do you have any questions?

Would you be interested in participating in this study or do you have any questions I could answer?

(If interested and needs a new packet)

Great. One of our study nurses will send a new packet to you**.** I show your address (x) and your phone number as (x). Are these correct? Is there an alternate phone number where we may reach you?

(if has questions for the nurse)

Great. I will send your contact information to one of the nurses working on this project. One of them will call you to answer any questions you have and to discuss the next steps in the process. I show your address (x) and your phone number as (x). Are these correct? Is there an alternate phone number where we may reach you? Do you preferred days or times for the nurse to call you? You may also call 1-866-278-5833 (ext 3271) and ask for Kristine or Brenda.

Thank you again for your time and interest in this important study. Have a great day.

[End call]

(If not interested),

I understand. Can you tell me why you are not interested? Thank you very much for your time. Have a great day.

[End Call]

Possible questions to phone interviewers

What is my time commitment?

The study consists of 2 questionnaires, which would take approximately 45 minutes each to complete; and potentially 2 phone calls with an Advanced Practice Nurse, lasting about 20 minutes apiece.

How long do the questionnaires take to complete?

Each questionnaire would take approximately 45 minutes to complete.

When will I get my money?

You will receive a check of $50 after we receive each completed questionnaire. You will receive the first questionnaire in a week or two, the second in 12 months.

What information do you need from me?

We ask that you provide us with the name/address/phone number of your primary care provider (PCP); and to let us know if you've had any cardiac screening to evaluate your heart muscle function within the past 5 years. We ask that you let us know when and how are the best time/method to reach you, i.e. phone, e-mail. The enrollment packet contains forms on which to give us this information. It also contains a postage-paid return envelope.

What should I do with this information I received in the mail?

Please complete the materials that you received and return them in the enclosed postage paid return envelope. If you have questions, one of the study nurses would be happy to talk with you.

I don't have a doctor or medical insurance.

I can have one of our study nurses contact you and they can provide you with information. Is there a best day and time to contact you? How do you prefer to be contacted? Can I verify your address, email, and phone number? [Update in database both time/day and new contact information]. One of our study nurses will be contacting you within the next few days. Thank you again for your time, have a wonderful/day.

If participants have health questions or questions not on list below, then offer to refer the prospective participants to a study nurse:

Would you like one of our study nurses to call you? They can answer any questions you have about the study.

If yes:

I will let them know to contact you. Is there a best day and time to contact you? How do you prefer to be contacted? Can I verify your address, email, and phone number? [Update in database both time/day and new contact information]. One of our study nurses will be contacting you within the next few days. Thank you again for your time, have a wonderful/day.

[End call]

After making the call:

Update all appropriate applicable fields in the database, per the guidelines listed in the "ECHOS SRC Database" section on pages 2 through 4 and the procedures listed in the "Pre-Post Procedure - ECHOS Calls ver1_1.docx," and update the Participant Call Log. Double check to make sure all fields have been updated appropriately, then begin working the next case in the Call Assignments Excel workbook. Contact the Coordinator or LSI if you encounter any unusual circumstances.

Revision Record Printed 7/13/2012 11:31 AM

Current Filename:		ECHOS Study Calls 1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1.1	6/4/12	D.Rinehart / B.Carson	Initial Development
1.2	6/14/12	Procedure Team	Content refinement

Expansion Baseline Online (Verbal) Consent Procedures

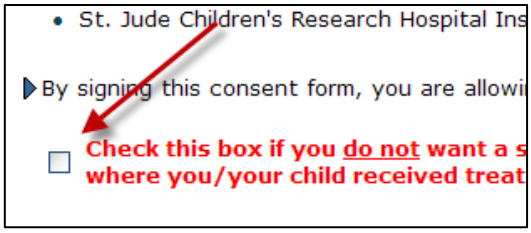
Background

This procedure provides a summary of key points for completing the Expansion Baseline informed consent form over the phone. See the SOP titled **Expansion Baseline Survey Calls** for further information.

Procedure

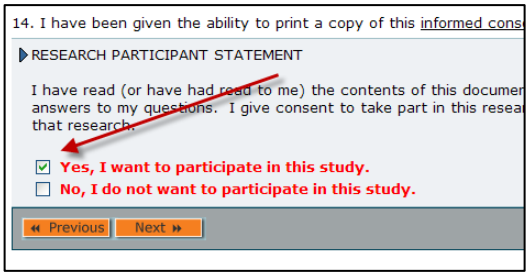
Before completing the Expansion Baseline survey, it is necessary to read the verbal consent script with each participant. The informed consent script should be read verbatim, the questions at the end of the form asked, and the answers recorded on the physical form.

1. For survivor participants, one of the questions asks if we can **share** a summary of the information s/he provides with the treating institution.



   A. If the **participant says yes**, leave the box in the online consent form unchecked.
   B. If the **participant says no**, check the box indicating s/he does not want us to share the information. This does not prevent the Survey Interviewer from continuing with the survey.

2. During the consent process, the participant is also asked if s/he understands the study and if s/he agrees to participate.



   A. If the participant **gives consent**, mark the **Yes** checkbox to indicate consent was given and the participant does want to participate.
   B. If the participant **does NOT consent**:
      i. Thank him/her for their time, and end the call. Do NOT collect survey data if the participant does not give consent and does not want to participate in the study.
      ii. Mark the **No** box to indicate that s/he does not want to participate. (Leave the **Yes** box unchecked.)

Revision Record Printed 12/23/2014 11:22 AM

Current Filename:		Expansion Baseline Online Verbal Consent Procedures ver1_4.docx	
Revision No.	Date	Responsible Author	Change Description
1		B. Benavides/Rinehart	Initial Development
1.1	5/31/12	Procedure Team	Content and formatting revisions
1.2	6/5/12	D. Rinehart	Deleted obsolete step, "HIPAA Authorization form"
1.3	6/12/12	D. Rinehart	Deleted "and HIPAA Authorization" from title, and added the reference "Baseline Survey Non-Responder Phone Calls" to the Background section.
1.4	12/20/2014	R. Massey	Content Revision: Updated SOP title in Background, Formatting

Expansion Baseline Participant Hold Process for the Call Center

Background

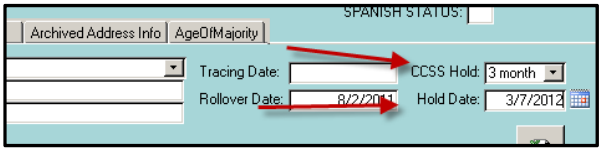
On occasion, an Expansion Baseline participant (case or sibling) will indicate to a LTFU study team member that they may wish to participate but would like to be placed on a 3-, 6-, 9- or 12-month hold or a "calls" hold. During a 3-, 6-, 9- or 12-month hold, the participant will not receive mailings or calls from the LTFU Study. During a "calls" hold, the participant may receive mailings but will not receive telephone calls.

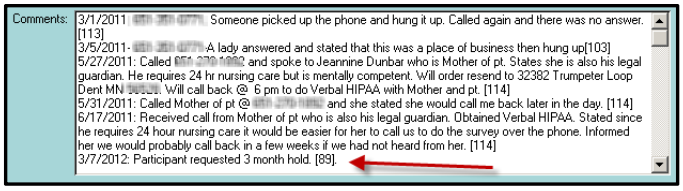
Fields in the Expansion Tracking database are used to indicate the hold status/request and provide a means for managing participants coming off hold and returning to call rotation.

Procedure

Placing a Participant ON HOLD - Case/Survivor:

- As indicated in the **Expansion Baseline Survey Calls** SOP, the SI will go to the Quest tab of the appropriate blue case record and:
  - Update the **CCSS Hold** field with the appropriate value using the drop-down menu and update the **Hold Date** field with the current date.
    NOTE: As with all special outcomes, the "calls" hold should be cleared with the LSI team or Call Center Coordinator before it is applied.
  - Enter a dated note with the SI's ID in the **Comments** field.





- The SI will *not* record a reminder to call the participant back when the hold expires. An LSI will assign the case to a Survey Interviewer upon expiration of the hold.
- The SI will update the MS Word **Phone Contact Log** for the appropriate case participant (CCSSID) indicating the date of the hold and the hold circumstances. See the SOP titled **Using and Creating Participant MS Word Call Logs (Phone Contact Log)** for details on how to find and use this document.

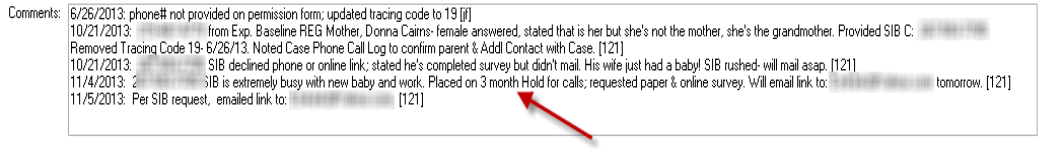
DATE (Mo/Day/Yr)	Day (i.e.: SU)	TIME (AM/PM)	INT. ID #	CONT-ACT (mark X if yes)	If yes, whom?	Out-come	Comments
3/7/12	WE	12:42PM	89	X	Pt.	10	Pt. would like us to call back in 3 months, after they get back from Hawaii, for their daughter's wedding.

Placing a Participant ON HOLD - Siblings:

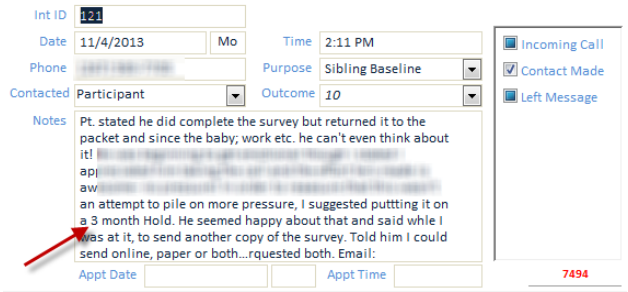
- As indicated in the **Expansion Sibling Cohort Survey Calls** SOP, the SI will go to the Sib Info tab of the appropriate green sibling record and:
  - Update the **Sib CCSS Hold** field with the appropriate value using the drop-down menu and update the **Hold Date** field with the current date.

NOTE: As with all special outcomes, the "calls" hold should be cleared with the LSI team or Call Center Coordinator before it is applied.

- Enter a dated note with the SI's ID in the **Comments** field.



- The SI will *not* record a reminder to call the sibling participant back when the hold expires. An LSI will assign the case to a Survey Interviewer upon expiration of the hold.
- The SI will ensure the hold is properly documented in the **Notes** field of the green database **Call Log** for the appropriate participant (SIBID) if the hold resulted from a telephone call.



Revision Record

Printed 1/21/2014 8:09 AM

Current Filename [69]:		Expansion Baseline pt Hold Process for the Call Center ver2_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	3/29/12	D. Rinehart, M. Jackson	Initial Development
1.1	5/23/12	Procedure Team	Content and format refinement
2.0	1/17/14	R. Massey	Content Revision

Expansion Baseline Questionnaire Mailing

Background

When Expansion Cohort participants are recruited to the study, information is added to the CCSS Expansion Tracking database. For cases recruited by the CCSS Coordinating Center, the information is added through the roll over procedure from the recruitment database. Currently, we use the Expansion Tracking database to send the booklet of baseline questionnaire and other study materials. The exception to this is Michigan, which still uses the Recruitment database because recruitment materials are included with the survey.

This procedure focuses on preparing the survey booklets. Virtually the same process is used for producing the materials for mailing. Note the following differences:

1. Teleform AutoMerge Publisher uses *different booklets*, depending on the group.
2. Print tables differ according to the specific survey.
    - Generic print tables cover MOST cases
    - There are institution-specific print tables for all University of Minnesota booklets and deceased Dana Farber booklets.

Three sections comprise this procedure document: (1) Printing instruments; (2) Creating cover letters and mailing labels, and (3) Assembling the package. To print INDIVIDUAL surveys, refer to the procedure ***Printing Individual Requested Resends for Expansion Baseline***.

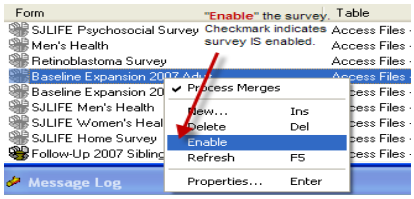
REMEMBER: A firewall separates *t*he Expansion Tracking database (used for recruited cases) from the Recruitment database (used by the Coordinating Center for recruiting process).

Procedures

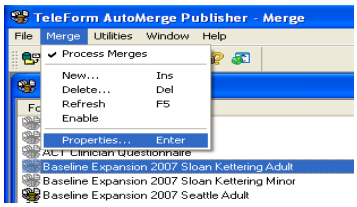
Print Instruments in batches

1. Open Automerge Publisher (in Cardiff TeleForm)
2. Open the database having the print tables: CCSS Expansion Tracking Database
3. Close the "opening form" that appears on the database opening screen.
4. In Automerge Publisher, on top of screen, select appropriate survey. Note that recruitment surveys are institution-specific.

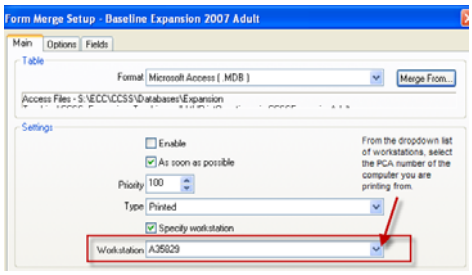
5. Right-click appropriate survey name, then click Enable to enable the survey. (A checkmark indicates the survey is enabled.)



6. From Teleform Automerge Publisher's menu, select **Merge**, and then **Properties…** This opens the Form Merge Setup window.

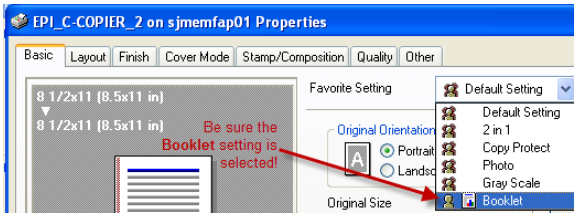


7. In the Form Merge Setup window, on the Main tab, check the box for Specify workstation (if it is not already checked), then click the **Workstation** dropdown arrow. Select the PCA number of the computer you are printing from.



8. Then click OK.

9. In Teleform Automerge Publisher's menu, select File, and then Print Setup.
   a. Select the appropriate Copier (e.g., EPI_C-Copier 2)
   b. Click on Properties and ensure the **booklet** option is selected.
   c. Click OK (twice).



10. In the database, open the appropriate print table. E.g.
    a. tblPrintQuestionnaireCCSSExpansionAdult
    b. tblPrintQuestionnaireCCSSExpansionUnder18
    c. tblPrintAdultMN or tblPrintMinorMN

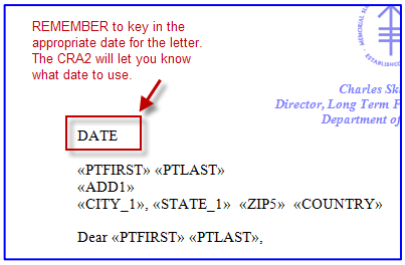
11. On the print table records assigned to you, set the printing flag to a **23** in the Record_Sta column. (This field will be blank if a questionnaire has never been printed for this record.)
    a. To determine which need to be printed, refer to the provided Excel file.
    b. For reprints, you will be changing the **20** already in the Record_Sta column to a **23**.
    c. *Note:* After surveys are printed, Record_Sta value will automatically switch to "20"

12. When the print job is completed (all your "23s" are changed to "20"), return to Automerge Publisher.
    a. Right-click the survey name. Click "Enable" to "un-enable" the survey.

13. Check the booklets as they are printed. Make sure there are no blank areas, the correct font is used, and the merged fill-in information is complete.

Create cover letters and mailing labels

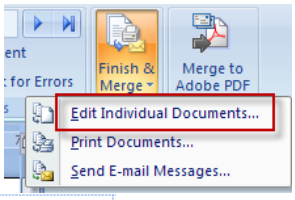
1. Create cover letters using the appropriate letter (under 18 or over 18; or DanaFarber specific) and the excel file provided to you by the project's CRA2.



   a. The CRA2 will tell you what DATE to use on the cover letter.

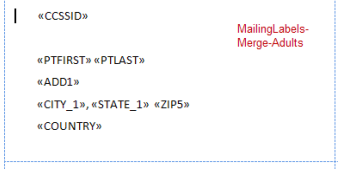
   b. *Expansion Baseline* letters are located at:
      …\ECC\CCSS\Expansion Baseline\IRB approved Letters.
      i. DanaFarber-specific letters are in a subfolder in this location as well.

   c. Be sure to merge letters to a new document. In Word2007, use the Finish & Merge option Edit Individual Documents…. Scroll to review the individual letters before you print the letters.



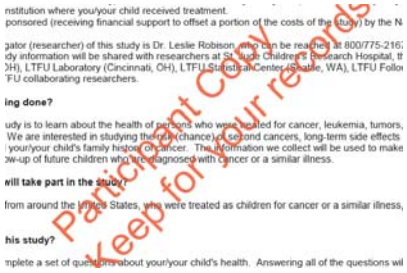
   d. Print letters on preprinted letterhead.

2. Produce mailing labels using MailMerge with the data file.
   a. Be sure to include the CCSSID on the label.



b. If you need additional information on creating cover letters and labels, see the procedure explaining this process.
c. Place labels on the white mailing envelope. Position in the lower right quadrant of the envelope.

Assemble the package



1. **Participant Copy**: Include extra copy of the Informed Consent Form and HIPPA Form with the "Keep for your records " watermark. These are for the participant to keep.
   a. There are usually extra copies in the storage room.
   b. Copies can be printed if needed (print "front and back" to save paper).
      i. Participant copies are located on the server in this path: …\ECC\CCSS\Expansion Baseline\PARTICIPANT COPIES
      ii. Print double sided to save paper.
      iii. Staple any multi-page participant documents.
   c. NOTE: Cases from inst 01 (University of Minnesota) require the use of the institution-specific participant copy (*Baseline Expansion Minnesota Over_Under 18 9-17-13_Participant Copy.pdf)*.

2. The final packets include(See also ***Baseline Batch Mailing Fact Sheet***)
   a. White mailing envelope with label (in lower right quadrant of envelope)
   b. Cover letter
   c. Questionnaire
   d. Blue Business Reply Envelope (reminder – use the addressed blue envelopes for Canadian residents and add Canadian stamps. Do not use the "BRE" for international mail.)
   e. Participant copy of the Informed Consent and HIPAA Forms

3. The packets are now ready for Q/A. Check
   a. Each survey, letter, and mailing label: for the SAME PERSON. Is the NAME the same on each?
   b. Compare address on survey back, in letter, and in mailing label. Are they the same?
   c. Is the correct date on the letter?
   d. Are the correct mailing and return envelopes used? (institution-specific when required)
   e. The correct participant copy is included (institution specific when required)
   f. The materials are "stacked" in the appropriate order
   g. Any other inserts specified for the job are included

4. After the quality assurance process, seal packets, and place in the mail pickup location. Notify the CRA2 for the project by email that the batch has been set out for mail pick up.
5. The CRA2 will (a) update the sent date in the database and (b) email the Call Center manager that surveys (type) were mailed, giving quantity and date. (e.g., 19 adult and 5 under-18 expansion baseline surveys from USC recruits were mailed mm/dd/yy) (This will assist the Call Center plan for the subsequent phone follow-ups.)

Revision Record
Printed 11/19/2013 2:39 PM

Current filename		Expansion Baseline Questionnaire Mailing ver 1_6_.doc	
Revision No.	Date	Responsible Author	Change Description
1	4/3/09	A. McDonald	Initial Release
1.1	10/22/09	J. Bates	Layout and illustrated annotation
1.2	11/5/09	J.Bates	Update send date
1.3	12/9/09	J.Bates	Add CCSS Recruit and remove mailing list production
1.4	5/10/11	J.Bates	Cross reference separate SOP for individual printing
1.5	7/6/11	J.Bates	Excise refs to USC and recruitment survey booklets
1.6	11/15/13	J. Ford	Update for Minnesota printing (now incentive)

Expansion Baseline Send Date Update and Historical Filing

Background

When Expansion Baseline surveys have been printed and assembled, and they pass quality assurance checks, the "date sent" in the Expansion database needs to be updated. This task is the responsibility of the CRA2. You will need to know (1) the send date and (2) number of surveys that were in the batch. For USC batches, you will need to know the Seq_no's used by the print table for that job. When completed, the spreadsheets used for generating the mailings are stored on the server.

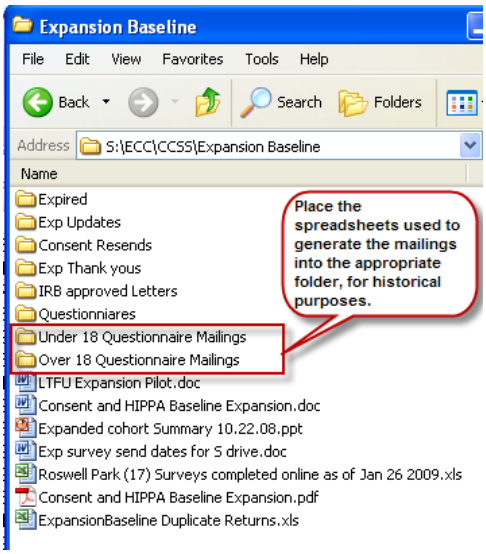
Procedure for StJude "Batches"

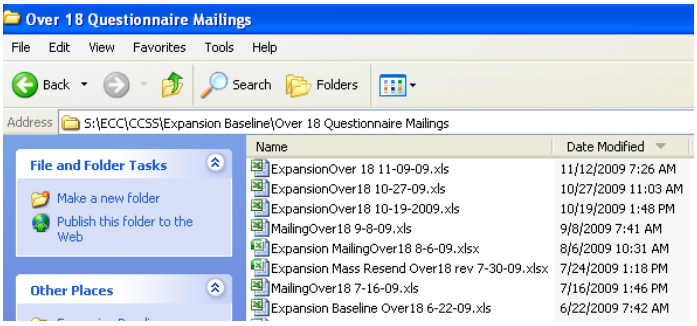
The simplest way to update the baseline date sent OR any of the resend dates is to IMPORT a list of the CCSSIDs from the data file used by the production team.

1. Create a combined Excel list of the over and under18 cases from the mailout data files.
2. Import this into a TEMPORARYsendList table. Once the updating is completed, you will DELETE this temporary table.
3. Create a TEMPORARY query which links the sendList table to the tblBaselineTrackingInfo. This temporary query will NOT need to be saved. If you do save it, you should delete it after completing the process.
4. For posting the **FIRST mailout** of baseline surveys
    a. In the query, use CCSSID and expbasedate fields
    b. View the query to be sure the numbers match the total in the mailout.
    c. Change the query to an update query, then update expbasedate field to the date sent.
    d. Change query back to select query to check to be sure the update "took"
5. For posting **RequestedResends** (cases sent because addresscode=82)
    a. ADD tblCCSSExpansionTrackingMain to the design. Connect to other table on CCSSID
    b. Use CCSSID, addresscode, tracingDate, and ALL the expbase…resend fields (expbaseresend, expbase2ndresend, expbase3rdresend, expbase4thresend, expbase5thresend). Bring in expbasedate (just in case some of the requested resends are actually the INITIAL mailing)
    c. View the query to be sure numbers batch total mailed out
    d. Scan the results to determine the "highest" resend field that has already been used.
    e. For the updating process to post the resend date, work backwards from the highest needed resend date, down to the initial mailing date (expbasedate). Alternate between select and update queries until all cases are posted.
    f. After all cases have the sent date posted, change the update query to update addresscode and tracingdate to null. This clears the resend flags.
    g. Change query back to select query to check final results.
6. Delete the temporary query and the temporary table.

Archiving the Mailing Spreadsheets

Once questionnaire batches are produced, packaged, mailed, and the SendDate has been updated, archive the spreadsheets used to generate the mailings, in the following manner. Place the Under and Over 18 files in their respective folder, located in …\ECC\CCSS\Expansion Baseline. Within the respective folders, notice the use of individual filenames helps identify the group (over/under) *and* the date of the mailing.

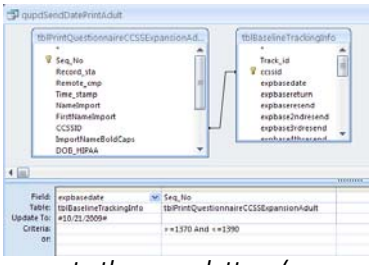


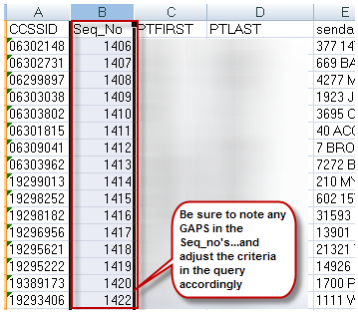


Procedure for USC Batches (Historical reference only)

Adult (over 18) surveys

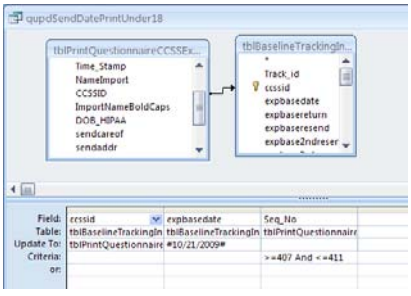
1. Recall how many surveys were sent.
2. Locate qupdSendDatePrintAdult
3. Change the date in the UpdateTo: for expbasedate
4. Modify the Seq_no's in the Criteria row. *If you do not remember the Seq_no's, refer to the spreadsheet used to generate the cover letters (see below).*
5. Run the Query: the number of records updated should match the number of surveys sent. If it does NOT, then recheck the values you entered in the query.





Under 18 surveys

Use the same procedure as for Over 18, but with qupdSendDatePrintUnder18



Revision Record

Printed 7/16/2012 10:43 AM

Current filename		Expansion Baseline Survey Send Date Update ver 1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	11/5/2009	J.Bates	Initial Release
1.1	11/12/2009	J.Bates	Add historical filing
1.2	3/18/11	J.Bates	Simplified process; USC batches for historical reference

Expansion Baseline Questionnaire: Scanning and Verifying Guide

Background

As of 4/11/11, when multiple items are specified in a coded box, we now capture the age for each item, when given. Additional fields have been added to the data tables to accommodate ages. Additional items, previously entered as text, have been changed to coded values.

Overview: General rules

1. If two answers are clearly marked, the answer should be changed to missing and noted in discrepancy log.
2. If two answers are marked, *but it is clear which one the participant intended*, choose the correct answer. If a *response is unclear*, then give the booklet to the LTFU CRA 2 for a decision.
3. If there is a percentage or decimal, round up from .5 and down from .4 and noted in discrepancy log.
4. If there are months for age: round down for up to 6 months; round up for 6 months or above; note in discrepancy log.
5. If you suspect that year is recorded instead of age, check with LTFU CRA 2 to confirm, then calculate age based on the year indicated. Note in discrepancy log.
6. If a month and day are left out of a date, July 15th should be used. If only a day is left out, use the 15th. Note in discrepancy log.
7. If there is more than one age in the box, choose the younger age if the item asks for the earliest age.
8. ANY change to the questionnaire should be noted in the discrepancy log.
9. In cases of insufficient text box space, fields for multiple conditions, or more space needed in Verifier, copy the page for the CRA 2 who will work with IT group. Write which survey version (over/under 18). When notified of changes, the additional information is to be added (during QA if batch has been committed).

Discrepancy Logs

Separate DISCREPANCY LOGS are available for EACH instrument in z:\...\ECC\CCSS. For Expansion Baseline, you will use either the Over18 or the Under18 log. (Specifically, Expansion Baseline-Over18_Discrepancies, and Expansion Baseline-UNDER 18_Discrepancies). Record the CCSSID#, the problem, page number and question, and the resolution. Use the next available row.

1	Expansion Baseline (OVER 18) Discrepancies			
2	**CCSSID#**	**PROBLEM**	**PAGE NUMBER and QUESTION**	**RESOLUTION**
225	11320812	two answers marked one marked out	pg 12 E 11	entered yes, and the condition is no longer present
226	11320792	two answers marked	pg 12 E8	entered no
227	11320792	unable to read answer	pg 21 O2	left blank
228	11320776	pt entered 1 1/2	pg 16 I 9	rounded to 2
229	← use NEXT AVAILABLE ROW			

II. Question by Question

FACE PAGE

- *Person completing questionnaire*: Enter name as written. If no name written but "self" chosen for relationship, add name from "The questions in this booklet relate to." If difficult to decipher, refer to the imprinted name for possible clarification.
- *Your relationship*: If not marked leave blank. If "parent" and "self" are marked, choose self.
- *Today's date*: if provided by the respondent, enter what was noted, otherwise it is the date we received the questionnaire (date stamped on face page).

SECTION A.

A1. *Date of birth.* (If left blank, show to the LTFU CRA 2 and ask what action to take.)

A2. Sex: if marked both, make a note in log and leave blank.

CRA

A3-4. (*Current Height/ Weight*) If there are decimals or percentages, round up for .5 (1/2) and above, and down for less than.5 (1/2). Make note in log. For example, if someone writes 140 ½ pounds, then enter 141 pounds.

A5. If more than one response is noted, make a note in log and leave blank.

A5a. (Hispanic). If marked both yes and no, leave blank and log.

A6. (Multiple birth) If marked both yes and no, leave blank and log.

A6a. If more than one response is noted, make a note in log and leave blank.

A7. (Adopted) If marked both yes and no, make a note in log and leave blank.

A8. (Full siblings). Enter whole number

A9. (Residence) If more than one response is noted, make a note in log and leave blank. If did not check "Other" but entered value in Other-specify, then type the comments as written.

A10. (Internet). If more than one response is noted, leave blank and log.

SECTION B: Medical Care

B1. This is a MARK ALL THAT APPLY question. Multiple answers are possible.

B2. This is a MARK ALL THAT APPLY question. Multiple answers are possible.

B3, 4, 5. If more than one response is noted, leave blank and log.

B6. (hospital admissions). Enter whole number.

B7(a-h). (after effects) If yes and no are marked, leave blank and log

B7-i. (Other-Specify) Enter codes from medical coder. If insufficient space, copy page to CRA2 who will request more fields, after which values can be added.

B8.1-9. (MEDICATIONS). Enter all medications in the order in which they are listed on the questionnaire using 4-digit code numbers from coder. If there are months for age, round down for under 6 months, round up for 6 months or above. For example, if someone writes 5 months old, then round down to zero. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank.

- *Update 4/11/11: items **B8.1-9.** Only code the medication (the 4-digit codes), not the diagnosis. (DO code reason/ICD9 for B10.)*

B8.10 (OTHER DRUGS). Enter all medications and conditions (reasons, ICD9 code) using numbers from coder.

SECTION C: MEDICAL CONDITIONS- Hearing/Vision/Speech

C1-22 If more than one response is noted, leave blank and log. Where indicated, specify the codes provided by the medical coder. If there are months for age, round down for under 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank. If you suspect that year is recorded instead of age, check with CRA 2 to confirm action to take, then (as advised) calculate age based on the year indicated.

Update 4/11/11: If multiple entries, and age given per each, enter the age for each, for the following items:

- *C7: Hearing Problems, other*
- *C13: Retina Condition*
- *C18: Eye Problems other*
- *C20: Speech Defects*

C8. (Legally blind one eye: if yes, any sight in this eye). Leave blank if they mark more than one response option, and log.

CRA

C9. (Legally blind both eyes: if yes, any sight at all). Leave blank if they mark more than one response option, and log.

SECTION D, E : (D) Urinary System, (E) Hormonal Systems

If more than one response is noted, leave blank and log. Where indicated, specify the codes provided by the medical coder. If there are months for age, round down for under 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank. If you suspect that year is recorded instead of age, check with CRA2 to confirm then calculate age based on the year indicated (if needed).

Update 4/11/11: If multiple entries, and age given per each, enter the age for each, for the following items:

- *D6: Kidney Disorder*
- *E11: Broken Bones*
- *E12: Hormonal Problems*

SECTION F: Heart and Circulatory System

F1-14 If more than one response is noted, leave blank and log. Where indicated, specify the codes provided by the medical coder. If there are months for age, round down for under 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank. If you suspect that year is recorded instead of age, check with _____ to confirm then calculate age based on the year indicated.

F5. Hypertension and taking medication. Leave blank if they mark more than one response option, and log.

F12. High Cholesterol and taking medication. Leave blank if they mark more than one response option, and log.

F13: Circulatory Problems. *Update 4/11/11: If multiple entries, and age given per each, enter age for each.*

F14. If yes and no are marked, leave blank AND LOG.

SECTION G: Respiratory System

G1-8. If more than one response is noted, leave blank and log. Where indicated, specify the codes provided by the medical coder. If there are months for age, round down for under 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank. If you suspect that year is recorded instead of age, check with CRA 2 to confirm, then calculate age based on the year indicated.

G8: Breathing Problems. *Update 4/11/11: If multiple entries, and age given per each, enter age for each.*

SECTION H: Digestive System

H1-9. If more than one response is noted, leave blank and log. Where indicated, specify the codes provided by the medical coder. If there are months for age, round down for under 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank. If you suspect that year is recorded instead of age, check with CRA 2 to confirm, then calculate age based on the year indicated.

H1-types. (If yes, types) This is a MARK ALL THAT APPLY question. Multiple answers are possible.

H3: Other Liver Trouble. *Update 4/11/11: If multiple entries, and age given per each, enter age for each.*

SECTION I: Surgical procedures

I1-37. If more than one response is noted, leave blank and log. Where indicated, specify the codes provided by the medical coder. If there are months for age, round down for under 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank. If you suspect that year is recorded instead of age, check with CRA2 to confirm, then calculate age based on the year indicated.

I1: Amputation. *Update 4/11/11: If multiple entries, and age given per each, enter the age for each.*

Update 4/11/11: the following items are now coded (instead of entered as text). If multiple entries, and age given per each, enter the age for each.

- I3. Spinal Surgery
- I5: Joint Replacement
- I6: Other Bone Surgery
- I13: Other Heart Surgery
- I23: Lung Surgery
- I30: Other Organ Transplant
- I37: Other Surgery

SECTION J: Brain and Nervous System

J1-J15. If more than one response is noted, leave blank and log. Where indicated, specify the codes provided by the medical coder. If there are months for age, round down for under 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank. If you suspect that year is recorded instead of age, check with CRA2 to confirm, then calculate age based on the year indicated.

J1. Memory problems: IF YES: rate severity. Leave blank if they mark more than one response option, and log.

J2. Seizures: IF YES, take meds: Leave blank if they mark more than one response option, and log.

Update 4/11/11: If multiple entries, and age given per each, enter the age for each, for the following items:

- J2: Epilepsy Seizure Problem
- J5: Headache Medication
- J14: Paralysis
- J15: Nervous System

J5. Balance: IF YES, rate severity: Leave blank if they mark more than one response option, and log.

J14.a-f. Stroke: IF YES, as a result: Leave blank if they mark more than one response option, and log.

SECTION K: Social Functioning (Adult and Minor have different items)

K1-x. If there are months for age, round down for under 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age. If there is a question mark for age, leave blank. If you suspect that year is recorded instead of age, check with CRA 2 to confirm, then calculate age based on the year indicated.

ADULTS:

K1-22. If more than one response is noted, make a note in log and leave blank.

K23. This is a MARK ALL THAT APPLY question. Multiple answers are possible. For Other-Specify, enter the codes from coder. (If more space needed, submit request.)

CRA

MINORS:

K1-10. If more than one response is noted, make a note in log and leave blank.

K11. This is a MARK ALL THAT APPLY question. Multiple answers are possible. For Other-Specify, enter the codes from coder. (If more space needed, submit request.)

SECTION L.

L1. (Another cancer) If answered NO and *also provided data for L2-L5: DO go ahead and enter the data they provide for L2-L5.*

L2. Type text

L3. If marked Yes and No *AND* left subsequent fields blank, make a note in log and leave blank; marked Yes and No *AND* entered a value for L3a (what treatments did you have), enter "Yes" for L3 and make a note in log. If marked NO for L3 *AND* entered value for L3a (treatment), L4 (where diagnosed), and/or L5 (recurrence/diagnosis), then leave L3 as "NO" and enter the value as given for L3a, L4, and L5.

L3a. This is a MARK ALL THAT APPLY question. Multiple answers are possible.

L4. This is not entered.

L5. If more than one response is noted, make a note in log and leave blank.

L5 date Month (2 digits), year (4 digits). If did not enter all digits, supply the leading zero for month; leading century for year.

L6. (More cancer). If answered NO and *also provided data for L7-L10: DO go ahead and enter the data they provided.*

L7. Type text

L8. If marked Yes and No *AND* left subsequent fields blank, make a note in log and leave blank; marked Yes and No *AND* entered a value for L8a (what treatments did you have), enter Yes for L8 and make a note in log. If marked NO for L8 *AND* entered value for L8a (treatment) , L9 (where diagnosed), and/or L10 (recurrence/diagnosis) , then leave L8 as "no" and enter values as given for L8a, L9, and L10.

L8a. This is a MARK ALL THAT APPLY question. Multiple answers are possible.

L9. This is not entered.

L10. If more than one response is noted, make a note in log and leave blank.

L10 date Month (2 digits), year (4 digits). If did not enter all digits, supply the leading zero for month; leading century for year.

ADDITIONAL CANCERS ON AN ADDITIONAL SHEET. Scan these at the end of the survey, with any other additional sheets that were included. Arrange sheets in order by question number.

SECTION M. MARITAL STATUS

M1. This is a MARK ALL THAT APPLY question. Multiple answers are possible.

M2-3. If more than one response is noted, make a note in log and leave blank.

M4. (how many times married). If more than one response is noted, take the highest selected value.

(NOTE: ITEMS M5-M14 appear only in the adult version)

CRA

M5. (Year first married-4 digits). If leading digits were left blank, supply them (E.g., entered "90", enter 1990). If the entry "looks like" an age (based on date of birth and other evidence), then ask the CRA 2 what to do.

M6-7. (Year stop living together.) If more than one response is noted, make a note in log and leave blank.

M8. Should only be answered if M7 was no. If they ignored the skip pattern, enter what they entered.

M9. If more than one response is noted, make a note in log and leave blank.

M10. (Year recently married) If leading digits were left blank, supply them (E.g., entered "90", enter 1990). If the entry "looks like" an age (based on date of birth and other evidence), then ask the CRA 2 what to do.

M11. If more than one response is noted, make a note in log and leave blank.

M12. Treat like M7

M13. Treat like M8

M14. If more than one response is noted, make a note in log and leave blank.

SECTION N: OFFSPRING/PREGNANCY HISTORY

N1. (Intercourse) If more than one response is noted, make a note in log and leave blank.

N2. If more than one response is noted, make a note in log and leave blank.

N3. (Vasectomy/ligation) This is a MARK ALL THAT APPLY question. Multiple answers are possible.

N3-age. If age given but item NOT checked, check "YES" (if the verifier pauses for input); then make note in log.

N4. (Currently pregnant) If more than one response is noted, make a note in log and leave blank.

N5. (Tried pregnant) If more than one response is noted, make a note in log and leave blank.

N6. (ever pregnant) If more than one response is noted, make a note in log and leave blank.

N7. (# live births). Enter number as given.

N8. (Pregnancy outcomes 1….5). For each pregnancy noted, if more than one outcome is noted, make a note in log and leave blank. For age and partner's age at start of pregnancy, if there are months for age, *round down* for up to 6 months; *round up* for 6 months or above. If there are decimals or percentages for weeks pregnancy lasted, round up for .5 (1/2) and above, and down if less than for .5 (1/2)

Extra If there are extra sheets, scan the pages at the end of the survey. Assemble extra scanned pages in order by question number.

SECTION O. HEALTH HABITS: ADULT VERSION

O1. If yes and no are marked, leave blank and note in log.

O2. If there are months for age, round down for up to 6 months round up for 6 months or above. If there is more than one age in the box, choose the younger age.

O3. If yes and no are marked, leave blank and note in log.

O4-6. If there are decimals or percentages, round up for .5 (1/2) and above and down if less than for .5 (1/2).

O7-8. If more than one response is noted, leave blank and note in log.

O9. If yes and no are marked, leave blank and note in log.

O10. If there are months for age, round down for up to 6 months round up for 6 months or above. If there is more than one age in the box, choose the younger age.

O11. If there are decimals or percentages, round up for .5 (1/2) and above and down if less than for .5 (1/2).

O12-15. If more than one response is noted, leave blank and note in log.

O16-19. If yes and no are marked, leave blank and note in log.

O20. If more than one response is noted, leave blank and note in log.

O21-26. If more than one response is noted, leave blank and note in log.

O27-29. If more than one response is noted, leave blank and note in log.

O30. If yes and no are marked, leave blank and note in log. If there are months for age, round down for up to 6 months, round up for 6 months or above. If there is more than one age in the box, choose the younger age.

SECTION O. HEALTH HABITS: MINOR VERSION

O1. If more than one response is noted, leave blank and note in log.

O2-5. If yes and no are marked, leave blank and note in log.

O6. If more than one response is noted, leave blank and note in log.

O7-12. If more than one response is noted, leave blank and note in log.

SECTION P. FAMILY HISTORY INFORMATION

P1. Enter data as it is noted on the questionnaire. If a month and day are left out of a date of birth or date of death, use July 15. If only a day is left out, use the 15th. If gender or vital status are not marked, leave blank.

SECTION Q. GENETIC CONDITIONS

Q1a.a-p. If more than one response is noted, leave blank and note in log.

Q1a.p. Enter coded value for other genetic disorder.

Q1b. This is a MARK ALL THAT APPLY question. Multiple answers are possible. For each family member checked, enter as many condition codes are indicated by coder.

Q2. If more than one response is noted, leave blank and note in log.

Q3.a-l If more than one response is noted, leave blank and note in log.

Q3.a.l Comment: enter code for Hole in heart

Q3.m-p. If more than one response is noted, leave blank and note in log.

Q3.p Comment: enter code as indicated

Q3b. This is a MARK ALL THAT APPLY question. Multiple answers are possible. For each family member checked, enter as many condition codes are indicated by coder.

Q4. This is a MARK ALL THAT APPLY question. Multiple answers are possible. For each family member checked, enter as many cancer codes are indicated by coder.

SECTION R. SCHOOL HISTORY

R1. Check for multiple marks. Choose the highest education marked (they are arranged in ascending order). (If checked an item and also marked Other, and we cannot determine whether the Other is a higher level, OR if entered Other text but did not check "other," bring to CRA 2 for review and determination.)

R2. If more than one response is noted, leave blank and note in log.

R3. This is a MARK ALL THAT APPLY question (learning disabled, talented, homebound). Multiple answers are possible

CRA

R4. This is a MARK ALL THAT APPLY question. Multiple answers are possible.

SECTION S. EMPLOYMENT HISTORY

S1. If yes and no are marked, leave blank and note in log.

S2. This is a MARK ALL THAT APPLY question. Multiple answers are possible. If Other is marked, there may be text to explain. If there is text to explain, but Other was NOT marked, type the text as given.

S3. Enter text given for main job title. If they said not working in S2 but then gave a job title, type the job title as written. Note: we do not enter the description from S3b.

S4-5. If yes and no are marked, leave blank and note in log.

SECTION T: INCOME

T1-3. If more than one response is noted, leave blank and note in log. (NOTE: T3 only appears in ADULT version)

SECTION U: INSURANCE

U1. If yes and no are marked, leave blank and note in log.

U2. If yes and Canadian Resident are marked, choose Canadian Resident.

U3. This is a MARK ALL THAT APPLY question. Multiple answers are possible. If Other is marked, there may be text to explain. If there is text to explain, but Other was NOT marked, type the text as given.

U3a. (exclusions: yes/no/don't know). If more than one response is noted leave blank and note in log. Always enter the Specify text entry regardless of yes/no/don't know.

U4. (tried to get; no/yes/never tried) If more than one response is noted, leave blank and note in log.

U5. If yes and no are marked, leave blank and note in log.

SECTION V: OTHER ISSUES

V1-6. (degree of concern). If more than one response is noted, leave blank and note in log.

V6-text (Any other issues, please specify). Type text as given.

BACK PAGE

Future planning Type verbatim.

Information correct? If more than one response is noted, leave blank and note in log.

Email Yes/No? If yes and no are marked, leave blank and note in log.

(No other information on the back page is entered into the survey database)

Revision Record Printed 7/9/2012 1:27 PM

Current Filename:		Expansion Baseline Scanning and Verifying guide v2_0.docx	
Revision No.	Date	Responsible Author	Change Description
2	4/11/11	J.Bates	Add age fields; chg text to coded values

Expansion Baseline Questionnaire-U of Minnesota

Background

A special version of the Expansion Baseline 2007 questionnaire is used for cases already recruited from The University of Minnesota (institution 01). This is necessary because that institution has an institution-specific consent form, approved for use in lieu of the standard LTFU consent form. The printed version of the survey is easily recognized by the addition of the U of Minn logo on the front page. Note that this survey is for individuals who have already been recruited (it does NOT replace the "recruitment packet" sent to individuals from University of Minnesota).

Procedure

1. Follow the same general procedure for generating surveys from Teleforms Automerge Publisher.
2. **Teleforms** specifications:
    a. For ADULTS,
        i. select Minnesota Adult v2 Baseline Expansion 2007.
        ii. Use the Expansion Tracking table **tblPrintAdultMN**.
    b. For MINORS,
        i. select Minnesota Minor v2 Baseline Expansion 2007.
        ii. Use the Expansion Tracking table **tblPrintMinorMN**.

3. Production **data files** will be generated by queries unique to the University of Minnesota.
4. The **cover letters** used when mailing these surveys are the standard baseline letters in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\IRB approved Letters**
5. Materials and assembly
    a. Use the U of Minnesota-specific **participant copy** (vNEGLIA_U of MN Full Authorization LIVING.pdf) from **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\1-University of Minnesota**
    b. Enclose the **brochure** (no pen, no $2)
    c. Use the **standard blue LTFU BRE** (not the U of Minn BRE); no stop label
    d. Mail in the **standard white LTFU mailer** (not the U of Minnesota white envelope)

Revision Record Printed 7/6/2012 11:25 AM

Current Filename:		Expansion Baseline Questionnaire-U of Minnesota v1_2.docx	
Revision No.	Date	Responsible Author	Change Description
1	1/14/11	J.Bates	Initial Development
1.1	1/20/11	J.Bates	Clarification materials/assembly
1.2	5/30/12	J.Bates	MN participant copy location

Expansion Baseline Survey Calls

Background

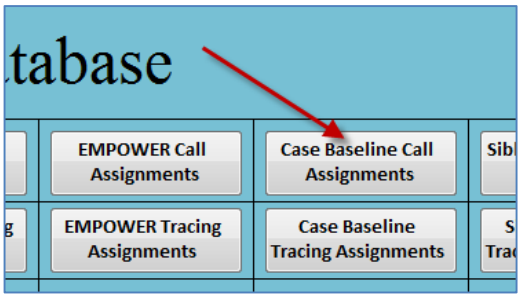
After a participant (or their representative) has completed the institutional HIPAA authorization, they are asked to complete the LTFU Study Informed Consent process and baseline survey as the final enrollment step into the expanded cohort. The participant may complete these via a paper copy, an online form, or by telephone with a Survey Interviewer (SI). Spanish-speaking participants and proxies for deceased participants must complete the survey by phone with an SI. Dana Farber participants only have the options to do the survey on paper or by phone with an SI.

All participants qualifying for a paper format are mailed a paper survey after the HIPAA is completed. Follow-up phone calls are made to non-responders beginning 3 weeks after the date the initial survey is mailed, two weeks after resends.

Note: If the eligible participant is a minor, the custodial parent or other legally authorized representative (LAR) contacted to complete the informed consent and baseline survey. If a minor participant turns 18 before the consent and survey are completed with the parents/LAR and can represent themselves (e.g., participant is not cognitively impaired), the now-adult participant is contacted to complete the informed consent and adult survey. For more information, please see a Lead Survey Interviewer (LSI) or the Call Center Coordinator.

Procedures

BEFORE MAKING THE CALL



1. Find the participant that needs to be called:
   A. Open the CCSS SI Assignments database, located at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*.
   B. Click the **Case Baseline Call Assignments** button.
   C. At the **SI ID:** field, enter the SI identification number, and then click the **OK** button.
   D. Participants to be called display and will be sorted by the date last called. The first participant to be called displays at the top of the list.
2. Open the Expansion Tracking database, located at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*.
3. Locate the participant in the database by searching for the applicable CCSSID.
   A. Click in the **CCSSID** field, and then click the binoculars on the Access Ribbon's Home tab to "find".
   B. Enter the CCSSID in the **Find What** field, and click the **Find Next** button.
4. When the correct record populates, review all pertinent information as instructed in the **Pre-Post Call Checklist – Expansion Baseline Survey**, found in the SOP Library.
5. Review all previous call history in:
   A. The MS Word **Phone Contact Log** (if applicable), which is a historical record by CCSSID located at *Z:\Departments\ECC\common\Interviewers\Expansion Survey Calls\Participant Call Logs*
   B. The database record's Call History and Trace History, which contain the most recent call activity
6. If making a call, note the time the call is placed.

DURING THE CALL: General

1. **Verify the identity** of the party reached using standard procedures (name, DOB, etc.). Do NOT provide protected information to anyone other than the case or his/her legally authorized representative (LAR).
2. Use the **Expansion Baseline Questionnaire Incentive Script**, located at *Z:\Departments\ECC\common\Interviewers\Expansion Survey Calls\Scripts*, during the call.
3. If the participant **declines to complete the baseline survey** (=REFUSAL to participate in the LTFU Study):
   A. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so.
   B. Ensure s/he understands that choosing not to complete the baseline survey means refusing all further participation in the study. Offer a hold if this is more appropriate.
4. If the participant **states they have completed and returned** the survey:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. Paper Survey
         a. Returned More Than One Month Ago – It may be lost in the mail. Offer to complete the survey over the telephone to avoid further losses.
         b. Returned Less Than One month Ago – It may still be in route. Thank the case for participating, and advise that the study team will follow up if the survey is not received.
      ii. Online Survey
         a. Returned Before Today – If the **Date Survey Returned** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday and Saturday will have the **Date Survey Returned** field populated the following Monday.
            1. Confirm s/he is referring to the LTFU Study's baseline survey. The case could be thinking of another study in which s/he participates.
            2. Try logging in to the online survey to determine the survey status. The participant could have neglected to click the **Submit** button.
         b. Returned Today - The **Date Survey Returned** field will be populated on the next business day (Monday through Friday). Thank the case for participating and advise that the study team will follow up if the survey is not received.
5. If we learn the case is now **incarcerated**:
   A. Attempt to obtain the anticipated release date. (In a few months? Several years?)
   B. If the participant is expected to be available again in a reasonable period of time, ask what the best number will be to reach him/her when s/he is released.
6. If we learn the case is now **deceased**:
   A. Complete the **Expired Participant Information Sheet**, located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*, with as much information as the person you are speaking with is able to supply.
   B. If appropriate and the proxy is willing to complete the survey, proceed to the section of this document titled ***DURING THE CALL: Completing the Survey Over the Phone*** or schedule an appointment to complete the survey at a later time. **Paper and online surveys are not available for deceased cases**.
7. If we learn the case has an **LAR or proxy** (See an LSI or the Coordinator for assistance determining an authorized proxy for a non-deceased adult participant.):
   A. Gather the name(s) and contact information for the LAR/proxy.
   B. Determine if the participant has a disability. Is the participant able to legally represent him/herself?
8. If the case prefers to do the expansion baseline survey in **Spanish**, non-Spanish-speaking SIs should refer the case to a Spanish-speaking SI. If there is not a Spanish-speaking SI available:

A. Whenever possible, try to secure a survey appointment at a time when a Spanish-speaking SI will be available.
B. Non-Spanish-speaking SIs can refer to the document titled **Basic Spanish Words**, located at Z:\Departments\ECC\common*Interviewers**Spanish*.

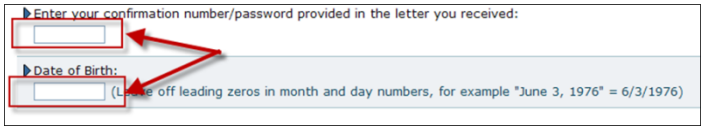
9. If a participant is willing to **complete the survey over the telephone**, proceed to the section of this document titled ***DURING THE CALL: Completing the Survey Over the Phone***.

DURING THE CALL: Completing the Survey Over the Phone

Click on the appropriate survey link. There are three versions of the survey:

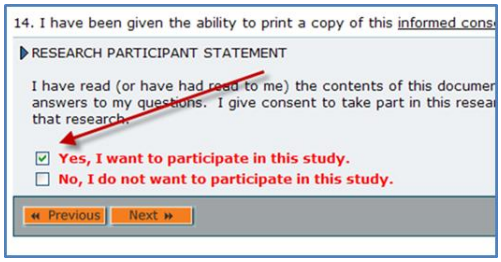
- **ADULT (cases 18 and older):** www.stjude.org/expansionbaseline OR https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name=CCSS_Expansion_Baseline&_RS_=1
- **MINOR (cases younger than 18):** www.stjude.org/expansionbaselineminor OR https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name=CCSS_Expansion_Baseline_Minor&_RS_=1
- **EXPIRED (deceased cases):** https://live.datstathost.com/stjude-Collector/Survey.ashx?Name=DECEASED_CCSS_Expansion_Baseline

1. **Enter the case's password and date of birth** (DOB) on the survey login page.



   A. The password is found in the header of the case's Expansion Tracking database record in the **PW** field. Copy and paste the password to ensure it is entered accurately.
   B. *If the participant's DOB has ever been changed*, it may be necessary to use the ORIGINALLY RECORDED DOB to login, even if that DOB was incorrect. This should be documented in the **Comments** field of the Quest tab in the case's record.
   C. For Dana Farber (DFCI) or institution 05 participants, see also the SOP titled **Dana Farber Cancer Institute (DFCI) Baseline Survey Calls**.
   D. *If the survey was previously accessed* by the participant or an SI, options to **Start Over** or **Restore** may be displayed after logging in to the survey. In general, click **Restore** to avoid clearing all previous responses.
2. Before starting the survey, obtain informed consent:
      A. **Read** the **Informed Consent with Incentive Expansion Baseline** script to the participant *exactly as written*. This is found in *Z:\Departments\ECC\common\Interviewers\Expansion Survey Calls\Scripts*.
   B. **Document** answers to all questions on the last page of the printed informed consent.
   C. When a **participant copy** is needed, document the requested format of the participant copy.
      i. Spanish – There is not currently an approved participant copy of the informed consent in Spanish. Spanish-speaking SIs should advise participants that their copy will be in English.

ii. Refuses Participant Copy – If a participant refuses to receive a copy of the consent form, clearly document the refusal in the contact or trace log, and add a dated note with SI ID to the **Comments** field of the Quest tab.

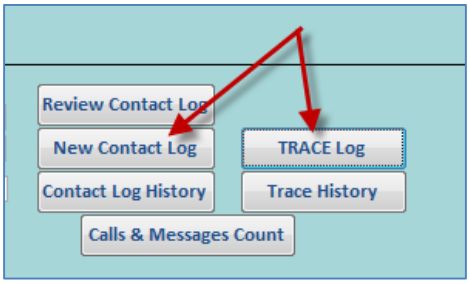


3. Document the **consent in the online survey** form. See the SOP titled **Expansion Baseline Online (Verbal) Consent Procedures** for full details.
4. If the participant consents to the study, **proceed** with the survey. Read all questions and all answers *exactly as they appear*.
5. Additional Notes Regarding **Deceased Participants**:
   A. When completing the survey with the proxy of a deceased participant, *always* fill out an **Expired Participant Information Sheet**, located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*.
   B. Determine if the proxy wants to receive LTFU newsletters, as s/he will *not* receive them automatically. If yes, mark the **Newsletter Requested?** checkbox at the top of the **Expired Participant Information Sheet**.

AFTER THE CALL: General

Based on the call outcome, follow the appropriate procedures below.

1. **Document all communication** in the contact or trace log. Each communication (telephone call, email message, etc.) should be documented individually.
   A. For calls made to or from a previously confirmed number, sent or received emails, and all other communications with an external party for non-tracing purposes, click on the **New Contact Log** button in the header.
   B. For calls made to or from an unconfirmed number, click on the **Trace Log** button in the header, then click on the **New Record** button.



   C. Populate the record as follows:
      i. **Int ID** – Enter the SI ID.
      ii. **Date** – Enter the date of the communication.
      iii. **Contact Mode** – Select the appropriate option from the drop-down menu.
      iv. **Phone** – For telephone calls, enter the telephone number to which the call was placed or from which the call was received. For non-telephone communication, leave this field blank.
      v. **Email** – For emails, enter the email address to which the message was sent or from which the message was received. For non-email communication, leave this field blank.
      vi. **Contacting** – Use the drop-down menu to select the appropriate option.
         a. For outgoing communication, choose the party reached or, when no one is reached, choose the party you are trying to reach.
         b. For incoming communication, choose the party contacting the LTFU Study.
         c. If unsure of the exact relationship, use 8-Other.
      vii. **Name** – Enter the name of the party with whom the communication is conducted.
         a. For outgoing communication, choose the party reached or, when no one is reached, choose the party you are trying to reach.
         b. For incoming communication, choose the party contacting the LTFU Study.
         c. If unsure, type "unknown" in this field.

viii. **Time START** – Enter the time the communication began. For calls, this will be the time the phone was dialed or rang. For emails, this will be the time the email was sent or received.

ix. **Time END** – Enter the time the communication ended. For calls, this will be the time the telephone was hung up. For emails, this will be the time the email was sent or received (i.e. same as **Time START**).

x. **Project** – Choose 3-Case Baseline from the drop-down menu.

xi. **Contact Reason** – Select 4-Survey from the drop-down menu.

xii. **Email Type** – For emails sent or received, select the appropriate option from the drop-down menu. For non-email communication, leave this field blank.

xiii. **Outcome** – Select the appropriate option from the drop-down menu to describe the outcome of the communication. NOTE: Refusals *MUST* be documented with 7-Refused, and clear notes regarding the refusal should be in the **Notes** field.

xiv. **DB Change** – If an LSI-level database change is needed (e.g. DOB change, gender change, case suspected to be ineligible, legal name change, survival status change, etc.) or if a survey was partially completed or completed in Spanish, flag the change request or survey event using the drop-down menu in this field. *IMPORTANT: Clear notes regarding the change request or event must be documented in the **Notes** field of the same contact record.*

xv. **Notes** – Enter clear, concise, thorough notes about the communication and its outcome.

a. If a database change is requested in the **DB Change** field, clearly document the change in this field (e.g. "*change DOB from 1/7/85 to 11/7/85*", "*gender is listed as F, please change to M*", or "*change name from Robin Penn to Robin Wright due to divorce*").

b. *Clearly* document LAR situations.

c. If calling one party and reaching another, specify this. *Example: "Called for case. Case's mother answered and…"*

d. For email communication, enter only a summary of what was sent. Do not paste the full body of the email into this field.

xvi. **Appt Date** – If an appointment was set for a particular date and time, enter the date of the appointment.

xvii. **Appt Time** – If an appointment was set for a particular date and time, enter the time of the appointment *in Central Time*.

xviii. **Incoming Call** checkbox – Mark this checkbox if the record is for an incoming call. Leave this checkbox blank for outgoing calls and all non-telephone communication.

xix. **Contact Made** checkbox – Mark this checkbox if someone was contacted during an incoming or outgoing call. Leave this box blank for all non-telephone communication.

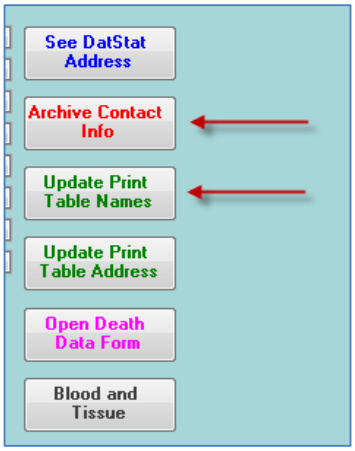
xx. **Left Message** checkbox – If a message was left on an answering device, check this box. This will update the tally displayed in the **Calls & Messages Count** report. DO NOT check this box for messages left with a live person or for non-telephone communication.

xxi. **Add Record to Call Log** – Found in the Trace Log only. Click this button if the case or an associate was reached during a tracing call.

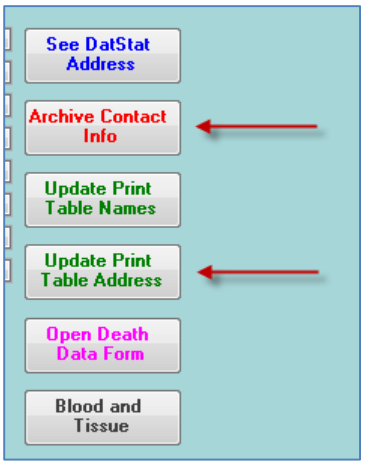
2. **Update the Expansion Tracking database** with information *confirmed with a live person*. See the section of this document titled ***AFTER THE CALL: Updating Expansion Tracking Database***. NOTE: The database is NOT updated with unconfirmed information.
3. For **survey outcomes** including partially-completed and completed surveys, see the section of this document titled ***AFTER THE CALL: Survey Outcomes***.

AFTER THE CALL: Updating Expansion Tracking Database

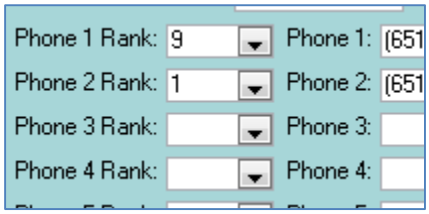
1. Special Note Regarding **Former St. Jude Patients** (institution 15): If the case's CCSSID # begins with 15 and any contact information has changed, send screen shots highlighting the changes made to the CRA coordinating St. Jude Life recruitment. See an LSI to identify the appropriate CRA.
2. If the **Date of Birth**, **Gender**, or **Survival Status** fields need to be populated or changed, request this action through the contact or trace log's **DB Change** field. See the section of this document titled *AFTER THE CALL: General*.
3. **Send Q-aire To** field (Quest tab) – Choose the most appropriate option from the drop-down list.
4. **Participant Name** (Quest tab) – If the participant's legal name has changed (e.g. due to marriage or adoption):
   A. Click the **Archive Contact Info** button.
   B. **To Whom Letter Sent** – Update the field keeping the formatting of the name and the address consistent (i.e. if the address is in ALL CAPS, the name should also be in ALL CAPS). NOTE: Although the header should always display the case's *legal* name, the **To Whom Letter Sent** field can be populated as follows:
      i. If the case's preferred name is not specified, enter the name as Firstname Lastname.
      ii. If the participant goes by his/her first name, enter the name as Firstname Lastname.
      iii. If the participant goes by his/her middle name, enter the name as F. Middlename Lastname (e.g. *J. Edgar Hoover*).
      iv. If the participant goes by both his/her first and middle names, enter the name as Firstname Middlename Lastname (e.g. *Billy Bob Thornton*).
      v. If the participant's preferred name is not part of his/her legal name, enter the name as Preferredname Lastname (e.g. *Bill Clinton*).
   C. **Comments** – Add a dated note with your SI ID fully explaining the name change, including any indicated preferred name.
   D. Save the changes by moving the cursor to a new field, then clicking on the **Save** icon in the Records group of the Ribbon's Home tab. Failure to save the changes will result in failure of the Update Print Tables operation.
   E. Click on the **Update Print Table Names** button.
   F. **DB Changes** field in the contact or trace log – Request a change to the **First Name**, **Middle Name**, and/or **Last Name** fields of the header, if appropriate. See the section of this document titled *AFTER THE CALL: General*.
   NOTE: The header fields should always contain the case's LEGAL names.



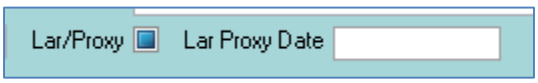
5. **Participant Mailing Address** (Quest tab)
   A. If the participant's name and address are in different formats (e.g. name in ALL CAPS and address in Upper-lower case), proactively correct the address to be uniformly formatted with the name.
   B. Confirmed: Update the **Addr Date** field with the date the existing address was confirmed and update the **Addr Source** field with the appropriate source.
   C. New:
      i. Click the **Archive Contact Info** button.
      ii. Enter the new address. If the **To Whom Letter Sent** field is in all CAPS, the rest of the address should also be in all CAPS.
      iii. Save the changes by moving the cursor to a new field, then clicking on the **Save** icon in the Records group of the Ribbon's Home tab. Failure to save the changes will result in failure of the Update Print Tables operation.
      iv. Click on the **Update Print Table Address** button.



6. **Participant Telephone Numbers** (Quest tab)
   A. **Archive Contact Info** button – If updating any information on this tab where data *would otherwise be lost*, click this button first.
   B. Confirmed: Update the **Phone # Date** field with the date the number was confirmed, and update the **Phone # Source** field with the appropriate source.
   C. New:
      i. Enter the new number in the top-most empty row: Populate the **Phone # Rank** field, the **Phone #** field with the number and type, the **Phone # Date** field with the date the number was confirmed, and the **Phone # Source** field.
      ii. If all phone slots are taken, see the SOP titled **Handling Additional Phone Numbers**.
   D. Rank telephone numbers according to your best judgment. Use the drop-down menu in the appropriate **Phone # Rank** field.
      i. Rank of 1-5 identifies the preference in dialing with rank "1" being the best number at which to reach the participant, rank "2" being the second-best number at which to reach the participant, etc.
      ii. Rank "9" indicates that the number was found to be disconnected.
      iii. Rank "11" indicates that the number is a wrong number.
      iv. Rank "37" indicates that the number should NOT be called again.
      IMPORTANT: Every time a number is ranked "37", add an explanatory note in the **Comments** field formatted with leading double-asterisk, date, MESSAGE IN ALL-CAPS, and SI ID.
      *Example: **10/28/2015: DO NOT CALL 901-321-1231. CASE'S FATHER REQUESTED NO FURTHER CALLS AT THE HOME NUMBER HE SHARES WITH CASE. [174]*



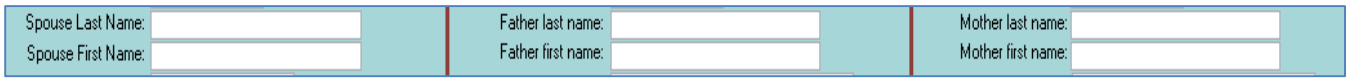
7. **Participant Email Address** (Quest tab) – Follow the same protocol used for updating participant telephone numbers including the **Email # Rank**, **Email #**, **Email # Date**, and **Email # Source** fields.
8. **LAR Status** – If it was determined that the participant has a Legally Authorized Representative (LAR) or proxy (See a member of the LSI team or the Coordinator for assistance determining an authorized proxy for a non-



deceased adult participant. This is NOT applicable for minor or deceased participants; these participants would always be represented by a proxy.):

A. **Lar/Proxy** (header) – Mark this checkbox.
B. **Lar Proxy Date** (header) – Enter the date the LAR status was discovered.
C. **Care of** (Quest tab) – Populate this field with "C/O" followed by the LAR/proxy's first and last name, move the cursor to a new field, click the Save icon in the Records group of the Ribbon's Home tab, then click the **Update Print Table Address** button. See the SOP titled **Use of Care of Field** for full details. NOTE: Keep the format of the name consistent with the rest of the address (e.g. ALL CAPS or Upper-lower case).
D. **Comments** (Quest tab) – Add a dated note with SI ID clearly documenting the LAR/proxy status and circumstances.

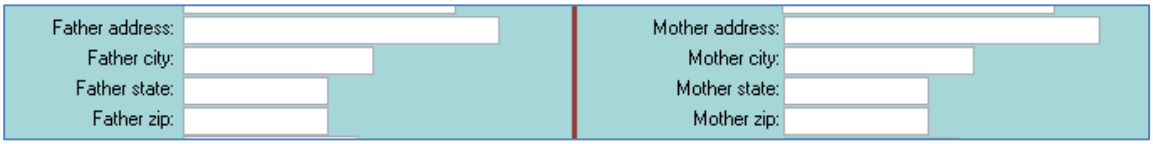
9. **Spouse/Father/Mother Names** (Reg tab) – Names are documented as the legal name with any preferred name, if known, in quotes in the **Spouse/Father/Mother First Name** field (e.g. *Robert "Bob"* or *Patricia "Pat"*).



Ensure details regarding any indicated preferred names are documented in the call notes and in the **Spouse/Father/Mother Notes** field. If the spouse/father/mother name is:

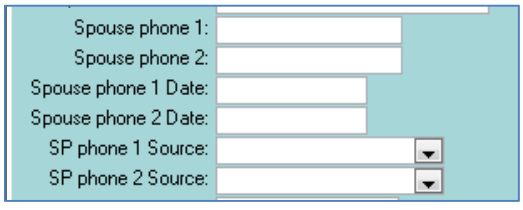
A. Newly gathered: Populate the **Spouse/Father/Mother Last Name** and **Spouse/Father/Mother First Name** fields.
B. Different than what we have documented:
   i. Ensure details regarding the name change, including any preferred names, are documented in the call notes and in the **Spouse/Father/ Mother Notes** field.
   ii. Update the **Spouse/Father/Mother Last Name** and/or **Spouse/Father/Mother First Name** field(s) on the Reg tab.

10. **Father/Mother Mailing Address** (Reg tab) – There is no archiving feature for parent addresses in the Expansion Tracking database. If updating any information on this tab where data would otherwise be lost:
A. Make a dated note in the **Father/Mother Notes** field documenting the data being removed, the source of the change, and your SI ID.
Example: 12/15/2015: Pt provided new address for mother, Lucy Liu. Updated address from 1111 Main St, Anytown, NM 11111 to 2323 Union St, Anytown, TN 89111. [63]



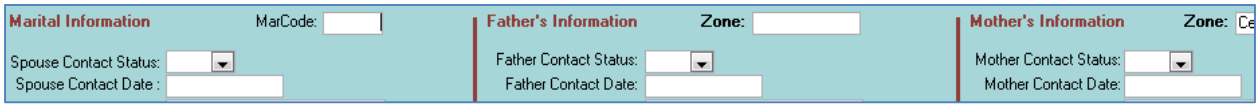
B. Once the old information has been documented, update the appropriate parent address fields.

11. **Spouse/Father/Mother Telephone Numbers** (Reg tab)
A. Confirmed: Update the corresponding **Spouse/FA/MO Phone # Date** and **SP/FA/MO Phone # Source** fields.
B. New:
   i. Add the new number to the top-most empty slot for the appropriate party.
   ii. Update the corresponding **Spouse/FA/MO Phone # Date** and **SP/FA/MO Phone # Source** fields.
   iii. If all phone slots are taken, see the **Handling Additional Phone Numbers** SOP.
C. Disconnected: Add a dated note with your SI ID in the **Spouse/Father/Mother Notes** field documenting the disconnected number. Do not remove the number.

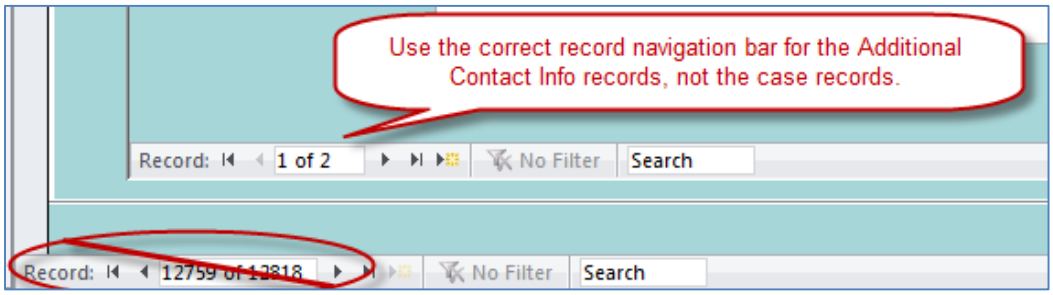


D. Wrong or "Do Not Call" Numbers: Add a formatted note to the **Spouse/Father/Mother Notes** field.
*Example: **6/27/2015: DO NOT CALL 901-321-1231. THIS IS FATHER'S WORK NUMBER. [162]*

12. **Contact Status** – In general, a **Contact Status** of "Yes" indicates that the *participant* authorized us to contact a particular associate if we are unable to contact the participant, and a **Contact Status** of "No" indicates that either the participant OR the associate has asked that we avoid contacting the associate. Associates authorized for contact *by the participant* are referred to as "additional contacts".
    A. If the *participant* authorizes one or both parents and/or his/her spouse as an additional contact, do NOT add the parent or spouse to the Associates tab. Instead, on the Reg tab:
        i. **Spouse/Father/Mother Contact Status** – Set to Yes.
        ii. **Spouse Father/Mother Contact Date** – Update with the date of the most recent *participant* authorization.
        iii. Update the parent's and/or spouse's contact information, as instructed above.
        iv. **Spouse/Father/Mother Notes** – Document the contact status in a dated note with SI ID.
        Example: 7/11/2015: Pt authorized mother as ADDITIONAL CONTACT. Updated Mother Contact Date from 12/31/2014 to 7/11/2015. [162]



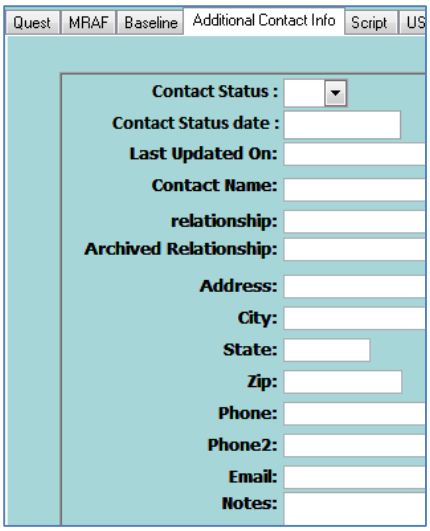
    B. If the *participant* authorizes an associate other than a parent or a spouse, on the Associates tab:
        i. Scroll through all existing records to determine if there is already a record for the associate.



        ii. If the additional contact person and contact information on file have not changed:
            a. **Contact Status** – Set to Yes.
            b. **Contact Status Date** – Populate with the date of the most recent *participant* authorization.
            c. **Last Updated On** – Update with date contact information was confirmed.
            d. **Notes** – Document the contact status in a dated note with SI ID.

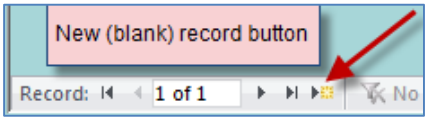
Example: 2/15/2015: Case confirmed sister, Lisa Morales, as ADDITIONAL CONTACT. [111]

iii. If the additional contact person is on file but has new contact information:



a. **Contact Status** – Set to Yes.
b. **Contact Status Date** – Populate with the date of the most recent *participant* authorization.
c. **Notes** – Document the additional contact authorization and archive the previous contact information by adding a dated note with SI ID. *Example: 4/21/2015: Pt confirmed Jada P. Smith as ADDITIONAL CONTACT. Updated address from 123 4th Street, Anytown, TN, 38123 to 234 5th Avenue, Anytown, TN 38234 and ph# from 901-234-5678 to 901-345-6789. [158]*
d. Enter the new contact information.
e. **Last Updated On** – Update with the date the new contact information was confirmed.

iv. If the additional contact person is not on file, create a new record in the Associates tab without deleting any previous records.



a. Click the New (blank) record button.
b. **Contact Status** – Set to Yes.
c. **Contact Status date** – Populate with the date of the most recent *participant* authorization.
d. **Last Updated On** – Populate with the date the contact information was confirmed.
e. **Contact Name** – Document the associate's name as the legal name with any preferred name, if known, in quotes (e.g. *Deadrick "Ricky" White*). Ensure details regarding any indicated preferred names are documented in the call notes and in the **Notes** field. NOTE: Only one contact/person should be recorded in each record. Do not list, for example, both grandparents on the same record (e.g. *John and Joan Doe*).
f. **Relationship** – Populate with the correct value. If unknown, use 15-Other.
g. Enter all contact information provided by the participant.
h. **Notes** – Enter a dated note with SI ID documenting the contact status.

C. If either an associate (spouse, parent, and/or additional contact) has requested not to be contacted OR the participant has requested that we no longer contact the associate:
   i. **Contact Status** – Set to No.
   ii. **Contact Status Date** – Populate with the date of the request.
   iii. Enter a dated note in the related **Notes** field indicating the change in contact status. *Example: 6/15/2015: Case requested that we do not contact his mother. She has Alzheimer's disease and is easily confused. [158]*

13. **Deceased/ Vital Status Update**

A. **Comments** (Quest tab) – Add a dated comment with SI ID documenting the change in vital status and its source.

B. For deceased participants:
   i. Using the instructions in the section of this document titled ***AFTER THE CALL: General***, log a request in the contact or trace log's **DB Change** and **Notes** fields to update the case record's **Survival Status** field.

ii. If applicable, file the **Expired Participant Information Sheet** completed during the call in the appropriate folder of cabinet A.

C. For deceased associates, go to the appropriate associate record:

i. **Contact Status** – Set to No.

ii. **Status Date** – Set to the current date.

iii. **Notes** – Add a dated comment with SI ID documenting the change in vital status and contact status.

14. **Case Prefers or Requires Spanish-Speaking Representative** – The SI should:

A. Update the **Spanish Status** field to indicate:

i. "1" if participant speaks only Spanish

ii. "2" if participant speaks both English and Spanish

iii. "3" if the participant speaks both English and Spanish but *prefers* Spanish

B. Request that the case be reassigned to a Spanish-speaking interviewer if the SI does not speak Spanish.

15. **No Proxy Available** – When a case is unable to represent himself/herself to participate in the LTFU Study and there is no party available to act as a proxy for the case, alert the leadership team that a "no proxy available" determination is needed. See the SOP titled **Requesting "No Proxy Available" Determination** for details.

16. Participant Is **Incarcerated**

A. If the incarceration is expected to last 12 months or less, apply a hold appropriate to the expected duration. See the "Participant Requests to be On Hold" directives, below.

B. For incarceration expected to last greater than 12 months:

i. **DB Change** (contact log) – Request an eligibility determination.

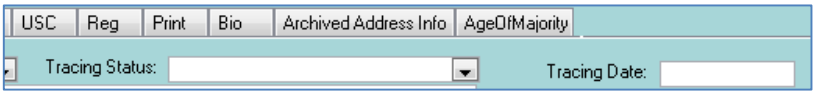
ii. **Notes** (contact log) – Include all details of the case's incarceration status.

iii. A member of the LSI team will consult with the Coordinator and Research Scientist to determine action to be taken.

17. **Tracing Status Update** (Quest tab)

A. If all available numbers in the database are disconnected, wrong, or "Do Not Call":

i. And the **Tracing Status** field is blank, update the field to be 19-Disconnect, and enter the current date in the **Tracing Date** field.



ii. And **Tracing Status** field is populated with 18-Search New Addr or 81-Newsletter Returned W/O New Addr, update the field to be 13-Needs Tracing, and enter the current date in the **Tracing Date** field.

iii. And the **Tracing Status** field is populated with 85-Bad Lexis Nexis Address, update the field to be 86-Bad Lexis Nexis Address & Phone(s), and enter the current date in the **Tracing Date** field.

iv. **Comments** – Add a dated note with your SI ID documenting the changes to these fields.

B. If calls to all numbers meet the following criteria, the participant may be placed in tracing for bad numbers, as directed above:

i. If the voicemail announcement indicates the participant's or his/her associate's name, and there has been no response after 5 calls and 3 messages

ii. If the voicemail announcement is generic, and there has been no response after 4 calls and 2 messages

iii. If there is no voice mailbox (i.e. we cannot leave a message), and no one has been reached after 3 calls

C. If we are notified that the case's mailing address is incorrect but an updated address is not provided:

i. When the **ADDRESS SOURCE** *is not* Lexis Nexis:

a. And the **Tracing Status** field is blank, update the field to be 18-Search New Addr, and enter the current date in the **Tracing Date** field.
b. And the **Tracing** Status field is populated with 19-Disconnect, update the field to be 13-Needs Tracing, and enter the current date in the **Tracing Date** field.
c. **Comments** – Add a dated note with your SI ID documenting the change to these fields.

ii. When the **ADDRESS SOURCE** *is* Lexis Nexis:
a. And the **Tracing Status** field is already populated with 13-Needs Tracing, update the field to be 86-Bad Lexis Nexis Address & Phone(s) and populate the **Tracing Date** field with the current date.
b. And the **Tracing Status** is already populated with 18-Search New Addr or 81-Newsletter Returned W/O New Addr, update the fields to be 85-Bad Lexis Nexis Address, and populate the **Tracing Date** field with the current date.
c. **Comments** – Add a dated note with your SI ID documenting the change to these fields.

D. If the **Tracing Status** field is currently set to 13-Needs Tracing and the case's contact information is confirmed:
i. If a telephone number for the case is confirmed but not an address:
a. **Tracing Status** – Update from 13-Needs Tracing to 18-Search New Addr
b. **Tracing Date** – Update to the current date
c. **Comments** – Add a dated note with your SI ID documenting the change to these fields.
d. Complete all appropriate database updates for the case's telephone number.

ii. If a mailing address for the case is confirmed but not a phone number:
a. **Tracing Status** – Update from 13-Needs Tracing to 19-Disconnect
b. **Tracing Date** – Update to the current date.
c. **Comments** – Add a dated note with your SI ID documenting the change to these fields.
d. Complete all appropriate database updates for a case's mailing address.

iii. If both a telephone number and a mailing address for the case are confirmed:
a. **Tracing Status** and **Tracing Date** – Clear both fields.
b. **Comments** – Add a dated note with your SI ID documenting the change to these fields.
c. Complete all appropriate database updates for a case phone number and address.

E. If the **Tracing Status** is currently set to 19-Disconnect and a telephone number for the participant is confirmed:
i. **Tracing Status** and **Tracing Date** – Clear both fields.
ii. **Comments** – Add a dated note with your SI ID documenting the change to these fields.
iii. Complete all appropriate database updates for a case's telephone number.

F. If the **Tracing Status** is set to 18-Search New Addr, 81-Newsletter Returned W/O New Addr, or 85-Bad Lexis Nexis Address and a mailing address for the participant is confirmed:
i. **Tracing Status** and **Tracing Date** – Clear both fields.
ii. **Comments** – Add a dated note with your SI ID documenting the change to these fields.
iii. Complete all appropriate database updates for a case's mailing address.

G. If the **Tracing Status** is set to 86-Bad Lexis Nexis Address & Phone(s) and contact information is confirmed:
i. If a telephone number for the case is confirmed but not an address:
a. **Tracing Status** – Update to be 85-Bad Lexis Nexis Address
b. **Tracing Date** – Update to be the current date
c. **Comments** – Add a dated note with your SI ID documenting the changes to the fields.
d. Complete all appropriate database updates for a case telephone number.

ii. If a mailing address for the case is confirmed but not a telephone number:

a. **Tracing Status** – Update to be 19-Disconnect
b. **Tracing Date** – Update to be the current date
c. **Comments** – Add a dated note with your SI ID documenting the changes to the fields.
d. Complete all database updates for a case mailing address.

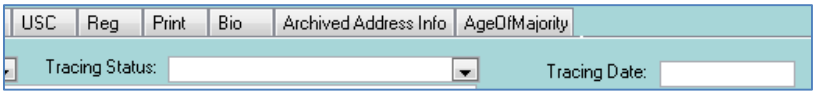
iii. If both a telephone number and a mailing address for the case are confirmed:

a. **Tracing Status** and **Tracing Date** – Clear both fields.
b. **Comments** – Add a dated note with your SI ID documenting the changes to the fields.
c. Complete all database updates for a case address and telephone number.

H. For all other Tracing questions, consult with an LSI or the Call Center Coordinator.

AFTER THE CALL: Survey Outcomes

1. **Participant Stated Paper Survey Previously Returned** – Make an appointment in Outlook to follow up with the case in 4 weeks.
2. **Appointment Made**
   A. Write the appointment on the calendar as indicated in the SOP titled **Call Center Appointment Calendar**.
   B. If the SI who scheduled the appointment will be covering it, s/he should add the appointment to his/her Outlook calendar.
   C. If the appointment needs to be assigned to another SI, send an email to the LSI team and copy the Call Center Coordinator for assignment. If there is no time to follow this procedure (i.e. The LSI team and Coordinator are out or otherwise unavailable before the appointment.):
      i. Coordinate with another SI to handle the appointment.
      ii. Document the scheduling/covering SI on the Call Center appointment calendar as indicated in the SOP titled **Call Center Appointment Calendar**.
      iii. Send an email to the LSI team, copying the Coordinator and the covering SI, with details about the appointment and who will cover it.
   D. If the participant provided a valid email address, use the instructions in the SOP titled **Email Appointment Reminders for Baseline Surveys** to email an appointment reminder, if appropriate.
3. **Resend of the Paper Survey** – Go to the Quest tab and:
   A. **Tracing Status** – Update to 82-Resend Survey.
   B. **Tracing Date** - Update with the current date.
   C. **Comments** – Add a dated note with SI ID documenting the change to the **Tracing Status** and **Tracing Date** fields.



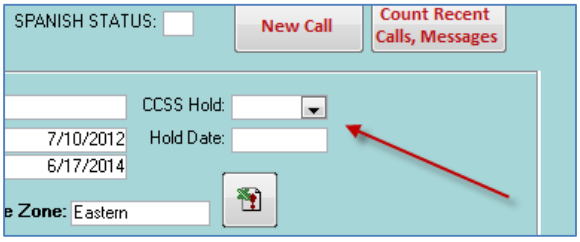
   D. Remember that DECEASED and SPANISH surveys must be done with an SI over the telephone. Do NOT record a request to resend the paper survey to a deceased case's proxy or a participant whose **Spanish Status** is 1.
4. **Survey Link Via Email** – Remember that Dana Farber Cancer Institute (institution 05) cases, proxies for deceased cases, and cases requiring Spanish should NOT be emailed the survey link.
   A. Follow the procedure to email the appropriate survey link. See the SOP titled **Emailing Expansion Baseline Survey Links** for details.
   B. After sending the email:

i. Document the email in the contact log. See the section of this document titled *AFTER THE CALL: General* for instructions.

ii. On the Baseline tab:
   a. Check the next available **Sent Email #** box, and enter the **Email # Date** as the date the email was sent. (If all 3 fields are already used, skip this step.)
   b. **Tracking Comments** – Enter a brief dated note with SI ID, and then copy the note. *Example: 11/2/2015: As requested, emailed baseline survey link to cutegirl@email.com. [121]*

iii. Paste the note into the **Comments** field of the Quest tab.

5. **Participant Declines To Complete Survey** (=REFUSAL To Participate In LTFU Study)
   A. **Outcome** (Contact Log) – Document the refusal as instructed in the section of this document titled *AFTER THE CALL: General*.
   B. Update the database with the refusal:
      i. **Comments** (Quest tab) – Enter a dated note with SI ID documenting the refusal. Copy the note.
      ii. **Tracking Comments** (Baseline tab) – Paste the Quest tab note documenting the refusal.
      iii. **Baseline Outcome** (Baseline tab) – Code as 7-Refused.
      iv. **Baseline Outcome Date** (Baseline tab) – Enter or update to be the date the information is being entered.
      v. **Outcome** (Reg tab) - Code to be 37-Refused all else.
      vi. **Outcome Date** (Reg tab) - Enter or update to be the date the information is entered.
6. **Participant Requests To Be On Hold**
   A. **CCSS Hold** (Quest tab) – Update with the appropriate value using the drop-down menu. Note:



      i. The "Calls" hold, which puts the participant on hold for outgoing calls but not for mailings or emailings, is applied on a case-by-case basis. As with all special outcomes, notify the LSI team and Call Center Coordinator of the circumstances to determine if a "Calls" hold is appropriate.
      ii. The "LN Hold" should not be applied by the Survey Interviewer team.
   B. **Hold Date** (Quest tab) – Update with the current date.
   C. **Comments** (Quest tab) – Enter a dated note with SI ID documenting the hold and circumstances. *Example: "10/22/2015: Due to father's illness, pt requests a six-month hold. [111]"*
   D. Do NOT add a reminder in Outlook to call the case when the hold expires. The LSI team will review expired holds as appropriate.
7. **Ineligibility** – If the case is suspected to be ineligible, request an eligibility determination using the **DB Changes** field in the contact log and document why the participant is believed to be ineligible in the **Notes** field of the log, as instructed in the section of this document titled ***AFTER THE CALL: General***. An LSI will address this with the Call Center Coordinator for an eligibility determination.
8. **Completed Surveys**
   A. Review each page of the online survey for accuracy or questions erroneously left blank. This must be done using the **Previous** and **Next** buttons <u>on the survey form</u>; NEVER use the back/forward arrows from your internet browser.
   B. Complete any information that was not entered during the interview, and check for missing information or any fields mistakenly left blank.

C. AFTER the survey information is checked for accuracy and completion and the Expansion Tracking database has been updated with confirmed contact information, click the **Submit** button on the last page of the survey. Click **Yes** at the next prompt to close the browser instance.

D. For surveys completed with someone other than the survivor/case (e.g. for expired participants, for minor participants, LAR of participant, etc.), add a dated note with SI ID in the **Comments** field of the Quest tab and the **Tracking Comments** field of the Baseline tab indicating the name and relationship of the proxy. *Example: 8/1/2015: Completed survey with minor pt's legal guardian, Marsha Brady. [176]*

E. For scheduled surveys, place a check mark on the Call Center appointment calendar to indicate the kept appointment. See the SOP titled **Call Center Appointment Calendar** for details.

F. For unscheduled surveys, email the CCSSID to the closing monitor to include the survey in the closing report.

G. Note the completed survey on the Call Center dry erase board (DEB).

H. Ensure the informed consent form is completely filled out with the case's CCSSID, answers to all questions documented, the date the consent was obtained, the date the survey was completed, and your SI ID.

I. File the informed consent form in the hanging file labeled "Daily Informed Consents" in file cabinet A.

J. Ensure all LSI-level database changes (e.g. DOB and/or gender for a Dana Farber case, name change, requested no newsletters, etc.) are clearly documented in the contact log's **Notes** field and the **DB Change** field indicates the requested change.

K. **Deceased Participants** – If the survey was completed with family of a deceased participant:

   i. Complete all online and database entry, as instructed above. Ensure your call notes include the first and last name of the proxy and the proxy's relationship to the expired case.

   ii. File the **Expired Participant Information Sheet** in the hanging file labeled "Daily Informed Consents" in file cabinet A along with the informed consent form.

L. **Spanish Surveys** – If the survey was completed with the participant over the phone in Spanish:

   i. Complete all online and database data entry, as instructed above. Ensure the **Spanish Status** field is properly populated.

   ii. Ensure the Spanish survey completion is clearly documented in the contact log's **Notes** field and the **DB Change** field.

   iii. Add a dated note with SI ID in the **Comments** field of the Quest tab and the **Tracking Comments** field of the Baseline tab indicating that the survey was completed in Spanish. *Example: 9/15/15: Completed survey with case in Spanish. [158]*

   iv. Email the CRA2 team, copying the LSI team and Coordinator, that an Expansion Baseline survey has been completed in Spanish. Include the CCSSID in the **Subject** line and body of the email.

   v. Make a personalized Spanish thank-you card insert to the participant. See the SOP titled **Sending Spanish Thank You Notes** for details.

   vi. Deliver the thank-you card insert to a member of the CRA2 team. If neither is available, give the insert to an LSI or the Coordinator for later delivery.

9. **Partial Surveys** (consented but did NOT complete survey)

A. Review each completed page of the online survey for accuracy or questions erroneously left blank. This must be done using the **Previous** and **Next** buttons on the survey form; NEVER use the back/forward arrows from your internet browser.

B. In the contact log, populate the **DB Change** field with "Partially Complete".

C. On the Quest tab, enter a dated note with SI ID in the **Comments** field. *Example: "11/9/2015: Gathered informed consent, partially completed survey with case through question J1. [162]"*

D. For scheduled surveys, note the partial survey outcome on the calendar according to the SOP titled **Call Center Appointment Calendar**.

E. For unscheduled surveys, email the CCSSID to the closing monitor to include the partial survey in the closing report.
F. Ensure the informed consent form is completely filled out with the case's CCSSID, answers to all questions documented, the date the consent was obtained, and your SI ID number.
G. File the informed consent form in the hanging file labeled "Daily Informed Consents" in file cabinet A.
H. Update the dry erase board (DEB) tally with a "p" to indicate the partial survey.

(71) Current Filename:		Expansion Baseline Survey Calls ver2_9.docx	
Rev. No.	Date	Responsible Author	Change Description
1	4/5/12	Rinehart/Jackson/Carson	Initial Development
1.2	4/27/12	Procedure Team	Formatting and content revisions
1.3	5/1/12	J.Bates	Format presentation
1.4	5/28/12	D. Rinehart	Standard call assignments updated, Spanish Call assignment procedures added.
1.5	6/5/12	D. Rinehart	Added screen shot to page 5, point viii.
1.6	6/29/12	D. Rinehart	Added point e., page 3, "…sending the participant an appointment reminder"
2.0	1/22/13	Rinehart, McDonald, Carson, Jackson	Multiple updates: AOM note; Sharepoint; Spanish; Spanish Thank You; gift card inquiries; no numbers available
2.1	1/24/13	D. Bowen, D. Rinehart	Added copy for the Partially Completed Survey Tracking Log
2.2	4/27/13	R. Massey, M. Jackson, D. Rinehart, B. Carson, T. Smith	Added instructions for the Survey Interviewers to update contact, parent, additional contact information, updated numbers and bullet points
2.3	4/30/13	J. Bates, R. Massey, D. Rinehart	Clarification and additional comments
2.4	10/1/13	R. Massey	Content Revision: Email SOP title, Spouse as Add'l Contact, Spanish Status=3, Completed expired surveys no longer in Call Outcomes Log
2.5	11/14/13	R. Massey	Content Revision: Add directives for ineligibles, "calls" holds, participant copies of informed consent, option for "requests no newsletters"
2.6	9/3/2014	R. Massey, A. Oyuela	Content Revision: remove references to Call Outcomes Log, add call and trace log instructions, update informed consent instructions
2.7	2/4/15	R. Massey	Content Revision: Added directives for new fields, new contact log, new trace log, reorganized associate directives
2.8	7/9/15	R. Massey	Content Revision
2.9	9/2/2016	A. Cobble, D Rinehart	Content Revision

Expansion Baseline Survey Mailing for Dana Farber

Background

Producing Dana Farber baseline survey mailings differs slightly from non Dana Farber mailings primarily due to the fact that Dana Farber participants cannot complete the survey online. This results in specialized Dana Farber cover letters. Additionally, there is a "baseline" booklet (and special participant copy) to send to deceased Dana Farber families. This booklet contains the LTFU consent and HIPAA authorization forms.

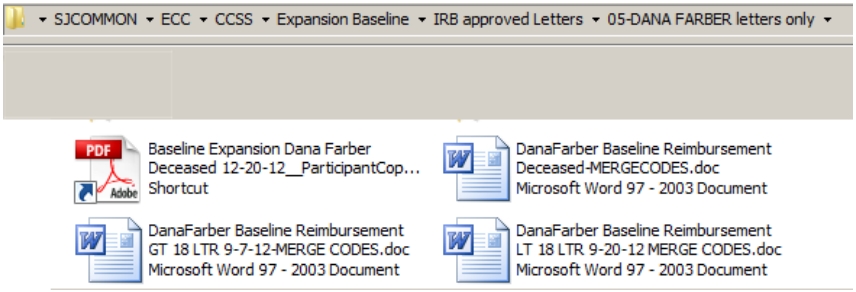
Procedure

Survey Production: Teleforms:

- Adults and Minors: use the standard baseline expansion 2007 survey
- Deceased: Select form called Baseline Expansion 2007 Dana Farber Deceased HIPAA Consent Inc

Mail out: Cover letters

- Print on St. Jude letterhead
- COVER LETTERS located here: …***\ECC\CCSS\Expansion Baseline\IRB approved Letters\05-DANA FARBER letters only***.
  These DIFFER FROM the standard USC cover letters.



PACKING: Include

- Use standard *blue BRE*, and *incentive mailer*.
- ***Participant copy***
  - For LIVING (adults/minors), use standard Participant copy
  - ***For Deceased,*** use (Dana Farber) deceased participant copy: Baseline Expansion Dana Farber Deceased 12-20-12__Participant Copy (located in same folder as other participant copies.)
- ***NOTE:*** Do **NOT** include brochure, as it directs them to the online survey site.
- **DO** include the gift card incentive flyer

Revision Record — Printed 6/18/2013 8:15 AM

[50] Current Filename:		Expansion Baseline Survey Mailing-Dana Farber ver 1_3.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	9/20/10	J.Bates	Initial Development
1.1	9/21/10	J.Bates	Location of deceased participant copy.
1.2	7/6/12	J.Bates	Correct file location
1.3	5/15/13	J.Bates	New dec. particip copy, teleform; NO BROCHURE
¼	6/18/13	J.Bates	Use incentive envelope/flyer

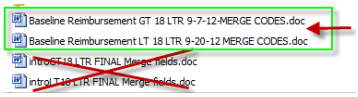
Expansion Baseline Survey Packet with Incentive

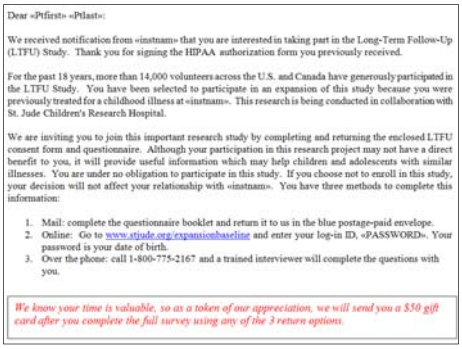
Background

The amended LTFU protocol includes an incentive to participants who complete the baseline survey. As a result of this amendment, our production process changes as follows: We ADD a flyer to the mail out. We also CHANGE the letter, the automerge publisher survey form, the participant copy, and the mailing envelope.

Production Item Summary

1. **Cover Letter**: Use the NEW cover letter that refers to the gift card incentive.
   a. Use the "**Baseline Reimbursement … MERGE CODES**" letters.
   b. Found in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\IRB approved Letters**




Dear «Ptfirst» «Ptlast»:

We received notification from «instnam» that you are interested in taking part in the Long-Term Follow-Up (LTFU) Study. Thank you for signing the HIPAA authorization form you previously received.

For the past 18 years, more than 14,000 volunteers across the U.S. and Canada have generously participated in the LTFU Study. You have been selected to participate in an expansion of this study because you were previously treated for a childhood illness at «instnam». This research is being conducted in collaboration with St. Jude Children's Research Hospital.

We are inviting you to join this important research study by completing and returning the enclosed LTFU consent form and questionnaire. Although your participation in this research project may not have a direct benefit to you, it will provide useful information which may help children and adolescents with similar illnesses. You are under no obligation to participate in this study. If you choose not to enroll in this study, your decision will not affect your relationship with «instnam». You have three methods to complete this information:

1. Mail: complete the questionnaire booklet and return it to us in the blue postage-paid envelope.
2. Online: Go to www.stjude.org/expansionbaseline and enter your log-in ID, «PASSWORD». Your password is your date of birth.
3. Over the phone: call 1-800-775-2167 and a trained interviewer will complete the questions with you.

We know your time is valuable, so as a token of our appreciation, we will send you a $50 gift card after you complete the full survey using any of the 3 return options.


DATE

Dear Parents of «Ptfirst» «Ptlast»:

We received a notification from «instnam» that you were interested in your child taking part in the Long-Term Follow-Up (LTFU) Study. Thank you for signing the HIPAA authorization form you previously received.

For the past 18 years, more than 14,000 volunteers across the U.S. and Canada have generously participated in the LTFU Study. You have been selected to participate in an expansion of this research study because your child was previously treated for a childhood illness at «instnam». This research is being conducted in collaboration with St. Jude Children's Research Hospital.

We are inviting you to join this important research study by completing and returning the enclosed LTFU consent form and questionnaire. Although your participation in this research project may not have a direct benefit to your child, it will provide useful information which may help children and adolescents with similar illnesses. You are under no obligation to participate in this study. If you choose not to enroll in this study, your decision will not affect your relationship with «instnam». You have three methods to complete this information:

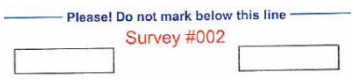
1. Mail: complete the questionnaire booklet and return it to us in the blue postage-paid envelope.
2. Online: Go to www.stjude.org/expansionbaselineminor and enter your log-in ID «password». Your password is your child's date of birth.
3. Over the phone: call 1-800-775-2167 and a trained interviewer will complete the questions with you.

We know your time is valuable, so as a token of our appreciation, we will send you a $50 gift card after you complete the full survey using any of the 3 return options.

   c. **Incentive Letters for Dana Farber (05)** ("DanaFarber Baseline Reimbursement….MERGE CODES") are located in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\IRB approved Letters\05-DANA FARBER letters only**

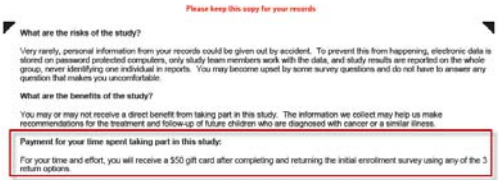
2. **Incentive Flyer**: Place the preprinted flyers *BEHIND the cover letter* so it is the first thing a person sees *after* reading the letter. Flyers are in the storage room.

3. **Survey**. Use the NEW form in Automerge Publisher (with revised consent form):
   a. Baseline Expansion 2007 {Adult|<18} *with Incentive* or Minnesota {Adult/Minor} v2 Baseline Expansion 2007
   b. The Survey # at the bottom of the first page also prints in RED.



4. **Postage Paid Business Reply Envelope**. This is the same BRE we have been using.

5. **Participant Copy**. Use the new participant copy Consent and HIPAA Baseline Expansion 12-20-12__Participant Copy.pdf, found on the server in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\PARTICIPANT COPIES**. Pre-printed supplies are available in the storage room.


Please keep this copy for your records

What are the risks of the study?

Very rarely, personal information from your records could be given out by accident. To prevent this from happening, electronic data is stored on password protected computers, only study team members work with the data, and study results are reported on the whole group, never identifying one individual in reports. You may become upset by some survey questions and do not have to answer any question that makes you uncomfortable.

What are the benefits of the study?

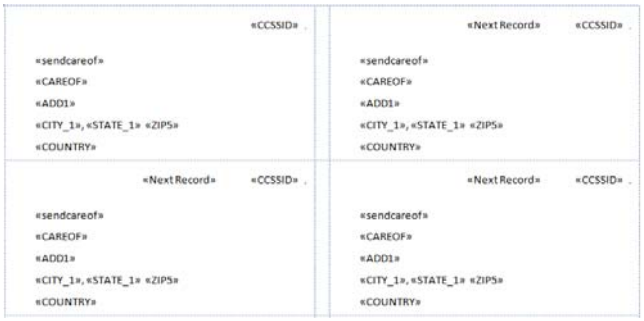
You may or may not receive a direct benefit from taking part in this study. The information we collect may help us make recommendations for the treatment and follow-up of future children who are diagnosed with cancer or a similar illness.

Payment for your time spent taking part in this study:

For your time and effort, you will receive a $50 gift card after completing and returning the initial enrollment survey using any of the 3 return options.

   a. When assembling packets, place the participant copy BEHIND the business reply envelope.
   b. *For Minnesota cases*, use of the institution-specific participant copy (*Baseline Expansion Minnesota Over_Under 18 9-17-13_Participant Copy.pdf*)

6. **Mailing Label**. You may create your own mailing label but you MUST include the CCSSID in the upper right corner of the label. Using the SeqNo is optional.


«CCSSID»
«sendcareof»
«CAREOF»
«ADD1»
«CITY_1», «STATE_1» «ZIP5»
«COUNTRY»
«Next Record»
«CCSSID»
«sendcareof»
«CAREOF»
«ADD1»
«CITY_1», «STATE_1» «ZIP5»
«COUNTRY»
«Next Record»
«CCSSID»
«sendcareof»
«CAREOF»
«ADD1»
«CITY_1», «STATE_1» «ZIP5»
«COUNTRY»
«Next Record»
«CCSSID»
«sendcareof»
«CAREOF»
«ADD1»
«CITY_1», «STATE_1» «ZIP5»
«COUNTRY»

7. **Mailing Envelope**. Use the NEW color-printed mailing envelope (instead of the white LTFU envelopes).

Revision Record
Printed 11/19/2013 3:29 PM

230 Current Filename:		Expansion Baseline Survey Packet with Incentive ver 1_2_Track Changes.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/31/12	J.Bates	Initial Development
1.1	1/8/123	J.Bates	Chg assembly sequence
1.2	11/19/13	J. Ford	Incorporating Minnesota

Expansion Baseline Survey:
Generating Participant Survey Production Lists

Background

As the Expansion Cohort participants are recruited to the study, we send the baseline questionnaire and other study materials. This procedure focuses on generating the participant mailing lists which will be sent to the assistants. The CRA2 is responsible for this process. Assistants use these lists to (1) print instruments using the batch method from Teleforms; (2) generate cover letters; (3) produce mailing labels for the assembled packets. A separate procedure is available for those processes.

The updated procedure identifies multiple situations needing the baseline survey:

1. Explicit resent requests (Tracing code = 82)
2. Cases that rolled over from recruitment over 3 days ago, but who were never sent a baseline survey
3. Cases that rolled over from recruitment over 3 days ago, were sent both the baseline survey and the HIPAAonly packet (but whose baseline survey was sent over three months ago), but to whom a survey has not yet been resent.

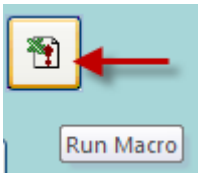
A separate procedure is used for Dana Farber cases imported into the Expansion database, who have not yet been mailed a survey booklet.

Procedure 1:

1. Run the "mop up" query (**qry_JB_Resend82-mopUp**) to identify cases that improperly have a resend request (82 in addresscode). Cases with improper 82 codes are those having an outcome code, those having returned a survey, or deceased cases that are not from DanaFarber. If the query lists any cases,
    a. Find each case by CCSSID in the database and review the background notes.
    b. Then clear the '82' and the date in the tracing date field.
2. Run the query that identifies all the resend cases (**qry_JB_IdentifyResendCases**). This is the "parent" query.
    a. Export this query to excel and save it on the local drive. You will need it when you are posting the resend dates later.
3. Run each of the following queries, which are based on the IdentifyResendCases query. Save each to the local drive. These will be the basis for the data files you distribute to the production team. These are the "child" queries.
    a. The "Standard" queries: (1) **Qry_JB_ResendStd-Over18**, (2) **Qry_JB_ResendStd-Under18**
    b. The Dana Farber queries:(1) **qry_JB_ResendDF-Over18**, (2) **qry_JB_ResendDF-Under18**, (3) **qryRESEND_JB_Deceased DanaFarber**.
    c. The University of Minnesota queries: (1) **qry_JB_ResendMN-Over18**, (2) **qry_JB_ResendMN-Under18**
    d. The queries for surveys that have to be printed from the Print Individual survey buttons: (1) **qry_JB_ResendINDIVIDUAL-Over18**, (2) **qry_JB_ResendINDIVIDUAL-Under18**

4. Tally the total number of cases shown in each of the child queries. It should total the cases in the parent query. Investigate if the totals do not match.

5. Check the data files for the following:
    a. See if any "under 18" cases have turned 18 or will turn 18 in the next 2 weeks. If you find such a case, go to the **QUEST** tab in the Expansion Tracking database click the button that runs the macro that refreshes the print tables. Rerun the Over and Under 18 queries to verify the change in print table assignment.



    b. Check the field **Sendcareof** to be sure it does not say "The Parents of The Parents of First Last". For such cases, make the correction in the excel data file only.
    c. Be sure the addresses are viable.
    d. Check the Country field
        i. If there are non-US addresses, make a note to alert the production team
        ii. If the Country field displays US or USA, clear it in the excel file AND make the correction in the database.

6. Once the data files are clean, create the production assignments/schedule and distribute to the production team. Include the mailing date and the date to be used on the cover letter. Send the production schedule and the data files.

7. **Update the database** with resend/expbasedate and clear the resend codes after the packets are in the mail:
    a. Open the Excel data file you created when you first ran qry_JB_IdentifyResendCases.
    b. Copy the CCSSID column and paste it on a new sheet. Name the new sheet ___TEMP_ResendList. Save the excel file and close it.
    c. Open Expansion Tracking
    d. Import the excel file, importing the sheet "___TEMP_ResendList". If prompted that this table already exists, click yes to replace it.

    e. Create an ad hoc query linking the TEMP file, tblB aselineTrackingInfo, and tblCCSSExpansionTrackingMain (or use qry_JB_TEMP__resendList-SelectForUpdate):
        i. SELECT [___TEMP__resendList].CCSSID, tblBaselineTrackingInfo.expbasedate, tblBaselineTrackingInfo.DateHIPAAonlySent, tblCCSSExpansionTrackingMain.addresscode, tblCCSSExpansionTrackingMain.TracingDate, tblCCSSExpansionTrackingMain.RolloverDate, tblBaselineTrackingInfo.expbaseresend, tblBaselineTrackingInfo.expbase2ndresend, tblBaselineTrackingInfo.expbase3rdresend, tblBaselineTrackingInfo.expbase4thresend, tblBaselineTrackingInfo.expbase5thresend
        FROM (___TEMP__resendList INNER JOIN tblBaselineTrackingInfo ON [___TEMP__resendList].CCSSID = tblBaselineTrackingInfo.ccssid) INNER JOIN tblCCSSExpansionTrackingMain ON [___TEMP__resendList].CCSSID = tblCCSSExpansionTrackingMain.CCSSID;

    f. This query should display the total number of records you were mailing.
    g. Set the criteria for updating the appropriate resend date field:
        i. View expbasedate, expbaseresend, expbase2ndresend, expbase3rdresend, expbase4thresend, and expbase5thresend (through 10th resend) to see which is the largest resend number you will need.
        ii. Modify the query with criteria so expbasedate and each resend date field IS NOT NULL, and the largest resend you need IS NULL. View, noting the number of records.
            1. Change the query to an update query , updating the largest resend field that you needed to the mailing date.

2. Switch back to a select query

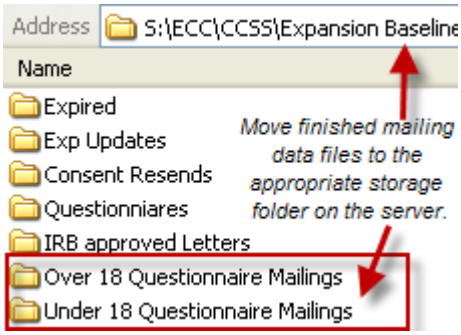
iii. Modify the criteria again so Largest and next largest are IS NULL. View to see how many records fit the next largest resend date.
   1. If any records show up, switch to an update query, clear previous update values, and update that next largest to mail out date.
   2. Switch back to a select query

iv. Continue to modify the query working backwards from the largest resend field needed back to the initial mailing (expbasedate).

h. Set the query to update the addresscode to null and tracing date to null
   i. CLEAR all the criteria
   ii. Switch to an update query, clear previous update values, and set addresscode to update to IS NULL and TracingDate to update to IS NULL.
   iii. Switch back to a select query.

i. Spot check the results. No record should have an 82 or a value in Tracing date. Every record should have the currently posted mailing date in ONE and ONLY ONE of the send fields.

j. Be sure you change the query to a select query before saving it. Save the query if you want to use it next time



8. **<u>File the data files</u>**. Add the mailing date to the end of each data file name. Copy the data files to the under/over/deceased file folders on the server. Archive the originals and the production schedule on your user drive.

9. **<u>Notify</u>** the Survey center that surveys have been mailed (to facilitate follow-up call scheduling)

Procedure 2: Initial Mailing for Dana Farber Cases

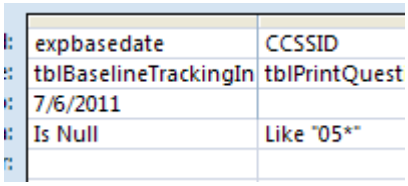
Dana Farber "recruits" its own cases to the LTFU study. The data manager uploads the list of new recruits to the St Jude Share site and then notifies the IT team. Our IT team processes the data file, places an excel file on the server in **Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Expansion Tracking\Dana Farber Updates** and uploads the records to the Expansion Tracking database. IT emails us when new Dana Farber cases are ready for the baseline survey. The email indicates how many adults, minors, and deceased cases there are. We prepare survey booklets for adults and minors as well as a consent form booklet for family of deceased individuals. In preparing production data files, we refer to the most recent Dana Farber Updates file as a cross-check to be sure our queries pick up the correct cases. For special production procedures for these cases, see *Expansion Baseline Survey Mailing for Dana Farber*.

1. When we are notified that new DanaFarber data have been imported into the Expansion database, we create the data files for the production staff to generate the cover letters and print the survey booklets.

2. Run the DanaFarber specific queries: **qryDanaFarberMailingOver18**, **qryDanaFarberMailingUnder18**, and **qryDanaFarberMailingDeceased**, as appropriate. Also run **qryDanaFarberMailingAll** to get a master list. The total in the master list should be the same as the number just imported into the Expansion database. Cross check the list with the excel file in the **DanaFarberUpdates** folder to ensure all cases are represented.

3. Assemble the production schedule and assignments and distribute with the data files.

4. **Update the database** after the surveys are mailed: update the field expbasedate with the survey mailing date. This is done most simply by re-using (without saving) the 3 Dana Farber queries. Change the query to an update query, and update expbasedate. BEFORE you run the query, make sure the number of records is the same as the number mailed.



5. **File the data files** the same as the resend data files (described earlier).

6. **Notify** the Survey center that surveys have been mailed (to facilitate follow-up call scheduling)

Revision Record
Printed 7/6/2012 11:29 AM

Current filename		Expansion Baseline Survey-Generating Survey Production Lists ver 2_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	4/3/09	A. McDonald	Initial Release
1.1	12/9/09	J. Bates	Generation of Mailing Lists: USC, CCSS groups
1.2	1/28/10	J.Bates	Specifications
2.0	7/6/11	J.Bates	New process/queries. Includes resends and initial mailings
2.1	3/8/12	J.Bates	DanaFarber background
2/2	5/30/12	J.Bates	Minor to adult function

Expansion Baseline Thank You and Incentive Gift Cards

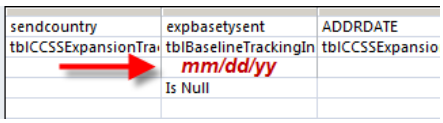
Background

The new IRB-approved baseline cover letter indicates study participants will be reimbursed with a gift card incentive when the completed survey is received (either online or in the mail). We enclose the gift card with the existing thank you card. Thank you cards will be mailed once a week (generally on Wednesdays) for surveys obtained by the Monday before. The project CRA2 documents the gift card inventory and transactions for each recipient in the project's incentive tracking database (**Expansion Baseline Incentive Transaction and Inventory Tracking rel m-d-yy.mdb,** located at **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\ExpansionBaseline**).

Procedures

PROCEDURE: Sending the thank you note with the enclosed gift card

1. **Identify Cases in Expansion Baseline**
   a. Run the 2 queries that generate the data files each Wednesday, for surveys obtained before Monday (calculate expbasereturn < date()-2)).
      i. **qryThankYouCases_Incentive**
      ii. Export to Excel, and save in Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\ThanksYous-Expansion\ThankYous
   b. POST date thank you sent in **expbasetysent** (temporarily change query to update query).



   c. For thank you's *sent with Spanish enclosure*, or *letter requesting form signatures*, manually enter note in Tracking Comments. E.g.,
      i. **m/d/y: TY included Spanish note [inits]**
      ii. **m/d/y: TY included ltr requesting signature on consent/MR forms [inits]**
      iii. NOTE: If this is the first time a MR Letter was sent, also post the date sent in MR Letter Date
   d. From the incentive query, *determine how many incentive gift cards you need*. (Based on volume, decide whether batching the preparation and posting is warranted.)

2. **Obtain cards**
   a. Generate Auditor List to use as cross-reference
      i. Open the project's incentive tracking database (ExpansionBaseline Incentive Tracking… found at **z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\ExpansionBaseline**)
      ii. Run **Auditor list** to list all cards in inventory (restocked/instock cards first)
      iii. Export Auditor list to Excel; store in folder with qryThankYouCases Excel files.
      iv. Close the Incentive tracking database
      v. In the Excel Auditor list, insert a numbering column in the leftmost column and use fill-down to add a sequential number down to the number of cards actually needed.

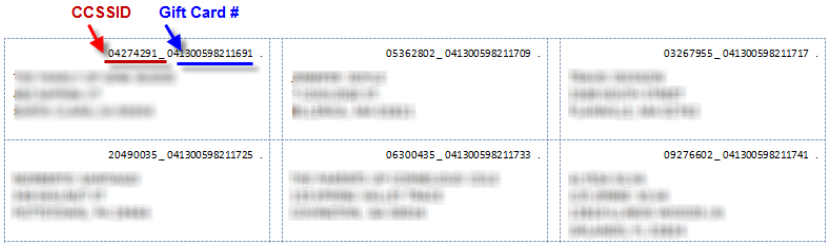
vi. Save the Excel file.
vii. Print the pages of the Excel file that list the cards you need to use.

b. Contact the 6th Floor admin to obtain the needed number of cards (net of restocked which are held in a secure location on the 5th floor). Use the Auditor List cross-reference pages to flag the expected "start" and "stop" card numbers.

3. **Assign a gift card to each case in the Incentive data file**
   a. Open both the **qryThankYouCases_Incentive.xls** excel data file and the sequentially numbered Auditor List file.
      i. In the Incentive file, locate the CARDno column (to left of CCSSID and NAME columns).
      ii. In the Auditor list file, copy the range of card numbers you obtained.
      iii. In the Incentive file, paste the list of actual card numbers you copied into the CARDno column.
   b. Save and close both excel files. You can DELETE the frm_AuditorList.xls from the ThankYou folder as it will be outdated when the transactions are posted.

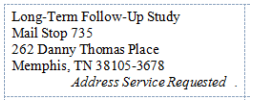
4. **Generate Mailing labels** and **assemble Thank You notes**
   a. **NO INCENTIVE** cases:
      i. Use **LabelMergeFile-ThankYouCases-NO incentive.docx** to merge with the **qryThankYouCases_NoIncentive** Excel data file.
      ii. Print the labels
      iii. ASSEMBLE:
         1. Use presealed thank yous
         2. Attach mailing label and set out for mailing.
         3. For case needing Spanish note, use hand-written Spanish note provided by SI in a new envelope. (Be sure to find correct address label.)

   b. **INCENTIVE** cases
      i. Mail merge the mailing labels.
         1. Use **LabelMergeFile-ThankYouCases-INCENTIVE.docx** to merge with **qryThankYouCases_INCENTIVE.xls** Excel data file.
         2. Finish & Merge the file so you can EDIT the labels.
         3. Check the merge labels for names or addresses that do not fit on a single line. Adjust the font size on those labels to make them fit.
         4. Save the merged file as **Thank You Labels-Incentive mm-dd-yy.docx**



ii. IF the INCENTIVE assembly is being distributed to production staff,
    1. Prepare a new excel file that ONLY lists the CCSSID, CardNo, and Name.
        a. Mark the production assignment file indicating assigned rows (in multiples of 3).
        b. Save as **ThankYouIncentiveProduction mm-dd-yy.docx.**
    2. Email the production assignments, attaching
        a. ThankYouIncentiveLabels PREMERGED (Word)
        b. ThankYouIncentiveProduction (Excel)
    3. Refer staff to procedure **Handling Baseline Thank You Incentive Batches**

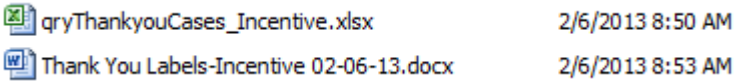
iii. ASSEMBLE (incentive cases):


Long-Term Follow-Up Study
Mail Stop 735
262 Danny Thomas Place
Memphis, TN 38105-3678
Address Service Requested

    1. Use the pre-stuffed (not yet sealed) thank you notes that have *Address Service Requested* return address label in the upper left corner
    2. Attach mailing label (with CCSSID and Gift Card #)
    3. Referring to the CardNo printed on the mailing label, find THAT SPECIFIC gift card in the stack of cards obtained from the safe. Insert that card into the thank you note (inside the note itself, not just inside the envelope).
    4. Special handing:
        a. *Spanish cases:* for cases needing Spanish note, either use the card containing the hand-written Spanish note, or place the personalized insert inside the standard card.
        b. Incentive cases with *Consent Discrepancies* (see **Handling LTFU Consent Discrepancies**): add the incentive thank you to the envelope having the consent documents and letter requesting consent (so respondent receives incentive along with the letter requesting additional information.
    5. WAIT to seal the thank you card until another person does a QC check that verifies that the listed Gift Card # is indeed inside the labeled envelope.
    6. QC person SECURELY SEALS the thank you note. If necessary, add tape to ensure the card is fully sealed (so the gift card will not fall out).
    7. Give sealed cards to CRA2 for final check and mail pickup.

5. **Post the incentive inventory distribution.** FOR INCENTIVE CASES, post a separate NEW TRANSACTION and update inventory, for each card in the distribution, using the project's incentive tracking database.
    a. To post a few transactions, post individually (see procedure **Posting Incentive Transactions**)
    b. To Batch post:
        i. Open the excel file **qryThankYouCases_INCENTIVE mm-dd-yy.xls**
        ii. Copy the sheet into a new sheet in which
            1. Rename the new sheet as _TEMPnewTrans
            2. Rename the CCSSID column as RecipientID
            3. Delete all columns EXCEPT for RecipientID and CardNo
            4. Save and close the excel file.
        iii. Open the Incentive tracking database
        iv. Import the _TEMPnewTrans sheet from qryThankYouCases_INCENTIVE mm-dd-yy.xls into a new table. You DO want to overwrite the previous copy of the table.
        v. Run the macro **mcr_RemakeNames-ExpansionOnly**
        vi. Run the macro **mcrNewBatchTrans**. When prompted for the me.projectname, key in Baseline
        vii. Messages will indicate each step the macro performs.
    c. When the macro is finished, COPY the _TEMPnewTrans table, and paste it as **z_TEMPnewTrans-mm-dd-yy** (It is very important that you *DO NOT RENAME* _TEMPnewTrans, as that would undermine all future uses of the mcrNewBatchTrans.)
    d. To see the results of the newly posted transactions, you can re-run the Auditor List. There should be new "OutOfStock" records at the bottom of the list.
    e. You may also refer to Batch Loading New Transactions in the **Technical Reference for Incentive Gift Card Tracking**.

6. **FILE the Excel and Word documents**. When all processing is completed, rename the ThankYou Excel and Word files by adding the date to the end of the file name, and then MOVE them to the archive location: **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\Exp Thank yous**:



PROCEDURE: Processing an incentive thank you returned to sender

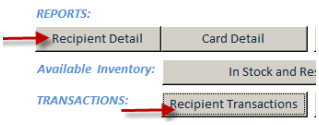
1. Note CCSSID from mailing label, open the return, recover the gift card.
2. In the project's incentive tracking database:
    a. Post a new transaction for the card number, enter transaction type (2-return), date, notes, project, and recipientID (CCSSID to whom the card had been mailed, per address label). In notes, indicate card returned to sender undeliverable (or other applicable note). Save Transaction.
    b. Change the returned card's inventory status to 2-restocked and enter new inventory status date. CLEAR the CCSSID from Inventory's RecipientID. Save Inventory Update
    c. (For more detail, see **Posting Incentive Transactions**)
3. In Expansion Tracking
    a. Record Tracing code 18, and tracing date
    b. For returned mail that included gift card, add NOTE on Baseline tab that thank you note and gift card were returned to sender
4. Store the returned card in a secure location on the 5th floor. (We normally re-issue returned cards with the next distribution.) When the card is re-issued, shred the original returned envelope and return thank you card to open stock.

PROCEDURE: Sending 2nd incentive to traced cases AFTER returned to sender

1. In **incentive tracking database**, identify cases where *card was returned to sender, placed in tracing, and successfully traced:*
    a. Build **query1** to identify cases having more than one transaction on file (total query that counts transactions by case and displays those where count >1).

    b. Use query1's RecipientID list to drive **query2** to display all transaction detail for those cases

    c. Print and then inspect query2 output to identify and mark cases where there are as many return transactions as there are send transactions. These are the cases that DO need a resend because all of the cards to date have been returned to sender. (Cases with more send transactions than return transactions do NOT need a resend.
        i. May also use Recipient Detail (Report) to identify the cases; or Recipient Transactions (which can be output to excel)



1. Recipient Detail (Report) example

11372632	[redacted]					
	Sent	10/22/2012	041300598209661	Baseline		1
	Returned	10/25/2012	041300598209661	Baseline	card sent to 11372632 returned to sender undeliverable	5

2. Recipient Transactions example:

11372632	[redacted]	Sent	10/22/2012	041300598209661	Baseline	
11372632	[redacted]	Returned	10/25/2012	041300598209661	Baseline	card sent to 11372632 returned

d. Use query1 RecipientID list to drive **query3** to pull mailing address, agetoday (calculated variable to build sendcareof string), from the Expansion tracking database for cases no longer in tracing (addresscode null or <> 13 or 18).

e. Export query3 to excel
   i. Inspect Excel file and flag cases that your review of query2 identified as needing a resend
   ii. Generate mailing labels for flagged cases

f. Obtain needed number of cards from safe.
   i. Assign a specific card number to each identified recipient.
   ii. Add the assigned CARDno to the mail merged label for the associated recipient, after the CCSSID.

g. Post a NEW TRANSACTION (type: distribution) for card being sent to the individual
   i. Follow **Posting Incentive Transactions**
   ii. E.g.,
      1. Record CardNo, Transaction Type (1-distribution), CCSSID (recipientID), date, and project (baseline).
      2. Document in notes that card is an <u>additional</u> card being sent to traced address, replacing previous card returned to sender
      3. Update inventory status of the specific card: status 1=out of stock, inventory status date, CCSSID (Recipient ID).

h. Insert card in new thank you note; affix label making sure the card number matches the CCSSID assigned to it.
   i. ***<u>QUALITY CONTROL CHECK before sealing!</u>***
   ii. Seal securely and set out for mail pickup.

2. In **<u>Expansion baseline</u>**
   a. On Baseline tab, add note that additional gift card sent to newly traced address (e.g., mm/dd/yy additional gift card sent post tracing returned gift card [inits])
   b. Do <u>NOT</u> change the previously posted date thank you sent.

PROCEDURE: Individual incoming call reports card not received

1. Verify mailing address. LSI will update as appropriate (THIS IS CRITICAL!) and if case was in tracing, clear the tracing code and date.
2. Consult the date the thank you was sent. (If not yet sent, inform caller that it will be sent soon. If already sent, inform caller of typical delivery time.)
3. Email the CRA2 (cc LSI) to report the call, providing specific information about address corrections or change of address.
4. If card already mailed, CRA2 will decide whether to send additional card
    a. Tentatively conclude whether the initial card was mailed to a different address and may not have been forwarded and/or has not yet been returned to sender, or is likely still in the USPS delivery system.
    b. **If decide to send a NEW CARD**
        i. In Expansion Tracking
            1. Make sure address has been confirmed and/or updated. (If not, check with 4th floor staff for clarification). If still in tracing, suspend activity.
            2. On Baseline tab, add note that additional gift card was **sent via FedEx signature required** b/c recipient reported not having received card (initial card not returned to sender).
            3. Do NOT change date thank you sent

        ii. In Incentive tracking post a NEW TRANSACTION for card being sent
            1. Record cardno, transaction type (1-distribution), CCSSID, date, project.
            2. Document in notes that the card is an additional card **sent via FedEx** because recipient reported not having received initial card
            3. Update inventory status of the specific card: Inv status 1=out of stock, inventory status date, CCSSID (Recipient ID).

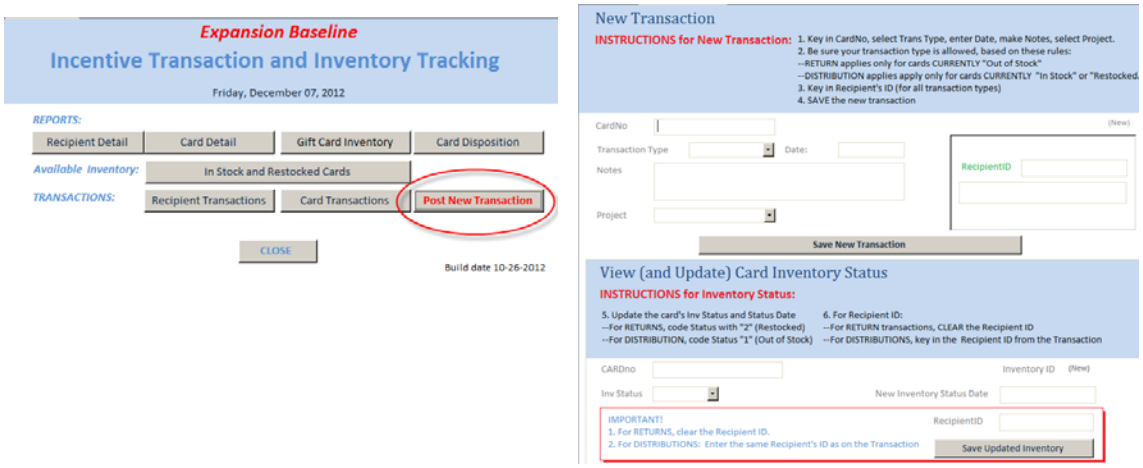
        iii. Prepare a new thank you note with gift card enclosed, hand addressed on thank you envelope with CCSSID and CardNo on label. ***QUALITY CONTROL CHECK*** that correct card number goes with correct CCSSID. Send pkg via **FedEx, signature required**. Retain FedEx receipt with tracking number so you can trace if needed.

    c. If decide NOT to send a new card
        i. In Expansion Tracking, document that case reported card not received, indicating that additional card NOT sent at this time.

CRA2, LeadSI

Incentive (Gift Card) Tracking *New Transaction* Screen

For more information, see **Posting Incentive Transactions**



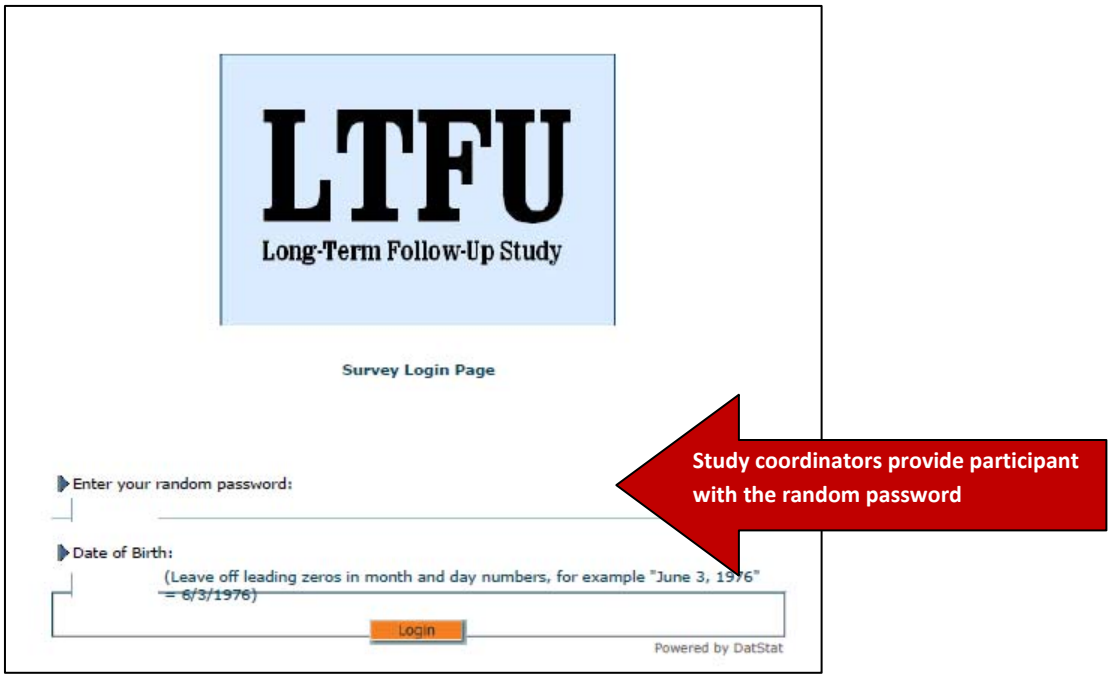
Revision Record

Printed 11/20/2013 8:49 AM

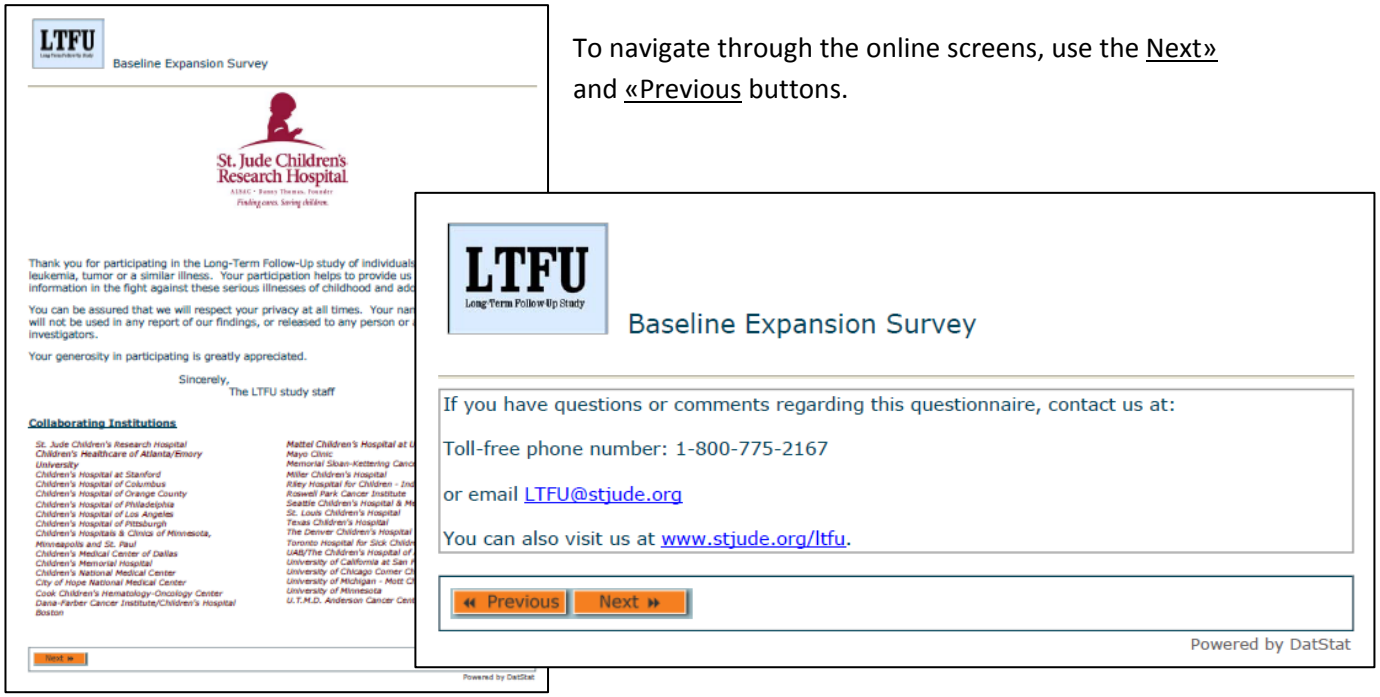
(228) Current Filename:		Expansion Baseline Thank You and Incentive Gift Cards ver 1_6_.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/13/12	J.Bates	Initial Development
1.1	1/4/13	J.Bates	Revise schedule (Wednesday vs Tuesday)
1.2	1/9/13	J.Bates	File locations; archiving source files
1.3	1/22/13	J.Bates	Spanish clarification
1.4	2/13/13	J.Bates	No comment needed; optional enclosure w/ ltr; sequencing; restocked cards
1.5	6/5/13	J.Bates	File locations
1.6	11/20/2013	J. Ford	Amended due to Mn now using gift cards

Expansion Login-Consent Process

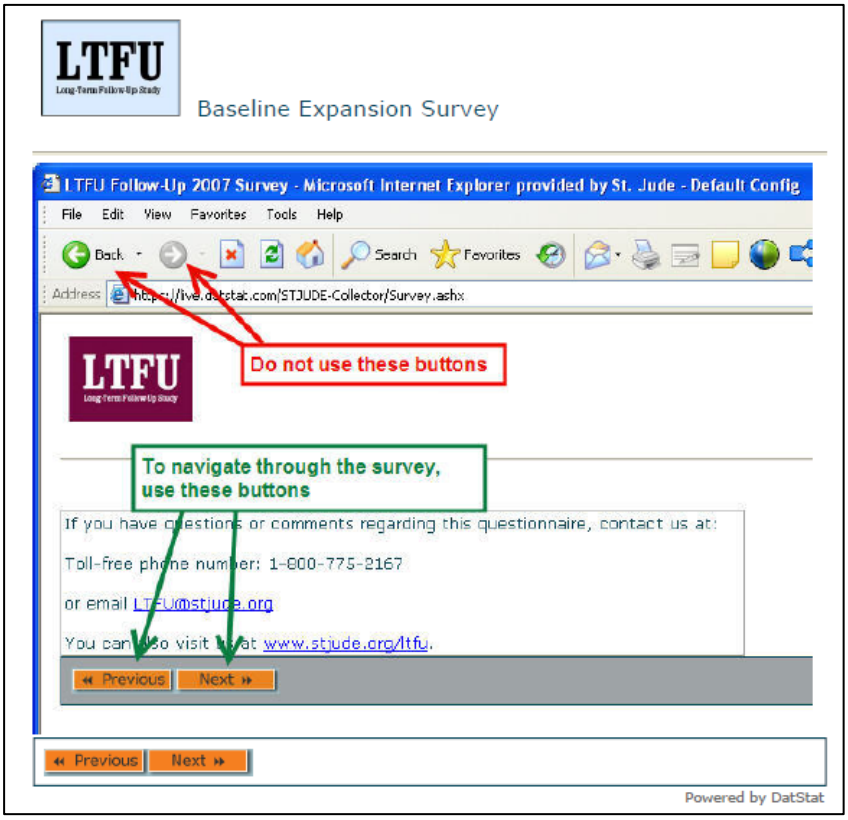
This document contains the screen images which display during the login and online consent process for the LTFU Expansion Survey. The purpose of the document is to illustrate the method for proceeding through the login and consent process.

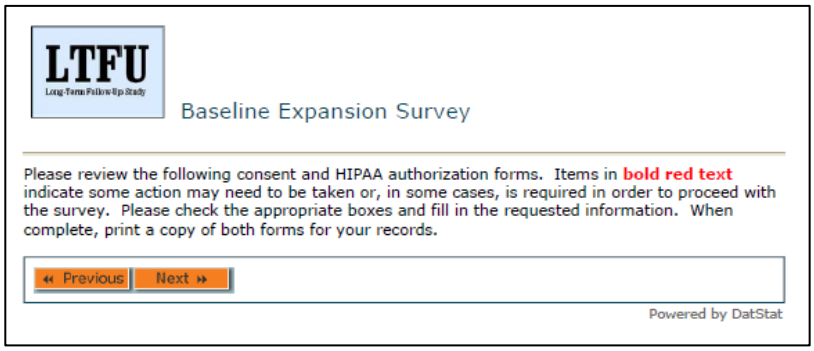


After entering the random password and date of birth, click the Login button. An introduction page follows.



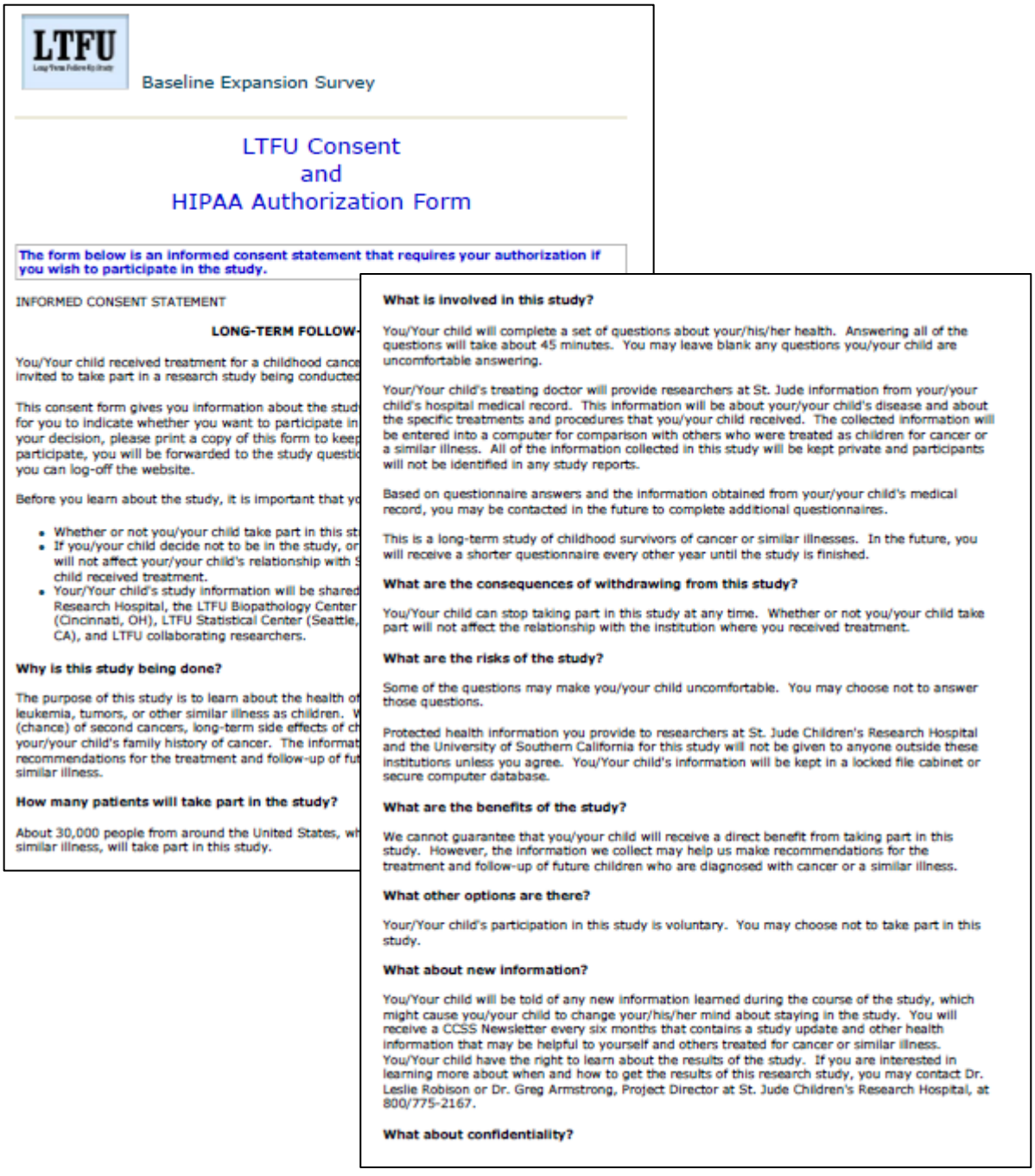
To navigate through the online screens, use the Next» and «Previous buttons.


LTFU
Baseline Expansion Survey
LTFU Follow-Up 2007 Survey - Microsoft Internet Explorer provided by St. Jude - Default Config
File Edit View Favorites Tools Help
Back Search Favorites
Address
Do not use these buttons
To navigate through the survey, use these buttons
If you have questions or comments regarding this questionnaire, contact us at:
Toll-free phone number: 1-800-775-2167
or email LTFU@stjude.org
You can also visit us at www.stjude.org/ltfu.
« Previous Next »
« Previous Next »
Powered by DatStat


LTFU
Baseline Expansion Survey
Please review the following consent and HIPAA authorization forms. Items in bold red text indicate some action may need to be taken or, in some cases, is required in order to proceed with the survey. Please check the appropriate boxes and fill in the requested information. When complete, print a copy of both forms for your records.
« Previous Next »
Powered by DatStat

Everyone

This is the Consent and HIPAA Authorization form presented for online reading. At the end of the multi-screen form, two options are provided: Yes, I do want to participate, and No, I do not want to participate.



LTFU

Baseline Expansion Survey

LTFU Consent
and
HIPAA Authorization Form

The form below is an informed consent statement that requires your authorization if you wish to participate in the study.

INFORMED CONSENT STATEMENT

LONG-TERM FOLLOW-

You/Your child received treatment for a childhood cance
invited to take part in a research study being conducted

This consent form gives you information about the stud
for you to indicate whether you want to participate in
your decision, please print a copy of this form to keep
participate, you will be forwarded to the study questio
you can log-off the website.

Before you learn about the study, it is important that yo

- Whether or not you/your child take part in this st
- If you/your child decide not to be in the study, or
will not affect your/your child's relationship with
child received treatment.
- Your/Your child's study information will be shared
Research Hospital, the LTFU Biopathology Center
(Cincinnati, OH), LTFU Statistical Center (Seattle,
CA), and LTFU collaborating researchers.

Why is this study being done?

The purpose of this study is to learn about the health of
leukemia, tumors, or other similar illness as children. W
(chance) of second cancers, long-term side effects of ch
your/your child's family history of cancer. The informat
recommendations for the treatment and follow-up of fut
similar illness.

How many patients will take part in the study?

About 30,000 people from around the United States, wh
similar illness, will take part in this study.

What is involved in this study?

You/Your child will complete a set of questions about your/his/her health. Answering all of the questions will take about 45 minutes. You may leave blank any questions you/your child are uncomfortable answering.

Your/Your child's treating doctor will provide researchers at St. Jude information from your/your child's hospital medical record. This information will be about your/your child's disease and about the specific treatments and procedures that you/your child received. The collected information will be entered into a computer for comparison with others who were treated as children for cancer or a similar illness. All of the information collected in this study will be kept private and participants will not be identified in any study reports.

Based on questionnaire answers and the information obtained from your/your child's medical record, you may be contacted in the future to complete additional questionnaires.

This is a long-term study of childhood survivors of cancer or similar illnesses. In the future, you will receive a shorter questionnaire every other year until the study is finished.

What are the consequences of withdrawing from this study?

You/Your child can stop taking part in this study at any time. Whether or not you/your child take part will not affect the relationship with the institution where you received treatment.

What are the risks of the study?

Some of the questions may make you/your child uncomfortable. You may choose not to answer those questions.

Protected health information you provide to researchers at St. Jude Children's Research Hospital and the University of Southern California for this study will not be given to anyone outside these institutions unless you agree. You/Your child's information will be kept in a locked file cabinet or secure computer database.

What are the benefits of the study?

We cannot guarantee that you/your child will receive a direct benefit from taking part in this study. However, the information we collect may help us make recommendations for the treatment and follow-up of future children who are diagnosed with cancer or a similar illness.

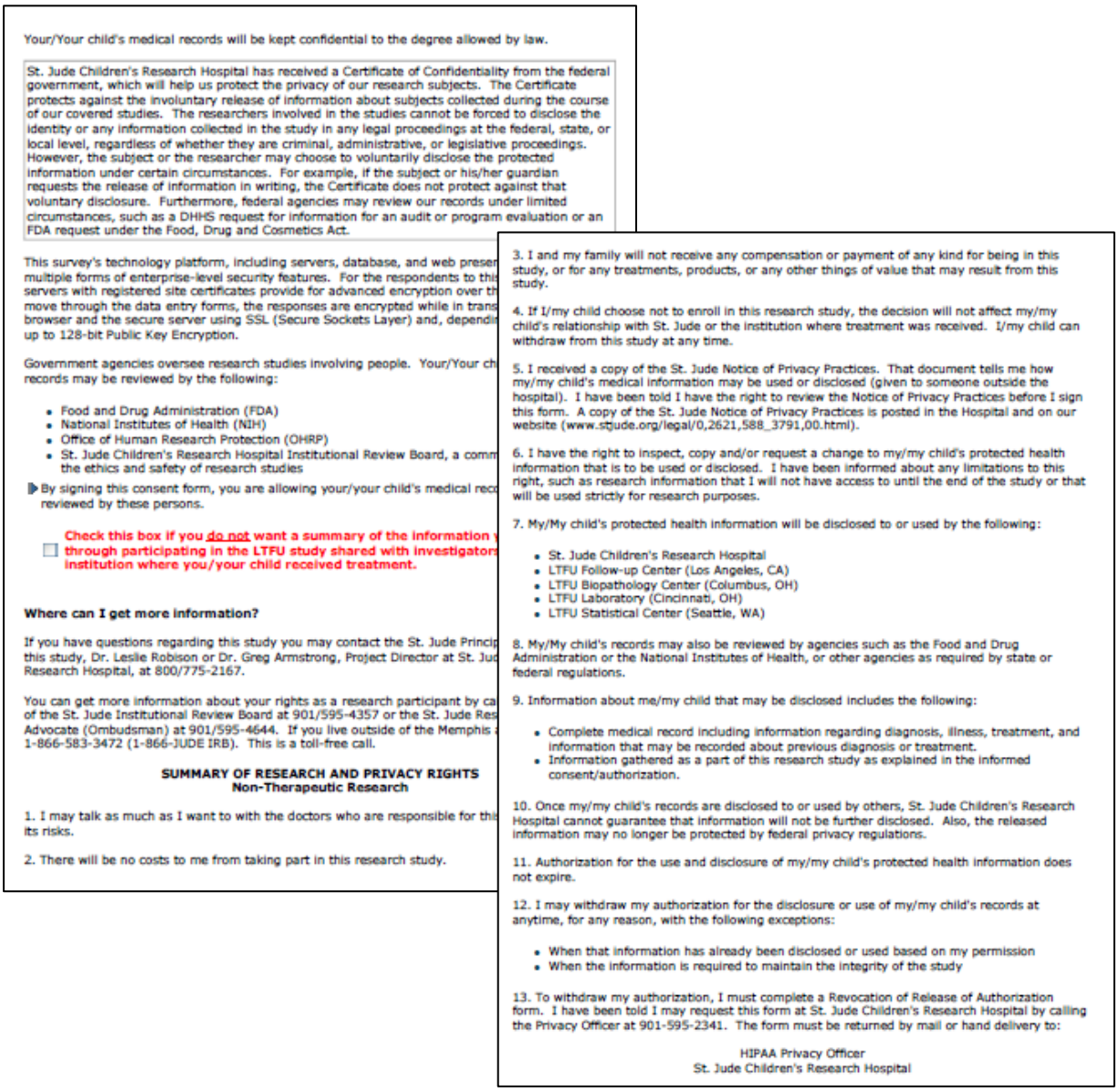
What other options are there?

Your/Your child's participation in this study is voluntary. You may choose not to take part in this study.

What about new information?

You/Your child will be told of any new information learned during the course of the study, which might cause you/your child to change your/his/her mind about staying in the study. You will receive a CCSS Newsletter every six months that contains a study update and other health information that may be helpful to yourself and others treated for cancer or similar illness. You/Your child have the right to learn about the results of the study. If you are interested in learning more about when and how to get the results of this research study, you may contact Dr. Leslie Robison or Dr. Greg Armstrong, Project Director at St. Jude Children's Research Hospital, at 800/775-2167.

What about confidentiality?



Your/Your child's medical records will be kept confidential to the degree allowed by law.

St. Jude Children's Research Hospital has received a Certificate of Confidentiality from the federal government, which will help us protect the privacy of our research subjects. The Certificate protects against the involuntary release of information about subjects collected during the course of our covered studies. The researchers involved in the studies cannot be forced to disclose the identity or any information collected in the study in any legal proceedings at the federal, state, or local level, regardless of whether they are criminal, administrative, or legislative proceedings. However, the subject or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, if the subject or his/her guardian requests the release of information in writing, the Certificate does not protect against that voluntary disclosure. Furthermore, federal agencies may review our records under limited circumstances, such as a DHHS request for information for an audit or program evaluation or an FDA request under the Food, Drug and Cosmetics Act.

This survey's technology platform, including servers, database, and web presen
multiple forms of enterprise-level security features. For the respondents to thi
servers with registered site certificates provide for advanced encryption over th
move through the data entry forms, the responses are encrypted while in trans
browser and the secure server using SSL (Secure Sockets Layer) and, dependi
up to 128-bit Public Key Encryption.

Government agencies oversee research studies involving people. Your/Your ch
records may be reviewed by the following:

- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Office of Human Research Protection (OHRP)
- St. Jude Children's Research Hospital Institutional Review Board, a comm
  the ethics and safety of research studies

By signing this consent form, you are allowing your/your child's medical rec
reviewed by these persons.

Check this box if you do not want a summary of the information
through participating in the LTFU study shared with investigators
institution where you/your child received treatment.

Where can I get more information?

If you have questions regarding this study you may contact the St. Jude Princip
this study, Dr. Leslie Robison or Dr. Greg Armstrong, Project Director at St. Jud
Research Hospital, at 800/775-2167.

You can get more information about your rights as a research participant by ca
of the St. Jude Institutional Review Board at 901/595-4357 or the St. Jude Res
Advocate (Ombudsman) at 901/595-4644. If you live outside of the Memphis
1-866-583-3472 (1-866-JUDE IRB). This is a toll-free call.

SUMMARY OF RESEARCH AND PRIVACY RIGHTS
Non-Therapeutic Research

1. I may talk as much as I want to with the doctors who are responsible for thi
its risks.

2. There will be no costs to me from taking part in this research study.

3. I and my family will not receive any compensation or payment of any kind for being in this study, or for any treatments, products, or any other things of value that may result from this study.

4. If I/my child choose not to enroll in this research study, the decision will not affect my/my child's relationship with St. Jude or the institution where treatment was received. I/my child can withdraw from this study at any time.

5. I received a copy of the St. Jude Notice of Privacy Practices. That document tells me how my/my child's medical information may be used or disclosed (given to someone outside the hospital). I have been told I have the right to review the Notice of Privacy Practices before I sign this form. A copy of the St. Jude Notice of Privacy Practices is posted in the Hospital and on our website (www.stjude.org/legal/0,2621,588_3791,00.html).

6. I have the right to inspect, copy and/or request a change to my/my child's protected health information that is to be used or disclosed. I have been informed about any limitations to this right, such as research information that I will not have access to until the end of the study or that will be used strictly for research purposes.

7. My/My child's protected health information will be disclosed to or used by the following:

- St. Jude Children's Research Hospital
- LTFU Follow-up Center (Los Angeles, CA)
- LTFU Biopathology Center (Columbus, OH)
- LTFU Laboratory (Cincinnati, OH)
- LTFU Statistical Center (Seattle, WA)

8. My/My child's records may also be reviewed by agencies such as the Food and Drug Administration or the National Institutes of Health, or other agencies as required by state or federal regulations.

9. Information about me/my child that may be disclosed includes the following:

- Complete medical record including information regarding diagnosis, illness, treatment, and information that may be recorded about previous diagnosis or treatment.
- Information gathered as a part of this research study as explained in the informed consent/authorization.

10. Once my/my child's records are disclosed to or used by others, St. Jude Children's Research Hospital cannot guarantee that information will not be further disclosed. Also, the released information may no longer be protected by federal privacy regulations.

11. Authorization for the use and disclosure of my/my child's protected health information does not expire.

12. I may withdraw my authorization for the disclosure or use of my/my child's records at anytime, for any reason, with the following exceptions:

- When that information has already been disclosed or used based on my permission
- When the information is required to maintain the integrity of the study

13. To withdraw my authorization, I must complete a Revocation of Release of Authorization form. I have been told I may request this form at St. Jude Children's Research Hospital by calling the Privacy Officer at 901-595-2341. The form must be returned by mail or hand delivery to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital

262 Danny Thomas Place
Memphis, TN 38105

14. I have been given the ability to print a copy of this informed consent document.

RESEARCH PARTICIPANT STATEMENT

I have read (or have had read to me) the contents of this document and have been encouraged to contact the Long-Term Follow-Up Center to ask questions. I have received answers to my questions. I give consent to take part in this research study and authorize the disclosure and use of my/my child's protected health information for the purposes of that research.

Particip
ation

Yes, I want to participate in this study.
No, I do not want to participate in this study.

« Previous Next »

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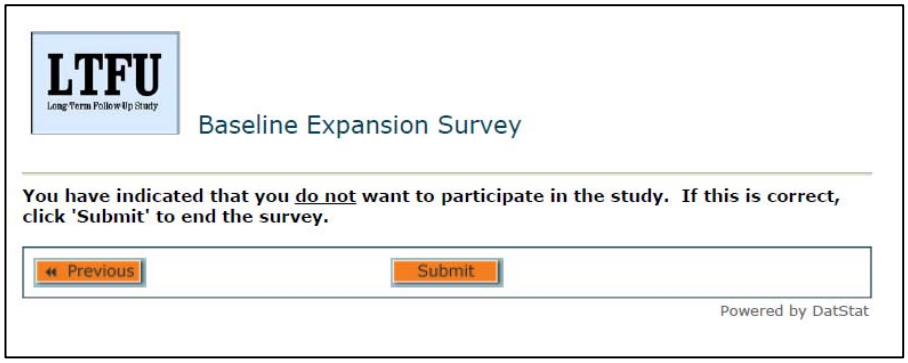
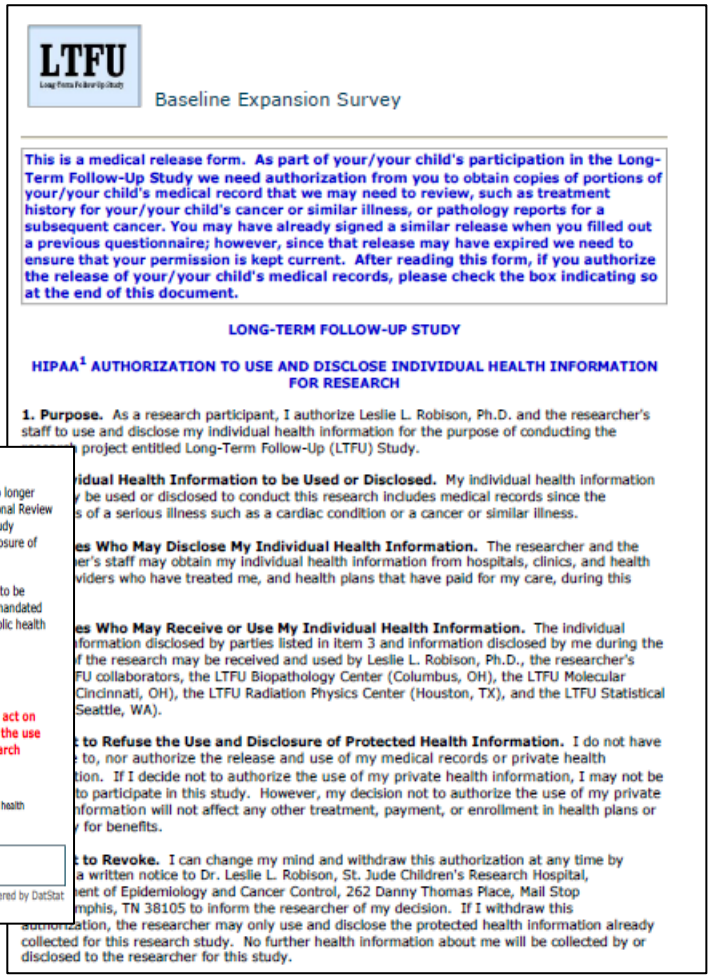
When "No, I do not want to participate in this study" is clicked, the following confirmation message appears. After clicking the Submit button, the process ends.



When "Yes, I want to participate in this study" is clicked, the following medical release form is presented, with an authorization checkbox at the end.



Current Filename:		Expansion Login-Consent Screens ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	12/24/09	J.Bates	Initial Development

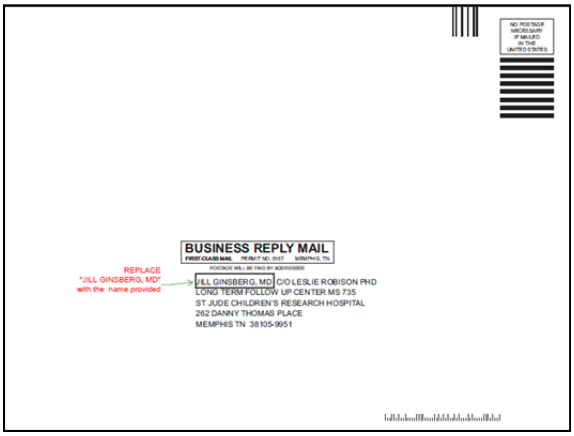
Expansion Recruiting Envelopes, Letterhead

Background

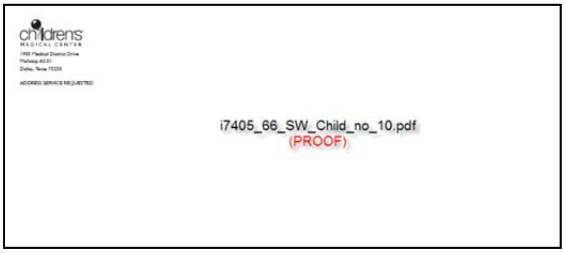
When recruiting expansion study participants on behalf of institutions, we use their letterhead, their PI signature on the letter, their return address on the mailing envelope, and the PI name in the BRE. This procedure describes the process of getting the source materials through placing material orders.

ENVELOPE ARTWORK

1. Get artwork image of return address (for outgoing envelope) from data manager. This will need to be in vector file format.
2. Identify the PI name exactly as it is to be used on the business reply mail envelope
3. Ask Julie.groff@stjude.org to prepare proofs for the necessary envelopes:
    a. For institutions whose recruitment packet *includes* the baseline survey, we need 2 envelopes:
        i. White 10 x 13 peel-and-stick outgoing mail envelope: A return address block printed per attached art, with ***Address Service Requested*** printed below the return address.
        ii. Blue 9 x 12 return mail envelope: A Business Reply Mail (BRM) envelope printed with the principal investigator's name C/O Leslie Robison PHD, at the LTFU MS 735 address (see sample)



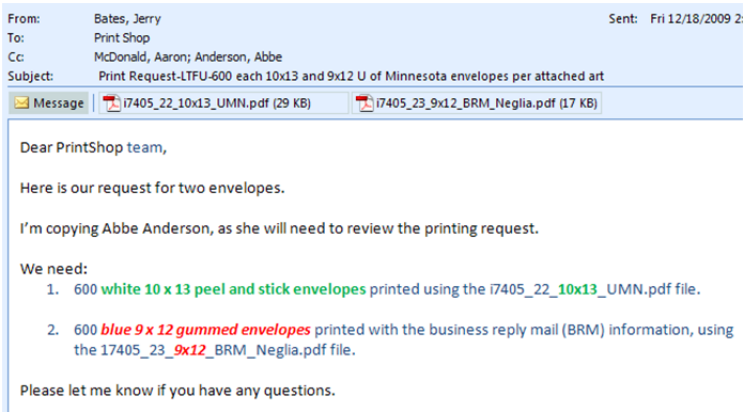
    b. For institutions whose recruitment packet uses the HIPAA only process, we only need 1 envelope (outgoing mail)
        i. A return address block printed per attached art on a white #10 (business-sized) gummed envelope with the ***Address Service Requested*** printed below the return address.



4. Review the pdf proof(s). For BRMs, be sure the permit number is correct. Then forward them to the data manager for approval. Work back and forth as needed with Julie Groff for a final acceptance copy.

PRINT SHOP REQUEST

5. Determine the number of envelopes to order. Generally we order twice the number of eligible cases per institution.


From: Bates, Jerry Sent: Fri 12/18/2009 2:
To: Print Shop
Cc: McDonald, Aaron; Anderson, Abbe
Subject: Print Request-LTFU-600 each 10x13 and 9x12 U of Minnesota envelopes per attached art
Message | i7405_22_10x13_UMN.pdf (29 KB) | i7405_23_9x12_BRM_Neglia.pdf (17 KB)

Dear PrintShop team,

Here is our request for two envelopes.

I'm copying Abbe Anderson, as she will need to review the printing request.

We need:
1. 600 white 10 x 13 peel and stick envelopes printed using the i7405_22_10x13_UMN.pdf file.
2. 600 *blue 9 x 12 gummed envelopes* printed with the business reply mail (BRM) information, using the 17405_23_*9x12*_BRM_Neglia.pdf file.

Please let me know if you have any questions.

6. Submit the print shop request:
   a. Send final approved art to the Print Shop group (Print Shop).
   b. Specify exactly what you need.
   c. Attach the final-approved pdf files. Julie Groff will provide the actual production document to the print shop.
   d. COPY Abbe Anderson so she can approve the print request.

7. The print shop will generate a Form 862 work order and send to Abbe for approval. Upon Abbe's approval, the work order can be filled.

8. Check the order when it is delivered to be sure it matches the approved proof.

LETTERS

1. Get electronic copy of letterhead (preferably in Word) from data manager
2. Get electronic version of PI signature (this should be in the webdocuments folder on the StJude share site, as part of the IRB/web documents)
3. Insert the copy of the various letters onto the electronic letterhead, adding the merge codes as appropriate.

Revision Record Printed 7/10/2012 12:49 PM

Current Filename:		Expansion Recruiting Envelopes Letterhead v2_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/18/9	J.Bates	Initial Development
2	7/20/11	J.Bates	Add #10 envelope

Expansion Recruitment Process for Survey Interviewers

Background

The Childhood Cancer Survivor Study (CCSS), known as the Long-Term Follow-Up (LTFU) Study to the survivor community, is a collaborative, multi-institutional project funded by a grant from the National Cancer Institute. CCSS is a retrospectively ascertained cohort of over 20,000 childhood cancer survivors diagnosed before age 21, between 1970 and 1986, and who survived at least 5 years after diagnosis. The cohort also includes approximately 4,000 siblings of these survivors that serve as a control group. The cohort was assembled through the efforts of more than 26 participating clinical research centers in the United States and Canada. Currently, the study is in the process of expanding the cohort to include an additional 14,000 childhood cancer survivors diagnosed before age 21, between 1987 and 1999, and who survived at least 5 years after diagnosis. The expanded cohort will also add 2,000 – 4,000 siblings of the expanded cohort survivors.

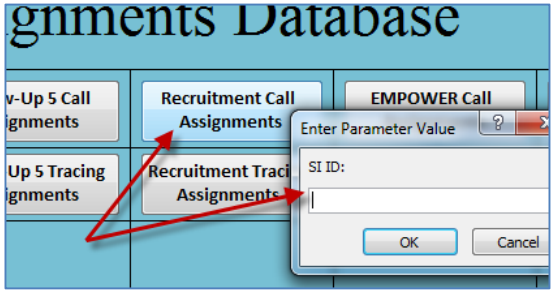
It is the job of the Survey Interviewer (SI) to contact potential participants in the expanded cohort who have not responded to recruitment mailings and to offer them the opportunity to participate in the LTFU Study. This document outlines the procedures involved in the SI recruitment process.

Procedures

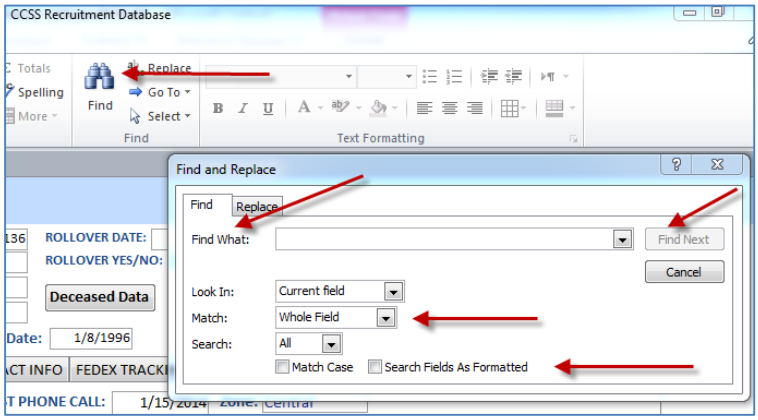
TOOLS YOU WILL NEED

- CCSS SI Assignments database (located at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
- CCSS Recruitment Database (located at *http://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
- **Pre-Post Call Checklist - Recruitment (Expansion Cohort) Calls** (located in the CCSS SOP Library at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
- **Institution and PI Phone Contact List** (located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*)
- **Expansion Recruitment Phone Scripts** (located at Z:\Departments\ECC\common\Interviewers\Expansion Recruitment Assignments\Scripts)
- Guidance for addressing participation barriers (located at *Z:\Departments\ECC\common\ Interviewers\Calling Tools\Overcoming Barriers to Participation Scripts*)
- **PHI Concerns** (located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*)
- **HIPAA Authorization Script** (located at *Z:\Departments\ECC\common\Interviewers\Expansion Recruitment Assignments\Scripts*)
- **Expired Participant Information Sheet** (located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*)
- **Phone Message Guidance** (located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*)
- **Riley (24) Verbal HIPAA Information Sheet** – (located in the CCSS SOP Library at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)

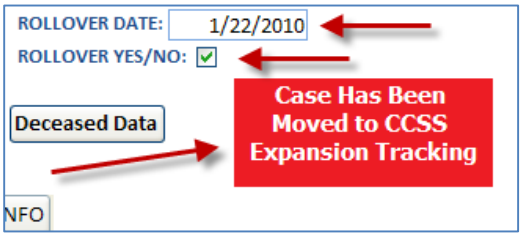
BEFORE THE CALL



1. Find the potential participant that needs to be called:
   A. Open the CCSS SI Assignments database.
   B. Click the **Recruitment Call Assignments** button.
   C. **SI ID:** – Enter the SI ID.
   D. Click the **OK** button.
   E. Cases assigned to the SI in question will display from oldest to newest based on the date of the last call.
2. Open the CCSS Recruitment Database.
3. Locate the potential participant by searching for the applicable CCSSID.
   A. Click in the **CCSSID** field.
   B. Either click the binoculars on the Home tab of the Access Ribbon or press <ctrl> and <F> to "find".
   C. In the Find and Replace window:
      i. **Find What** – Enter the CCSSID of the first case.
      ii. **Match** – Select the appropriate value.
      iii. **Search Fields As Formatted** – Uncheck the checkbox.
      iv. Click the **Find Next** button.



4. Check for indications that the HIPAA has already been completed. If so, move to the next assigned case.
5. Build a comprehensive profile of the case by reviewing all pertinent information from the **Pre-Post Call Checklist - Expansion Recruitment Calls**.



6. Confirm it is appropriate to make a call and determine whether a message may be left.
   A. Individual telephone numbers may be called once every 3 days.
   B. Calls should <u>not</u> be made before 9am or after 9pm *<u>in the time zone being called</u>*.
   C. A message may be left on an answering device 3 times in a given 60-day period. Messages left with a person, as opposed to a machine, do not count against the 3-message limit.
7. Identify the institution at which the case was treated using the CCSSID. See the SOP titled **Decoding CCSSID** for details.

DURING THE CALL: General

1. **Identify yourself** with your name and the institution on whose behalf you are calling. See the document titled **Phone Message Guidance** for details. In general, do not use the word "cancer" when it is part of an institution name. For example, MD Anderson Cancer Center would be identified simply as "MD Anderson".

2. Always **confirm the identity** of the person reached by verifying the name and date of birth (DOB) *<u>before</u>* providing any information that may violate the potential participant's privacy or HIPAA guidelines/laws.

A. Adults – If the case/survivor is 18 years old or greater, s/he is the only party authorized to receive information about the enrollment or to complete the enrollment UNLESS s/he has a *legally authorized* representative (LAR). If someone other than the adult case requests to discuss or complete the enrollment, clarify whether or not the alternate party is the case's "legally authorized representative". Only an LAR can complete the enrollment for an adult case in lieu of the case. For adult cases that are cognitively disabled but have no *legal* guardian, consult with the Lead Survey Interviewer (LSI) team and Call Center Coordinator.

B. Minors – If the case/survivor is less than 18 years old:
   i. A custodial parent may discuss and complete the enrollment. Minors, even if they will be 18 soon, may not complete the enrollment.
   ii. If someone other than a parent would like to discuss the enrollment for a minor case, clarify whether or not the alternate party is the case's "legally authorized representative". Only an LAR can discuss or complete the enrollment for a minor in lieu of the custodial parent.

C. Deceased – If the case/survivor is deceased (but lived at least 5 years after diagnosis), the case's parent or spouse are the preferred proxies to complete the survey. If any other party would like to complete the survey, gather information regarding why the substitution would be made, confirm that s/he would be able to answer questions about the case's health and life, and let him/her know that you will obtain permission for the substitution from your supervisor.

3. **Use the appropriate script(s)** during the call. They have been thoughtfully and carefully designed and have been IRB-approved. Always maintain a professional, friendly, courteous, and respectful tone.

4. **Verify the potential participant's contact information**: mailing address, telephone number(s), email address(es), and additional contact during the conversation.

5. If the potential participant agrees to **complete the verbal HIPAA**, refer to the section of this document titled *DURING THE CALL: Completing the Verbal HIPAA*.

6. When **leaving a message**, either with a person or a machine, leave the minimum amount of information necessary to generate a return call. Follow the guidelines specified in the document titled **Phone Message Guidance**. As this guidance states, always take a conservative approach.

7. If it is discovered during the call that the case is now **deceased**:
   A. Complete the **Expired Participant Information Sheet** with as much information as the person you are speaking with is able to provide.
   B. If the case survived at least 5 years after diagnosis and an appropriate proxy is available and willing to participate on the case's behalf, explain the study and pursue enrollment with the proxy.
   C. Remember that expired surveys must be completed with an SI via telephone interview.

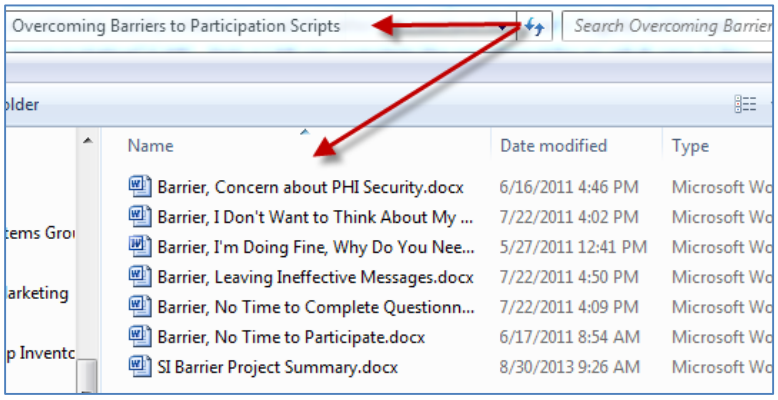
8. If it is discovered during the call that the case has a legally authorized representative (**LAR**) or proxy (See a member of the LSI team or the Coordinator for assistance determining an authorized proxy for a non-deceased adult case.):
   A. Gather the name(s) and contact information of the LAR(s)/proxy.
   B. Determine if the case has a disability and if the participant is able to legally represent himself or herself (e.g. Mother is a legal representative due to the case's hearing disability, but the case is a cognitively able adult.).

9. If it is discovered that the potential participant is **incarcerated**:

A. Attempt to obtain the anticipated release date. (Will it be a few months? Several years?)
B. If the potential participant is expected to be available again in a reasonable period of time, ask what the best number will be to reach him/her when s/he is available again.

10. If it is discovered that the potential participant is **residing out of the country**, attempt to obtain information about the circumstances:
    A. Is the case out of the country on U.S. military duty?
    B. Is the case's residence in the foreign country is permanent? If not, when will s/he return?
    C. Find out whether or not the case keeps a permanent mailing address in the U.S.

11. If the potential participant **refuses participation**:
    A. Try to capture a reason for the refusal. If there is a concern that can be addressed (see guidance for addressing participation barriers and **PHI Concerns**), do so.
    B. Offer a hold if this is more appropriate.
    C. Ensure the potential participant understands that refusal to complete the HIPAA and baseline survey means refusing all participation in the LTFU Study.



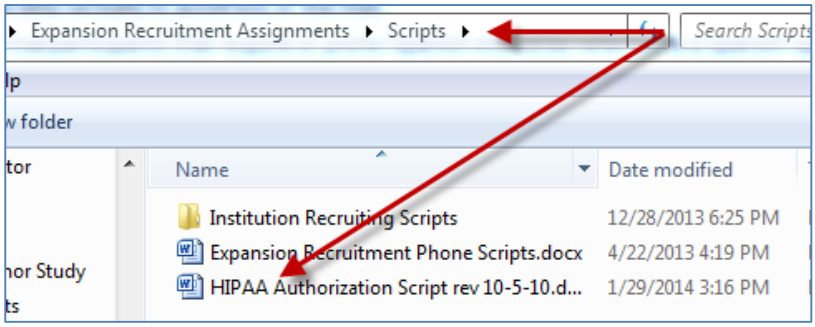
    D. Remind the potential participant that their participation will be welcome if they change their mind in the future.

12. If the potential participant indicates s/he has completed and **returned the paper enrollment** forms, ask for the approximate date of return. Mail takes up to a month to reach us. Enrollments returned more than one month ago likely need to be repeated, preferably verbally to avoid loss in the mail.

13. Potential participants that require or prefer **Spanish** should be referred to a Spanish-speaking SI.

DURING THE CALL: Completing the Verbal HIPAA

1. **Confirm Identity** – Ensure the case's identity has been confirmed with name and DOB.
2. **Confirm Contact Information** – Ensure the case's contact information and additional contact information have been verified.
3. **HIPAA Script** – Read the document titled **HIPAA Authorization Script *exactly as written*** as this verbiage has been approved by the appropriate IRBs. **Do not deviate from the scripted HIPAA.**



4. **HIPAA Questions** – Ask the two questions at the end of the document, ensuring that all outstanding questions have been answered to the case's satisfaction and that s/he has definitely given us permission to access the case's medical information for this study. (i.e. If the participant responds with something ambiguous, such as "Okay", clarify, "May I take that as a 'Yes'?")
5. **Participant Copy** – Determine if the participant previously received the recruitment package. If not, s/he must be sent a copy of the HIPAA. For any participant who did *not* receive the recruitment package (or who no longer has the package), advise that we will send a copy of the HIPAA authorization form for his/her records, and ask, "May I email your copy to you?"
   A. If yes, verify the email address to which the copy should be sent.
   B. If no, advise that we will mail the participant copy, and verify the mailing address to which the copy should be sent.
6. **Survey** – Determine how the participant would like to complete the baseline survey. Recall that participants requiring or preferring Spanish and proxies of deceased participants must complete the survey via telephone interview with a trained SI.
   A. Hardcopy/Paper Survey – A paper copy of the survey will automatically be mailed following a verbal HIPAA. Exception: No copy is mailed to participants who require Spanish or to proxies of deceased cases since the paper survey is not an option for these cases.
   B. Online Survey – Advise the participant that you will email a link to the online survey and confirm the email address to which this should be sent.
   C. Telephone Interview – Either begin the baseline survey (See the SOP titled **Expansion Baseline Survey Calls** for details.) or schedule an appointment during normal Call Center hours.
7. **Welcome** the participant to the LTFU Study, give them information about how to contact the study team if questions arise, and let them know the study team will call in 3 – 4 weeks to follow up if the survey has not been returned.

AFTER THE CALL: General

Based on the outcome of the call, follow the appropriate procedure, below.

1. Document the call in the contact log as outlined in the section of this document titled *Updating the CCSS Recruitment Database*.
2. For completed verbal HIPAAs, see the section of this document titled *AFTER THE CALL: Completed Verbal HIPAAs*.
3. For contact information that has been *confirmed* via telephone contact, update the Recruitment database as outlined in the section of this document titled *Updating the CCSS Recruitment Database*.
4. File any indicated forms in file cabinet A.
   A. **Expired Participant Information Sheet** – File in the "Refusals and Deceased" folder in the top drawer.
   B. **Riley (24) Verbal HIPAA Information Sheet** – File in the "Riley (24) VH Forms" folder in the top drawer.
5. For all other outcomes not clearly outlined in this document, see an LSI or the Call Center Coordinator for assistance.

AFTER THE CALL: Completed Verbal HIPAAs

1. Document the call in the **contact log** as outlined in the sections of this document titled *AFTER THE CALL: General* and *Updating the CCSS Recruitment Database*.
   A. **Outcome** – Select the option based on whether or not the baseline survey link was requested:
      i. Verbal HIPAA, No Survey Link Sent – If the participant completed the verbal HIPAA but the SI did not send a survey link, choose 1-Completed.

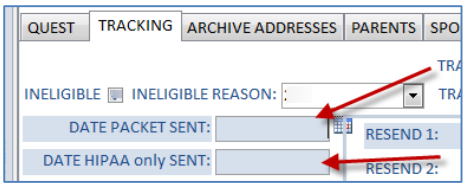
ii. Verbal HIPAA with Survey Link – If the participant completed the verbal HIPAA *and* the SI sent the survey link, choose 12-Completed VH – Sent Link.

B. **Notes** – Ensure the call notes indicate:
   i. Who completed the verbal HIPAA
   ii. His/her relationship to the case if someone other than the case
   iii. Clear LAR confirmation/documentation, if applicable
   iv. Whether or not the participant previously received a copy of the HIPAA in the mail
   v. If appropriate, in what form the participant wants their copy of the HIPAA form
   vi. In what form the participant will complete the survey

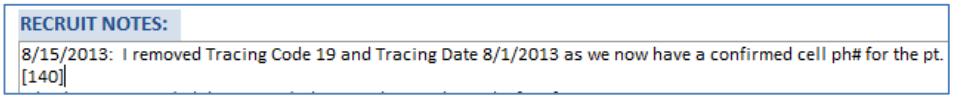
C. Copy your note documenting the HIPAA call.

2. On the Quest tab:
   A. Enter the date on the first blank line in the **Comments** field.
   B. Paste the call notes behind the date.
   C. Type your SI ID in brackets (e.g. *[158]*).
   D. Copy your note documenting the HIPAA call, including the date and your SI ID.

3. On the Tracking tab:



   A. **Recruit Notes** – Paste your note documenting the HIPAA call.
   B. **VERBAL MR INT ID** – Enter your SI ID.
   C. **DATE PACKET SENT** field or the **DATE HIPAA only SENT** – Ensure there is a value in at least one of these fields. If these are *both* blank, enter the current date in the **DATE HIPAA only SENT** field.
   D. **Resend Request** – Populate with the appropriate post-HIPAA code:
      i. **5-Pt paper copy** – The participant needs a copy of the HIPAA and requested the copy on paper. The copy will be sent in English only.
      ii. **6-Pt paper copy-SP** – The participant needs a copy of the HIPAA and requested the copy on paper in Spanish.
      iii. **7-Pt email copy** – The participant needs a copy of the HIPAA and requested the copy via email. The copy will be sent in English only.
      iv. **8-Pt email copy-SP** – The participant needs a copy of the HIPAA and requested the copy via email in Spanish.
      v. **9-No copy needed** – Participant already has a copy of the HIPAA and does not need a copy.
   E. **Date Resend Request** – Populate with the current date.
   F. Review the **Tracing Code**, **Tracing Date**, **Outcome Code**, and **Outcome Date** fields.
      i. If appropriate, clear these fields, then add a dated note with SI ID in the **Recruit Notes** field indicating the value removed, the new value, and the reason for the status change.



      ii. Do NOT populate the **Outcome Code** field with 1-Recruited. The 5th floor team will do so during the record rollover procedures.

4. For contact information that has been *confirmed* via telephone contact, update the Recruitment database as outlined in the sections of this document titled *AFTER THE CALL: General* and *Updating the CCSS Recruitment Database*.
5. For all institutions *EXCEPT RILEY (institution 24)*, log the new HIPAA at www.longtermfollowup.org. Refer to the SOP titled **Online Registration of Verbal HIPAA Authorizations** for full details.

6. For Riley HIPAAs, see the SOP titled **Verbal HIPAA Authorization Process for Riley (Institution 24)** for details.
7. If necessary, take action on the requested survey format.
   A. Paper – Paper surveys are automatically mailed for every HIPAA when the case rolls over to the CCSS Expansion Tracking database (except those on behalf of a deceased case and those requiring or preferring Spanish). No action is required for eligible participants who chose to complete the survey on paper.
   B. Online – For participants who requested to complete the survey online, send the link via email using the SOP titled **Emailing Expansion Baseline Survey Links**. This option is NOT available for proxies of deceased cases or those who require or prefer Spanish.
   C. Telephone – For participants who scheduled appointments to complete the survey via telephone, see the "Appointment Made for HIPAA or Survey" heading in the section of this document titled *Updating the CCSS Recruitment Database*.
8. Update the Dry Erase Board (DEB) to indicate the completed HIPAA.
9. For *scheduled* verbal HIPAAs, update the Call Center calendar to indicate the appointment was completed.
10. For *unscheduled* verbal HIPAAs, email the closing monitor to advise the CCSSID and event so that the HIPAA can be included on the day's closing report.

Updating the CCSS Recruitment Database

IMPORTANT: (1) NEVER update the database with *unconfirmed* contact information. (2) Save work on a record by moving to a new field, then clicking the Save icon on the Home tab. (3) After updating a record, navigate to a new record to ensure your work is not accidentally erased by another party accessing the same record.

1. Special note regarding **former St. Jude patients** (institution 15): If the case's CCSSID begins with "15" and any contact information has changed, send screen shots highlighting the changes made to the CRA in charge of St. Jude Life recruitment.

2. All communication with external parties should be documented in the contact or trace log:
   A. For calls to/from confirmed numbers, emails sent or received from the participant or his/her associates, or other communications with an external party for non-tracing purposes, click the **New Contact Log** button in the header of the case's record.
   B. For calls to/from unconfirmed numbers or other communication with external parties for tracing purposes, click on the **Trace Log** button in the header of the case's record, then click on the **New Record** button.
   C. Once the contact log or trace log record appears, populate the fields as follows for each communication event:
      i. **IntID** – Enter your SI ID.
      ii. **Date** – Enter the date of the communication.
      iii. **Contact Mode** – Select the appropriate option from the drop-down menu.
      iv. **Phone** – For telephone calls, enter the telephone number to which the call was placed or from which the call was received. For non-telephone communication, leave this field blank.
      v. **Email** – For emails, enter the email address to which the message was sent or from which the message was received. For non-email communication, leave this field blank.
      vi. **Contacting** – Use the drop-down menu to select the appropriate option.
         a. For outgoing communication, choose the party reached or, when no one is reached, choose the party you are trying to reach.
         b. For incoming communication, choose the party contacting the LTFU Study.
         c. If unsure of the exact relationship, choose 8-Other.
      vii. **Name** – Type the name of the party with whom the communication is conducted.

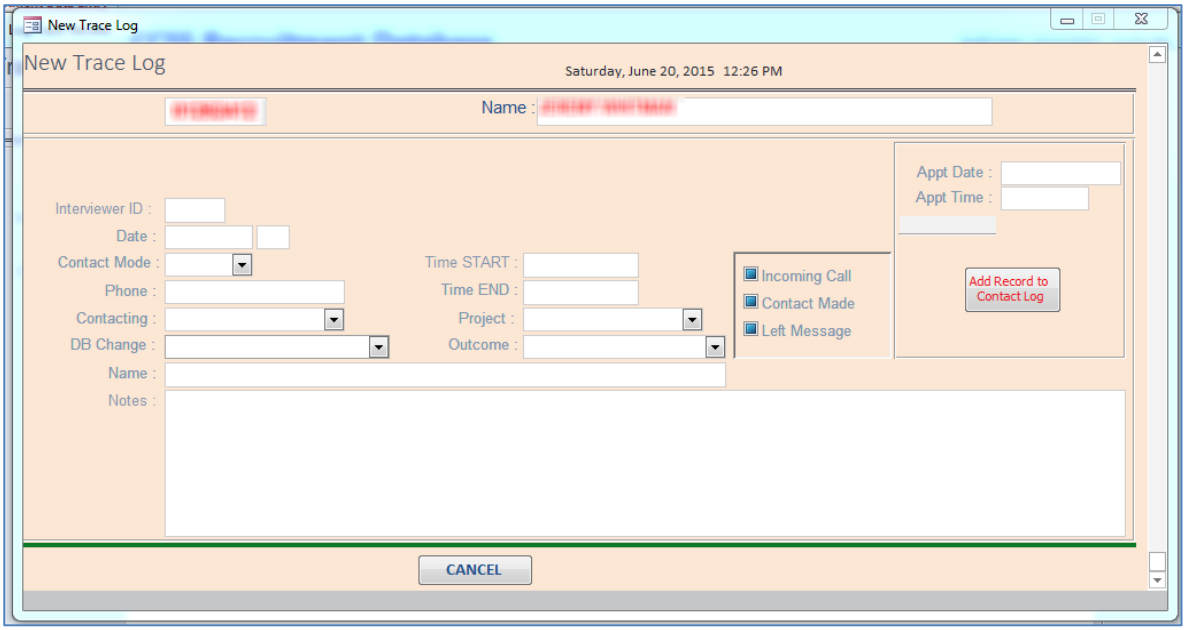
a. For outgoing communication, type the name of the party reached or, when no one is reached, type the name of the party you are trying to reach.
b. For incoming communication, type the name of the party contacting the LTFU Study.
c. If unsure, type "unknown".

viii. **Time START** – Enter the time the telephone number was dialed (for outgoing calls), the time the call was received (for incoming calls), or the time the email was sent/received (for email communication). Contact/trace log records on the same date for the same SI should not have overlapping times.

ix. **Time END** – Enter the time the telephone was hung up (for calls) or the time the email was sent/received (for emails). Note that email communication will have the same time in both the **Time START** and **Time END** fields.

x. **Project** – Select 12-LTFU Recruitment.

xi. **Contact Reason** – Select 5-HIPAA.



xii. **Email Type** – For emails sent or received, select the appropriate option from the drop-down menu. For non-email communication, leave this field blank.

xiii. **Outcome** – Select the option that most appropriately describes the outcome of the communication. Importantly:

a. Verbal HIPAA, No Survey Link Sent – If the participant completed the verbal HIPAA but the SI did not send a survey link, choose 1-Completed.
b. Verbal HIPAA with Survey Link – If the participant completed the verbal HIPAA *and* the SI sent the survey link, choose 12-Completed VH – Sent Link.
c. Refusals – If the participant refused participation, choose 7-Refused.

xiv. **Incoming Call** checkbox – Mark this checkbox if the record is for an incoming telephone call. Leave this checkbox blank for outgoing calls and all other types of communication.

xv. **Contact Made** checkbox – Mark this box if someone was contacted during an incoming or outgoing telephone call. Leave this box blank for all non-telephone communication.

xvi. **Left Message** checkbox – If a message was left on an answering device, mark this checkbox. This will update the tallies displayed in the **Calls & Messages** report. Do *not* check this box when leaving a message with a live person or for non-telephone communication.

xvii. **Appt Date** – If an appointment was set to complete the verbal HIPAA or the baseline survey during the call, specify the date of the appointment.

xviii. **Appt Time** – If an appointment was set to complete the verbal HIPAA or the baseline survey during the call, enter the time of the appointment in Central Time, regardless of the case's time zone.

xix. **DB Change** – If an LSI-level change needs to be made to the database or if a survey was partially completed or was completed in Spanish, flag the change request or survey event using the drop-down menu in this field. *IMPORTANT: Clear notes regarding the requested change or event must be documented in the **Notes** field*.

a. DOB – Specify the wrong and the correct DOB.
b. Gender – Specify the wrong and the correct gender.
c. Spanish Survey Completed
d. Ineligible – Specify the reason for suspected ineligibility.
e. Name Change – Specify name changed from, name changed to, and the change reason.
f. Survival Status – Specify wrong the vital status and the correct vital status.
g. Other – Specify what is being requested.
h. Partially Complete
i. No Proxy Available – Specify the circumstances that lead to this request.

xx. **Notes** – Enter clear, concise, thorough notes about the communication and its outcome.

a. If a database change was requested in the **DB Change** field, specify the change needed.
b. *Clearly* document LAR situations.
c. If calling one party and reaching another, specify this. *Example: "Called for case. Case's mother answered and…"*
d. For email communication, enter only a summary of what was sent. Do not paste the full body of the email into this field.

xxi. **Add Record to Contact Log** button (found in the Trace Log record only) – If a call to or from an unconfirmed number results in contact with the case or an associate of the case, click this button to add an identical record to the contact log.

xxii. Save the record(s) by clicking the red X exit button at the top of the window, or cancel all records by clicking the **Cancel** button located below the last contact card.

3. **Case Contact Information** (located on the Quest tab) –

A. **Case Name** – If the case's name needs to be updated, go to the Quest tab and:

i. **Archive Address** – Click this button before making any changes.

ii. **To whom Letter sent** – Update the case's name. Keep the formatting of the name and the address consistent to keep LTFU mailings looking professional. (i.e. If the address is in ALL CAPS, the name should also be in ALL CAPS.) Although the header should always display the case's *legal* name, names can be entered in the **To whom Letter sent** field as follows:

a. If the case's preferred name is not specified, enter the name as Firstname Lastname.
b. If the participant goes by his/her first name, enter the name as Firstname Lastname.
c. If the participant goes by his/her middle name, enter the name as F. Middlename Lastname. (e.g. *C. Renée Massey*)
d. If the participant goes by both his/her first and middle names, enter the name as Firstname Middlename Lastname. (e.g. *Billy Bob Thornton*)
e. If the participant's preferred name is not part of his legal name, enter the name as Preferredname Legallastname.

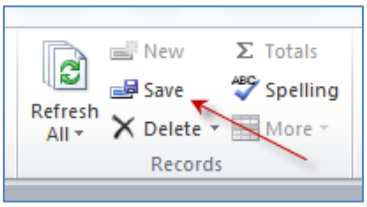
iii. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.

iv. Header – If a change is needed to the case's *legal* name in the record header, record the request using the **DB Change** field in the contact or trace log as instructed above.

v. Ensure details regarding the name change, including any indicated preferred name, are documented in the **Notes** field of the contact log and with a dated note in the Quest tab's **Comments** field.

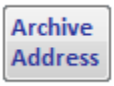
B. **Case Mailing Address** (Quest tab) –

i. If the case's name and address are in different formats (e.g. name in ALL CAPS and address in Upper-lower case), proactively correct the address to be uniformly formatted.



ii. Confirmed – If the existing address has been confirmed:
   a. **ADDRESS DATE** – Update with the confirmation date.
   b. **ADDRESS SOURCE** – Update with the confirmation source.
   c. Save – Move to a new field, then click the Save icon.

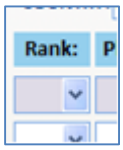
iii. New – If there is new address information to enter:
   a. **Archive Address** – Click this button before making any changes.
   b. **Address**, **City**, **State**, and **ZIP5** – Update to the new address. Keep the formatting of the name and the address consistent to keep LTFU mailings looking professional. (i.e. If the name is in ALL CAPS, the address should also be in ALL CAPS.)
   c. **CareOf** – If using this field, see the SOP titled **Use of "Care of" Field** for guidance.
   d. **ADDRESS DATE** – Update with the date the new address was obtained.
   e. **ADDRESS SOURCE** – Update with the source of the new address.
   f. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.
   g. **Tracing Code** and **Tracing Date** (Tracking tab) – Update as described below, if appropriate.



C. **Case Telephone Numbers** –

i. Do not move telephone numbers from one line to another.

ii. **Rank** – Update, if necessary.
   a. Rank valid telephone numbers using ranks 1 – 5 according to your best judgment. Rank 1 indicates the best number at which to reach the participant, rank 2 indicates the second best number, etc.
   b. Rank 9 indicates a disconnected telephone number. Ensure the disconnection is also documented in your call notes when changing a rank to "9".
   c. Rank 11 indicates the number is an incorrect number for the case or his/her associate.
   d. Rank 37 indicates a number that should not be called again (e.g. we have been asked never to call the number again). When rank 37 is used, a note should be entered in the **Comments** field of the Quest tab using the following format: 2 leading asterisks, date, message in all caps with explanation, [SI ID].
   *Format Example: **2/3/15: DO NOT CALL 901-555-1234. CASE REQUESTED NO FURTHER CALLS TO HOME NUMBER. [162]*



iii. Confirmed – If an existing telephone number has been confirmed:
   a. **Phone Date** – Update with the confirmation date.
   b. **Phone Source** – Update with the confirmation source.
   c. Save – Move to a new field, then click the Save icon on the Home tab.

iv. New – If there is a new participant telephone number to enter:
   a. Enter the new number in the top-most empty row. If all available slots are taken and you need to enter a new number, see the SOP titled **Handling Additional Phone Numbers**.

1. **Rank –** Populate using your best judgment, as described above.
2. **Phone Number** – Enter the new number.
3. **Phone Type** – Choose the best option from the drop-down menu.
4. **Relationship** – Choose the best option from the drop-down menu. In general, phone numbers on the Quest tab should be for the case.
5. **Phone Date** – Enter the date the number was obtained.
6. **Phone Source** – Choose the best option for the source of the number.

b. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.
c. **Tracing Code** and **Tracing Date** (Tracing tab) – Update as described below, if appropriate.

D. **Case Email Address** – Follow the same protocol used for updating case telephone numbers.

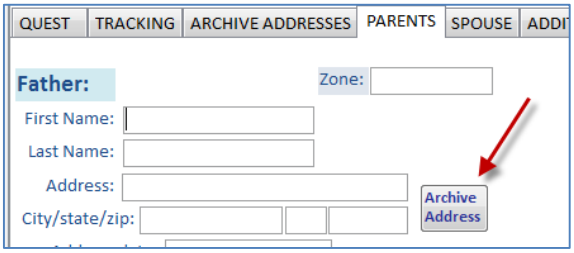
4. **Parent Contact Information** (located on the Parents tab) –

A. **Parent Name Change** – If it is discovered that we have an incorrect name listed for the case's parent:

i. Document – Ensure details regarding the name change, including any indicated preferred names, are documented in your call notes and in a dated note in the Quest tab's **Comments** field.

ii. **Archive Address** – Click the appropriate button on the Parents tab, corresponding to either the father or mother.

iii. Update – Update the appropriate name fields on the Parents tab. Names are documented as the legal name with any preferred name in quotes. (e.g. Robert "Bob" Smith)



iv. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.

B. **Parent Mailing Address** –

i. Confirmed – If a parent's existing mailing address has been confirmed:
   a. **Address date** – Update with the date the address was confirmed.
   b. **Address source** – Update with the source of the confirmation.
   c. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.

ii. New – If a parent's mailing address needs to be updated to a new value:
   a. **Archive Address** – On the Parents tab, click the appropriate button, corresponding to either the father or mother.
   b. **Address** and **City/state/zip** – Update to the new address.
   c. **Address date** – Update with the date the new address was obtained.
   d. **Address source** – Update with the source of the new address.
   e. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.

C. **Parent Telephone Number** –

i. Do NOT move phone numbers from one line to another.

ii. Confirmed – If the parent's existing telephone number has been confirmed:
   a. **Phone # Date** – Update with the date the number was confirmed.
   b. **Phone # Source** – Update with the source of the confirmation.
   c. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.

iii. New – If there is a new parent telephone number to enter:
   a. Enter the new number in the top-most empty row. If all available slots are taken, and you need to enter a new number, see the SOP titled **Handling Additional Phone Numbers**.
      1. **Phone #** – Enter the new telephone number.

2. **Phone # Date** – Enter the date the number was obtained.
3. **Phone # Source** – Enter the source of the number.

b. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.

iv. Disconnected – If a parent number is discovered to be disconnected, clearly document this in the call notes and in a dated note in the Quest tab's **Comments** field.

v. Do Not Call – If a parent number needs to be marked as a "Do Not Call" number, enter a note in the Quest tab's **Comments** field using the following format: 2 leading asterisks, date, message in all caps with explanation, [SI ID]. *Format Example: **7/2/15: DO NOT CALL 901-555-6789. CASE'S FATHER REQUESTED NO FURTHER CALLS. [121]*

D. **Parent Contact Status** – In general, the **Contact Status** field and the corresponding **Contact Status date** field will be blank for the case's parents. Exceptions:

i. Additional contacts are those parties that the case has AUTHORIZED us to contact if we are unable to reach the case. *We do NOT indicate someone as an additional contact without the case's authorization*. If the *participant has authorized* a parent to be an additional contact:

a. **Contact Status** – Set to "Yes".
b. **Contact Status date** – Populate or update with the date of the case's authorization.
c. **Notes** – Add a dated note with SI ID documenting the authorization and the field changes.

ii. If the case OR the parent has asked us to avoid calling the parent:

a. **Contact Status** – Populate with or update to be "No".
b. **Contact Status date** – Populate with or update to be the date of the request.
c. **Notes** – Add a dated note with SI ID documenting the request and the field changes.

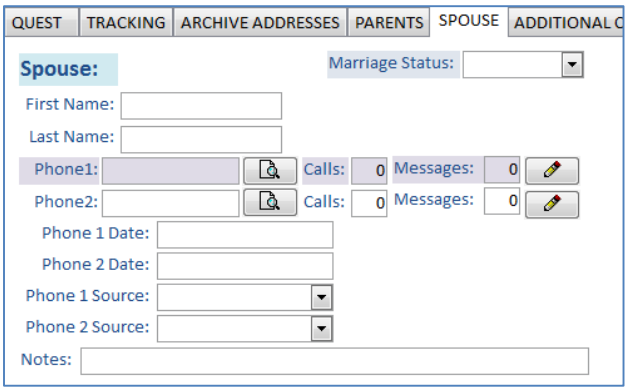
5. **Spouse Contact Information** (located on the Spouse tab) –

A. **Spouse Name** – If it is discovered that we have an incorrect name listed for the case's spouse:

i. Document – Ensure details regarding the name change, including any indicated preferred name, are documented in the call notes and in the Quest tab's **Comments** field. Manually archive the existing name in the notes.

ii. Update – Update the appropriate name fields on the Spouse tab. Names are documented as the legal name with any preferred name in quotes. (e.g. Deidre "Dee" Smith)

iii. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.



B. **Spouse Phone Numbers** –

i. Do NOT move phone numbers from one line to another.

ii. Confirmed – If the spouse's existing telephone number has been confirmed:

a. **Phone # Date** – Update with the date the number was confirmed.
b. **Phone # Source** – Update with the source of the confirmation.
c. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.

iii. New – If there is a new spouse telephone number to enter:

a. Enter the new number in the top-most empty row. If all available slots are taken, and you need to enter a new number, see the SOP titled **Handling Additional Phone Numbers**.

1. **Phone #**: Enter the new telephone number.
2. **Phone # Date** – Enter the date the number was obtained.
3. **Phone # Source** – Enter the source of the number.
4. Save – Move to a new field, then click the Save icon on the Home tab of the Access Ribbon.

iv. Disconnected – If a spouse's number is discovered to be disconnected, clearly document this in the call notes and in the Quest tab's **Comments** field.

v. Do Not Call – If a spouse number needs to be marked as a "Do Not Call" number, enter a note in the Quest tab's **Comments** field using the following format: 2 leading asterisks, date, message in all caps with explanation, [SI ID]. *Format Example: **8/21/15: DO NOT CALL 901-555-3456. CASE'S SPOUSE REQUESTED NO FURTHER CALLS. [174]*

C. **Spouse Contact Status** – In general, the **Contact Status** field and the corresponding **Contact Status date** field will be blank for the case's spouse. Exceptions:

i. Additional contacts are those parties that the case has AUTHORIZED us to contact if we are unable to reach the case. *We do NOT indicate someone as an additional contact without the case's authorization*. If the *participant has authorized* the spouse to be an additional contact:
   a. **Contact Status** – Set to "Yes".
   b. **Contact Status date** – Populate or update with the date of the case's authorization.
   c. **Notes** – Add a dated note with SI ID documenting the authorization and the field changes.

ii. If the case OR the spouse has asked us to avoid calling the spouse:
   a. **Contact Status** – Populate with or update to be "No".
   b. **Contact Status date** – Populate with or update to be the date of the request.
   c. **Notes** – Add a dated note with SI ID documenting the request and the field changes.

6. **Associate Contact Information** (located on the Associates tab) – Associates are all parties related to or otherwise associated with the case and may include family members (other than parents or spouses, both of whom have special tabs), friends, neighbors, and others.

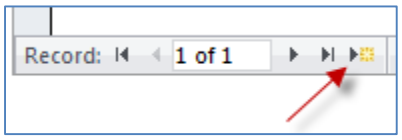
A. To add a **new Associate record**:

i. Review all existing records to verify that the associate is not already documented. There should be only one associate record per associate. For existing associates, see below directives for Associate Name, Associate Address, Associate Phone Number, Associate Email Address, and Associate Contact Status.

ii. If the new associate is a brother or sister of the participant, confirm the associate is not also a case being recruited or already recruited to the LTFU Study.
   a. If the associate IS also a case being recruited or already recruited to the LTFU Study:
      1. **Comments** (Quest tab) – Log a dated comment with your SI ID documenting that the participant has an associated sister or brother that is also a case. Include the CCSSID for that case.
      2. Click the **New (blank) record** button at the bottom of the Associates tab to make a new associate record.
      3. Enter the name of the sister or brother associate who is also a case using the **Associate Name** instructions, below.
      4. **Relationship** – Populate with the appropriate value.
      5. Document the additional contact status, if applicable. See the **Associate Contact Status** instructions, below, outlining the procedure.

6. Do NOT enter the sister or brother associate's contact information in the associate record. Make a dated note in the **Note** field that this will be documented only in his/her primary study record.
7. Update the contact information in the sister or brother's primary record.

b. If the new associate IS NOT also a case being recruited or already recruited to the LTFU Study:



1. **New (blank) record** – Click this button at the bottom of the Associates tab.
2. **Relationship** – Populate with the associate's relationship to the case. If the relationship is unknown, populate this field with 15-Other.
3. Enter the associate's name, address, telephone number(s), email address, and contact status information as indicated below.

B. **Associate Name** – Associate names are recorded in individual records on the Associates tab. Only one party should be recorded in each associate record (e.g. Do NOT list "John and Joan Doe" in the name fields of a single record.) If our record of an associate's name needs to be changed:

i. **Note** – Add a dated note with your SI ID documenting what the name is being changed from, what the name is being changed to, and why the change is being made.
ii. **Archive Additional Address** – Click this button before making any changes.
iii. **First Name** – Make the appropriate changes. The name should be formatted as Legalfirst "Preferredname".
iv. **Last Name** – Make the appropriate changes.

C. **Associate Address** –

i. If the associate's existing address has been confirmed, and the associate IS NOT also a case being recruited or already recruited to the LTFU Study:
   a. **Address Date** – Update with the date the mailing address was confirmed.
   b. **Address Source** – Update with the source of the confirmation.
ii. If there is new address information for the associate, and the associate IS NOT a case being recruited or already recruited to the LTFU Study:
   a. **Archive Additional Address** – Click this button before making any changes.
   b. **Address**, **City**, **State**, and **Zip** – Enter the new associate address.
   c. **Address Date** – Update with the date the mailing address was confirmed.
   d. **Address Source** – Update with the source of the confirmation.
iii. If the recorded address is for the associate is *known* to be incorrect, no new address information is provided, and the associate IS NOT a case being recruited or already recruited to the LTFU Study:
   a. **Archive Additional Address** – Click this button before making any changes.
   b. **Address**, **City**, **State**, **Zip**, **Address Date**, **Address Source** – Remove the incorrect mailing address.
   c. **Note** – Add a dated note with your SI ID documenting the circumstances and the action taken.
iv. If the associate IS a case being recruited or already recruited to the LTFU Study:
   a. Update the associate's contact information in his/her primary record.
   b. **Archive Additional Address** – Click this button before making any changes.
   c. Clear the address information currently documented in the associate record.
   d. **Note** – Log a dated comment with your SI ID indicating that the associate's contact information can be found in his/her primary record.

D. **Associate Telephone Number** –

i. If an existing associate telephone number has been confirmed, and the associate IS NOT also a case being recruited or already recruited to the LTFU Study:
   a. **Phone # Date** – Update with the date the number was confirmed.
   b. **Phone # Source** – Update with the source of the confirmation.

ii. If there is a new associate telephone number, and the associate IS NOT also a case being recruited or already recruited to the LTFU Study:
   a. Enter the number in the first empty row, and populate the associated **Phone # Date** and **Phone # Source** fields.
   b. If all available slots are taken, and you need to enter a new number, see the SOP titled **Handling Additional Phone Numbers**.

iii. If the associate IS also a case being recruited or already recruited to the LTFU Study:
   a. Update the associate's telephone information in his/her primary record.
   b. **Note** – Archive the telephone information currently documented in the associate record by making a dated note with SI ID. Specify that the associate's contact information can be found in his/her primary record.
   c. Clear the telephone information currently documented in the associate record.

iv. Disconnected – If an associate number is discovered to be disconnected, clearly document this in the call notes and in the **Note** field.

v. Do Not Call – If an associate number needs to be marked as a "Do Not Call" number, enter a comment in the **Note** field using the following format: 2 leading asterisks, date, message in all caps with explanation, [SI ID]. *Format Example: **6/20/15: DO NOT CALL 901-888-3456. CASE'S AUNT REQUESTED NO FURTHER CALLS. [176]*

E. **Associate Email Address** –

i. If an existing email address has been confirmed, and the associate IS NOT also a case being recruited or already recruited to the LTFU Study:
   a. **Email Date** – Update with the date the email address was confirmed.
   b. **Email Source** – Update with the source of the confirmation.

ii. If there is a new participant email address to enter and the associate IS NOT also a case being recruited or already recruited to the LTFU Study:
   a. Enter the new email address, **Email Date**, and **Email Source**.
   b. If all available slots are taken, and you need to enter a new email address, see the SOP titled **Handling Additional Phone Numbers** and handle the email addresses the same way.

iii. If the associate IS also a case being recruited or already recruited to the LTFU Study:
   a. Update the associate's email information in his/her primary record.
   b. **Note** – Archive the email information currently documented in the associate record by making a dated note with SI ID. Specify that the associate's contact information can be found in his/her primary record.
   c. Clear the email information currently documented in the associate record.

F. **Associate Contact Status** – In general, the **Contact Status** field and the corresponding **Contact Status date** field will be blank for associates of the case. Exceptions:

i. Additional contacts are those parties that the case has AUTHORIZED us to contact if we are unable to reach the case. *We do NOT indicate someone as an additional contact without the case's authorization*. If the *participant has authorized* the associate to be an additional contact:
   a. **Contact Status** – Set to "Yes".
   b. **Contact Status date** – Populate or update with the date of the most recent authorization.

c. **Note** – Add a dated note with your SI ID documenting the most recent authorization and the updates to the fields.

ii. If either the associate has requested not to be contacted OR the participant has requested that we avoid contacting the associate:
   a. **Contact Status** – Update to be "No".
   b. **Contact Status date** – Update with the date of the status.
   c. **Note** – Add a dated note with your SI ID documenting the contact status and the changes to the fields.

7. **Deceased/Vital Status Update** –
   A. **Comments** (Quest tab) – Add a dated comment with SI ID documenting the change in vital status and its source.
   B. For participants – Request to update the case's vital status in the **DB Change** and **Notes** fields of the contact log.
   C. For deceased associates:
      i. **Contact Status** – Set to "No".
      ii. **Status Date** – Populate or update with the current date.
      iii. **Notes** – Add a dated comment with your SI ID documenting the change in vital status and contact status.

8. **LAR Status** – If it was determined that the case has an LAR or proxy (See a member of the LSI team or the Coordinator for assistance determining an authorized proxy for a non-deceased adult case. This is NOT applicable for minor or deceased cases; these cases would always be represented by a proxy.):
   A. **LAR/Proxy** checkbox (header) – Mark the checkbox.
   B. **LAR Proxy Date** (header) – Enter the date the LAR or proxy status was discovered.
   C. **CAREOF** (Quest tab) – Populate with "C/O" plus the LAR/proxy's first and last name. NOTE: Keep the name format consistent with the rest of the address (e.g. ALL CAPS or Upper-lower case).
   D. **Comments** (Quest tab) – Add a dated note with SI ID clearly documenting the LAR/proxy status and circumstances.
   E. Parents, Spouse, or Associates tab – Check the tab appropriate to the LAR's/proxy's relationship to the case to determine if the LAR/proxy is already listed on the case's record.
      i. If yes, update the LAR's/proxy's contact information in the appropriate record using the Parent Contact Information, Spouse Contact Information, or Associate Contact Information instructions, above.
      ii. If no, add the LAR/proxy to the appropriate tab using the Parent Contact Information, Spouse Contact Information, or Associate Contact Information instructions, above.

9. **No Proxy Available** – When a case is unable to represent himself/herself to participate in the LTFU Study and there is no party available to act as a proxy for the case, alert the leadership team that a "no proxy available" determination is needed. See the SOP titled **Requesting "No Proxy Available" Determination** for details.

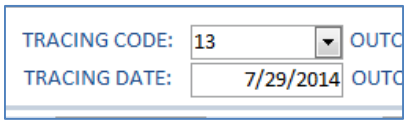
10. **Tracing Status Update** (located on the Tracking tab) –
   A. If all numbers in the database for the case and all his/her associates are disconnected and/or wrong:
      i. And the **Tracing Code** field is currently blank, update the field to be 19-Disconnect/Wrong Num, and populate the **Tracing Date** field with the current date.

ii. And the **Tracing Code** field is already populated with code 18-Undeliverable, update the field to be 13-Tracing, and update the **Tracing Date** field with the current date.
iii. And the **Tracing Code** field is already populated with code 85-Bad Lexis Nexis Address, update the field to be 86-Bad Lexis Nexis Address & Phone(s), and update the **Tracing Date** field with the current date.
iv. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.

B. If calls to all numbers meet the following criteria, the participant may be placed in tracing for bad numbers, as directed above:
i. If the voicemail announcement indicates the participant's or his/her associate's name, and there has been no response after 5 calls and 3 messages
ii. If the voicemail announcement is generic, and there has been no response after 4 calls and 2 messages
iii. If there is no voice mailbox (i.e. we cannot leave a message), and no one has been reached after 3 calls

C. If we are notified that the mailing address on the Quest tab is invalid but an updated address is not provided:
i. When the **ADDRESS SOURCE** is not Lexis Nexis:
a. And the **Tracing Code** field is currently blank, update the field to be 18-Undeliverable, and populate the **Tracing Date** field with the current date.
b. And the **Tracing Code** field is already populated with code 19-Disconnect/Wrong Num, update the field to be 13-Tracing, update the **Tracing Date** field with the current date.
c. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
ii. When the **ADDRESS SOURCE** is Lexis Nexis:
a. And the **Tracing Code** field is already populated with 13-Tracing, update the field to be 86-Bad Lexis Nexis Address & Phone(s), and update the **Tracing Date** field to be the current date.
b. And the **Tracing Code** field is already populated with 18-Undeliverable, update the field to be 85-Bad Lexis Nexis Address, and update the **Tracing Date** field to be the current date.
c. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.

D. If the **Tracing Code** field is currently set to 13-Tracing and contact information is confirmed:
i. If a telephone number for the case is confirmed but not an address:
a. **Tracing Code** – Update from 13-Tracing to 18-Undeliverable.
b. **Tracing Date** – Update with the current date.



c. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
d. Complete all appropriate database updates for a case telephone number.
ii. If a mailing address for the case is confirmed but not a telephone number:
a. **Tracing Code** – Update from 13-Tracing to 19-Disconnect/Wrong Num
b. **Tracing Date** – Update with the current date.
c. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
d. Complete all appropriate database updates for a case address.
iii. If both a telephone number and a mailing address for the case are confirmed:

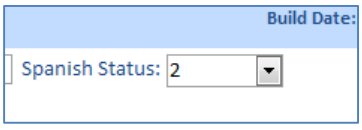
a. **Tracing Code** and **Tracing Date** – Clear both fields.
b. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
c. Complete all appropriate database updates for case telephone numbers and addresses.

E. If the **Tracing Code** is currently set to 19-Disconnect/Wrong Num and a telephone number for the case is confirmed:
   i. **Tracing Code** and **Tracing Date** – Clear both fields.
   ii. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
   iii. Complete all appropriate database updates for a case telephone number.

F. If the **Tracing Code** is currently set to 18-Undeliverable or 85-Bad Lexis Nexis Address and a mailing address for the case is confirmed:
   i. **Tracing Code** and **Tracing Date** – Clear both fields.
   ii. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
   iii. Complete all appropriate database updates for a case address.

G. If the **Tracing Code** is currently set to 86-Bad Lexis Nexis Address & Phone(s) and contact information is confirmed:
   i. If a telephone number for the case is confirmed but not an address:
      a. Update the **Tracing Code** field from 86-Bad Lexis Nexis Address & Phone(s) to 85-Bad Lexis Nexis Address, and update the **Tracing Date** field with the current date.
      b. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
      c. Complete all appropriate database updates for a case telephone number.
   ii. If a mailing address for the case is confirmed but not a telephone number:
      a. Update the **Tracing Code** field from 86-Bad Lexis Nexis Address & Phone(s) to 19-Disconnect/Wrong Num, and update the **Tracing Date** field with the current date.
      b. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
      c. Complete all appropriate database updates for a case address.
   iii. If both a telephone number and a mailing address for the case are confirmed:
      a. **Tracing Code** and **Tracing Date** – Clear both fields.
      b. **Recruit Notes** – Add a dated note with your SI ID indicating what the fields were changed from, what the fields were changed to, and why.
      c. Complete all appropriate database updates for case telephone numbers and addresses.

11. **Spanish** – If we discover that a potential participant speaks Spanish:



A. **Notes** (contact log) - Leave clear notes regarding the Spanish status.
B. **Spanish Status** (header) - Update as follows:
   i. 1-Spanish – Case requires a Spanish-speaking SI.
   ii. 2-Both – Case can speak both English and Spanish.
   iii. 3-Spanish Preferred – Case can speak both English and Spanish but prefers Spanish.
C. **Comments** (Quest tab) – Leave a dated note with SI ID documenting the change to the **Spanish Status** field.
D. SIs that do not speak Spanish should email the CCSSID to the Coordinator, copying the LSI team, to request that cases preferring or requiring Spanish be re-assigned.

12. **Appointment Made for HIPAA or Survey** –
    A. Update the Call Center appointment calendar as instructed in the SOP titled **Call Center Appointment Calendar**.
    B. If the scheduling SI will be covering the appointment, s/he should add the appointment to his/her MS Outlook calendar.
    C. If the appointment needs to be assigned to another SI, send an email to the LSI team, copying the Coordinator, requesting that the appointment be reassigned. Include the CCSSID and appointment type/date/time. If there is no time to follow this procedure (e.g. The appointment is scheduled for the same day, and the LSI team and Coordinator are out or unavailable before the appointment.):
        i. Coordinate with another SI to handle the appointment.
        ii. Document the covering SI's number with the appointment on the Call Center calendar according to the SOP titled **Call Center Appointment Calendar**.
        iii. Email details about the appointment and who will cover it to the LSI team, the Coordinator, and the covering SI.
    D. If the participant provided an email address and approved sending an emailed appointment reminder, use the SOP titled **Email Appointment Reminders for Baseline Surveys** to send a reminder.

13. Requesting a **Resend** of the Recruitment Packet – Request a resend of the paper recruitment package on the Tracking tab:
    A. **Resend Request** – Choose 2-Packet.
    B. **Date Resend Request** – Enter the current date.
    C. **Recruit Notes** – Log a dated note with your SI ID documenting what the fields were changed from, changed to, and why.
    D. Do NOT make an entry in the next available **Resend #** and corresponding **Resend # Mode** fields. The 5th floor team will populate the appropriate fields upon fulfillment of the resend request.

14. **Enroll Online** – If a potential participant requests to complete the enrollment online:
    A. Send the enrollment link using the instructions in the SOP titled **Emailing Expansion Recruitment HIPAA Links**.
    B. Document the email communication in the database's contact log.
        i. The email sent to the participant should be documented separately from the telephone call.
        ii. Do not copy the body of the email into the contact log's **Notes** field; enter a summary only.

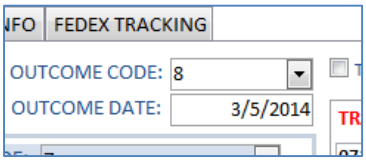
15. **Refusals** – If a potential participant refuses to complete the HIPAA and/or complete the baseline survey:
    A. Contact Log
        i. **Outcome** (contact log) – Choose option 7-Refused.
        ii. **Notes** (contact log) – Ensure the call notes clearly document the refusal and any reason provided.
    B. **Comments** (Quest tab) – Add a dated note with SI ID clearly documenting the refusal and any reason provided. Copy the entire dated note with the SI ID.
    C. Tracking tab
        i. **Recruit Notes** – Paste the dated note with the SI ID.
        ii. **Outcome Code** – Populate with 4-Refused.
        iii. **Outcome Date** – Enter the current date.

16. Potential Participant is **Out of the Country** –

A. If the participant is expected to be out of the country for 12 months or less, apply a hold appropriate to the expected duration. See the "Requests to be On Hold" directives, below.
B. If the participant is expected to be out of the country for more than 12 months.
   i. **DB Change** (contact log) – Request an eligibility determination.
   ii. **Notes** (contact log) – Include all details of the case's residential status.
   iii. Do NOT code the **Outcome Code** field on the Tracking tab with 2-Out of the Country.
   iv. A member of the LSI team will consult with the Coordinator and Research Scientist to determine action to be taken.

17. Potential Participant Is **Incarcerated** –
   A. If the incarceration is expected to last 12 months or less, apply a hold appropriate to the expected duration. See the "Requests to be On Hold" directives, below.
   B. For incarceration expected to last greater than 12 months:
      i. **DB Change** (contact log) – Request an eligibility determination.
      ii. **Notes** (contact log) – Include all details of the case's residential status.
      iii. Do NOT code the **Outcome Code** field with 3-In Prison unless deemed appropriate by the LSI team and/or Coordinator. A hold code may be determined to be more appropriate.
      iv. A member of the LSI team will consult with the Coordinator and Research Scientist to determine action to be taken.

18. **Requests to be On Hold** –
   A. **Notes** (contact log) – Clearly document the circumstances leading to the hold, the duration of the hold, and any additional information provided.
   B. **Comments** (Quest tab) – Clearly document the circumstances leading to the hold, the duration of the hold, and any additional information provided in a dated note with SI ID. Copy the dated note with the SI ID.
   C. **Recruit Notes** (Tracking tab) - Paste the dated note with the SI ID.
   D. **Outcome Code** (Tracking tab) – Select the appropriate hold code:



      i. 7 for a 3-month hold
      ii. 8 for a 6-month hold
      iii. 9 for a 1-year hold
      iv. Do not use 11-LN Hold.
      v. 12 for a Calls hold – NOTE: Use of this hold must be approved by a member of the LSI team, the Call Center Coordinator, or the Research Scientist, and this approval must be documented in the **Comments** and **Recruit Notes** fields, above. A "Calls" hold is a special outcome that puts the case on hold for outgoing calls but not for mailings and emailings.
   E. **Outcome Date** (Tracking tab) – Enter the current date.
   F. Do NOT create a reminder to contact the participant when the hold expires. The LSI team will return the case to call rotation when appropriate.

19. Believed to be **Ineligible** –
   A. If a potential participant is believed to be ineligible:
      i. **DB Change** (contact log) – 4-Ineligible
      ii. **Notes** (contact log) – Clearly document the reason for the suspected ineligibility.
      iii. The LSI team will discuss the case with the Coordinator and/or Research Scientist for a final eligibility determination.

B. Possible causes for ineligibility:
   i. Survived less than 5 years after diagnosis
   ii. Diagnosed and treated at a non-CCSS institution
   iii. Diagnosis date not in specified range
   iv. Not under 21 at the time of diagnosis
   v. Ineligible diagnosis
   vi. Does not speak English or Spanish
   vii. Lived out of the country at the time of recruitment

Revision Record Printed 9/20/2016 9:14 AM

Current Filename:		Expansion Recruitment Process for Survey Interviewers ver2_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/20/11	D. Rinehart	Initial Development
1.1	12/23/11	D. Rinehart	Clarifications; voicemail
1.2	5/9/12	Procedure Team	Formatting and content revisions
1.3	8/9/13	D. Rinehart	Content revision
2.0	2/14/14	R. Massey	Removed “Summary” from title, expanded content
2.1	12/2/2014	R. Massey	Removed refs to assignments workbooks and Call Outcomes Log, added directives for pt copy of HIPAA, call log, and trace notes.
2.2	6/20/2015	R. Massey	Content Revision: Updates to correlate with database changes
2.3	8/31/2016	A. Cobble	Content Revision: Updates to correlate with database changes

Expansion Sibling Cohort Permission Calls

Background

Siblings eligible to be recruited to the expansion cohort are the full-blooded siblings *closest in age* to the case. Eligible siblings may be deceased, but they need to have lived to be at least five years old. The first step in recruiting siblings for the LTFU study is to obtain permission from the case to contact the appropriate sibling. When a case is a minor, deceased, or has not yet been reconsented to the study since becoming an adult, we obtain permission from the case's parent, proxy, or LAR.

Initially, we mail permission letters with a form for the recipient to provide permission for us to contact the sibling and, if permission is granted, to provide the sibling's contact information. When we do not receive a response from the mailing, we make sibling permission phone calls to obtain verbal permission. If we obtain verbal permission, we collect the sibling's full name, date of birth, vital status, mailing address, and phone number so we can mail the sibling baseline survey. In situations where the recipient is thought to speak only Spanish, the case goes directly into permission call rotation; we do not mail a packet.

Procedures

The Tools you will need:

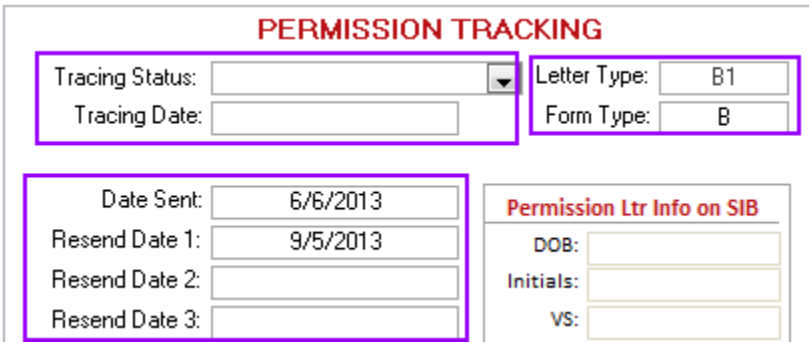
1. **Sibling Cohort Recruitment Call Assignments** workbook (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Call Assignments)*
2. Expansion Tracking database
3. MS Word **Phone Contact Log** for the case
4. Permission support materials:
   a. Permission forms A, B and D (several copies each, see individual forms for guidance, located at *Z:\…\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Letters and Forms\Recruitment*)
   b. Permission Letters A1, A2, B1, B2, and D (one copy each for reference, located at *Z:\…Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Letters and Forms*)
   c. The **Guide to Expansion Sibling Permission Forms, SI Packet** (located at *Z:\…\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Letters and Forms*)
   d. **Expired Participant Information Sheet**
5. The **LTFU Expansion Cohort Sibling Permission and Recruitment Call Guidance** (located at *Z:\…\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Scripts)*
6. The **New Contact Data Form** (optional, located at *Z:\…Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Letters and Forms*)
7. **Pre-Post Call Checklist - Expansion Sibling Permission**

PROCEDURES: BEFORE MAKING THE CALL

1. Open your **Sibling Cohort Recruitment Call Assignments** workbook and select the first appropriate row on the Sibling Calls tab whose **Call Purpose** column is set to "Permission".
2. Open the Expansion Tracking database, select **Siblings** from the main switchboard, and then use the Find feature in Access to search for the sibling by SIBID.
3. Review the **Outcome** field in the Permission Tracking box of the Permission Tab to determine if any type of permission outcome has already been obtained. If yes, see table below for action required:

Code	Meaning	Explanation	Action Required
Blank		No outcome to date	Proceed with the permission call.
1	Received	Permission has been received from the LAR/Proxy/Case	*No permission call is needed, but a survey call may be appropriate:* 1. Confirm sibling contact information is complete by reviewing the Header and Sib Info tab. 2. Determine the status of the sibling *survey* by reviewing the **Date Survey Sent** and **Date Survey Returned** fields on the **Sib Baseline** tab. a. Survey sent and returned? NO FURTHER ACTION. b. Survey sent, but not returned? If the survey was sent over 3 weeks ago, you may proceed with a *survey* call. See the SOP titled **Expansion Cohort Sibling Survey Calls**. c. Survey *not* sent? Surveys are sent on a two week cycle, so the survey may be scheduled for mailing soon. If more than 2 weeks have elapsed since the permission was obtained, inquire about the delay.
2	Denied	Permission has been denied	**DO NOT CALL.**
3, 4 and 5	3/6/9 Month Hold	Applied case-by-case for various reasons	Review **Outcome Date** to calculate when the hold expires. If hold HAS expired, add a dated comment to the **Comments** field on the Permission tab documenting the data currently in the **Outcome** and **Outcome Date** fields, clear the **Outcome** hold code and **Outcome Date** and *proceed with the permission call*.
6	Sib in Jail	Sibling has been determined to be incarcerated	Review the **Outcome Date**, **Comments** on the Permission tab, **CALL Log** and case's MS Word **Phone Contact Log** to determine if there is an estimated date of release. If that date has passed, *proceed with the permission call*. If you learn the sibling has been released, add a dated note to the **Comments** field on the Permission tab documenting the data currently in the **Outcome** and **Outcome Date** fields, and then clear these fields. As appropriate, re-code and re-date permission outcome (received, denied, additional hold).
10	Ineligible	Sibling has been determined to be ineligible	**DO NOT CALL.**

4. If no permission outcome has been obtained (or a hold has expired), build the permission call profile:
    a. On the Permission tab in the green sibling record:
        i. Review if/when the permission packet was sent by reviewing the **Date Sent** and any **Resend Dates** in the Permission Tracking box. We may still try to obtain permission verbally, even if no packet has been mailed.
        ii. Refer to the **Letter Type** and **Form Type** as a cue for which form to use during the call. Keep in mind, however, that information gained during the call may indicate use of a different form.

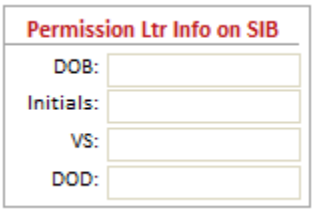


        iii. Review the **Tracing Status** and **Tracing Date** fields in the Permission Tracking box. Code 82 indicates that a "resend" of the permission packet has been requested. Code 18 indicates the permission packet was returned to sender, code 19 indicates all phone numbers we have for the case and his/her associates are bad, and code 13 indicates the address *and* all the phone numbers are bad. To locate possible phone numbers to reach the case or his/her LAR/proxy:
            1. Click on the **Trace Log** or **Trace History** buttons at the bottom of the screen to see if the Tracing team located possible numbers for you to try. You may call

any unconfirmed numbers for the case/LAR/proxy/parents/associates. If contact is made with the permitting entity, proceed with permission call.

2. Access the blue case record (either by choosing **Cases** on the main switchboard or by going to the green Case tab, then clicking on the **Open Sibling's Case** button), and click on the **Trace Log** or **Trace History** buttons at top of the screen to see if the Tracing team located possible numbers for you to try. You may call any unconfirmed numbers for the case/LAR/proxy/parents/associates. If contact is made, proceed with permission call.
3. Check the Tracer's Comments by CCSSID folder (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\ Tracing\05. Tracer's Comments by CCSSID*) to see if the Tracing team previously located possible numbers for you to try. You may call any unconfirmed numbers for the case/LAR/proxy/parents/associates. If contact is made with the permitting entity, proceed with permission call.

iv. Review the **Permission Ltr Info on SIB** inset in the Permission Tracking box for probable information on the target sibling. This information is obtained from the case's baseline survey but should be confirmed at the time of permission. Blank fields in this inset do not preclude a permission call. The **VS** field is for "Vital Status", and the **DOD** field is for "Date of Death". If there is a date of death, avoid calling near the death anniversary.



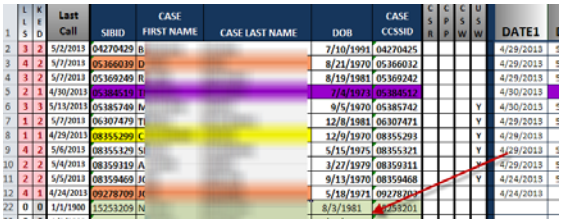
v. Review all information documented in the **Comments** field.

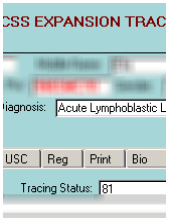
b. On the blue case record associated with this green sibling record (accessed either by choosing **Cases** on the main switchboard or by going to the green Case tab, then clicking on the **Open Sibling's Case** button):
   i. Review the Reg tab's **Outcome** field, the Quest tab's **CCSS Hold** field, and all "Before the Call" fields in the **Pre-Post Call Checklist - Expansion Baseline Survey** checklist.
   ii. Review all call history in the case's MS Word **Phone Contact Log**. If no call log exists, create one using instructions in the SOP titled **Using and Creating Participant MS Word Call Logs (Phone Contact Log)**.

PROCEDURES: MAKING THE CALL

When calling for permission to contact a sibling, we call the case or the case's parent/proxy/LAR (for minors, deceased survivors, adult survivors requiring legal guardians, or adult cases who were minor at the time of the baseline survey who have not been reconsented). We also call cases who are in tracing only due to a bad address or cases who are in Tracing and have possible numbers located by the Tracers.

1. Call the case or his/her appropriate representative:
   a. Call the case's highest ranking phone number first and proceed accordingly.
   b. NOTE: Light green cell fill in the **Sibling Cohort Recruitment Call Assignments** workbook indicates the case has a bad address Tracing Code (18 or 81). The phone numbers may still work.





c. Try all available documented numbers in:
   i. The blue case's record in the Expansion Tracking database (accessed either by choosing **Cases** on the main switchboard or by going to the green Case tab, then clicking on the **Open Sibling's Case** button) – Check the Quest tab, the Additional Contact Info tab, and the Reg tab.
   ii. The case's MS Word **Phone Contact Log** (*Z:\…\Interviewers\Expansion Survey Calls\Participant call logs*)
   iii. The St. Jude Life database and MILLI (if the CCSSID begins with "15")

2. If contact is made, verify the identity of the permitting party following standard identity verification procedures (i.e., date of birth confirmation).

3. Verify the contact information for the case or their parent/proxy/LAR. (Optional Step: Record the information on the **New Contact Data Form**. This will be used to update the database after call has ended). Recite it back to confirm the accuracy of the documented information. Verify or update:
   a. Mailing address
   b. All phone numbers
   c. Email address
   d. Additional contacts
   e. Parent information. Is the same parent information accurate for the sibling?

4. Using the **LTFU Expansion Cohort Sibling Permission and Recruitment Call Guidance** as script guidance, ask for permission to contact the sibling (or their parent/proxy/LAR) who:
   a. Is nearest in age, including deceased siblings, AND
   b. Has the same biological mother AND father as the case, AND
   c. Lived to be at least 5 years old. (If the nearest-in-age, full-blooded sibling did not live to be 5 years old, they may be ineligible. See a member of the LSI team for assistance.)

5. If the respondent indicates the nearest sibling had cancer, refer to **General Guidance on Discovering the Sibling Had or Has Cancer** (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Scripts*) for guidance on information to gather, and then continue with the permission call.

6. If permission is GRANTED:
   a. Complete the appropriate permission form (and **Expired Participant Information Sheet**, if applicable) with the case or their parent/proxy/LAR.
   b. Ask the case or their parent/proxy/LAR to contact the sibling or the sibling's parent/proxy/LAR and advise them to expect to receive information from the LTFU Study soon, by phone or in the mail.

7. If permission is DENIED:
   a. Ask if there is a reason. Be prepared to offer a hold or discuss barriers, if appropriate.
   b. Complete the appropriate permission form.

8. Thank the individual for accepting the call, for their past participation, and/or for granting permission.

PROCEDURES: AFTER THE CALL

General:

1. Record the call outcome in the **Sibling Cohort Recruitment Assignments** workbook. NOTE: If permission was gained, change the **Call Purpose** column from "Permission" to "Survey", update the name from the case's name to the sibling's name, and update the DOB from the case's DOB to the sibling's DOB.
2. Update the case's MS Word **Phone Contact Log**, prefacing the note in the **Comments** column with "SIB", "SIBLING", or an appropriate project identifier. See the SOP titled **Using and Creating Participant Call Logs (Phone Contact Log)** for guidance on updating this document.
3. Log the call in the green sibling record of the Expansion Tracking database using the **CALL Log** button at the bottom of any tab in the record.
4. If contact was made, see the section of this document titled *Updating the Expansion Tracking Database*, below, to update the appropriate content in the Expansion Tracking database.
5. If a permission appointment was set, update the Call Center calendar. See the SOP titled **Call Center Appointment Calendar** SOP for guidance.
6. If permission was gained:
    a. Update the Call Center Dry Erase Board (DEB).
    b. Email the closing monitor to include unscheduled permissions on the closing report.
    c. If a survey link email was requested, do not send the link until you have received confirmation that the DatStat upload for this permission has been completed. The Outlook calendar may be helpful in reminding the SI to send the link. See the SOP titled **Emailing LTFU Internet Links to Expanded Cohort Participants** for full details on this process.
7. File applicable forms properly:
    a. *Completed* permission forms should be filed in the hanging folder labeled "Completed Permission Forms - Siblings", located in the file cabinet by the Call Center printer.
    b. *Incomplete* permission forms (e.g. missing a sibling address, DOB, etc.) should be secured at the SI's desk until the necessary information is obtained. Subsequent calls to obtain the missing information will have a **Purpose** of "Sibling Permission" in the green database call log, regardless of the party called to obtain the information.
    b. File the **Expired Participant Information Sheet** in the hanging folder labeled "Refusals and Deceased", located in the file cabinet near the Call Center printer.
    a. The **New Contact Data Form**, if used, should be placed in the shredder.

Updating the Expansion Tracking Database:

1. Update the case's blue record:
    a. Any contact information for the case or the case's parents or associates that is confirmed or updated during a permission call should be entered in the blue case record. See the SOP titled **Expansion Baseline Survey Calls** for full details on how to update the blue case record, including **Tracing Status** and **Tracing Date**.
    b. To open the full case record to confirm data only, use the **Open Sibling's Case** button on the Case tab of the green sibling record. If you need to update the case's name, address, phone number(s), or email address(es), use the main switchboard's **Cases** option to access the case record. The **Archive Contact Info** button in the blue case Quest tab *does not work* when accessed through the **Open Sibling's Case** button in the green sibling record.

c. If the recorded address and/or all recorded phone numbers for the case and his/her contacts is/are found to be INCORRECT and no corrected contact information can be obtained, post the appropriate **Tracing Status** code and **Tracing Date** on the blue case record's Quest tab. See the SOP titled **Expansion Baseline Survey Calls** for full details on how to update the blue case record, including **Tracing Status** and **Tracing Date**.

2. Update the green Permission tab:
   a. If the permission effort remains unresolved, update the case's contact information in the green Permission tab.
      i. This tab has no archive feature, so any changes to the contact information should be "archived" by making a dated note with your SI ID in the **Comments** field.
      ii. If the cancer survivor/case is the contact information source, the appropriate source selection is "phone contact w/family" when working *in the green sibling record*. Only the case's sibling is referred to as "the sibling" for "phone contact w/sibling".
   b. In the Permission Tracking box, determine if the **Tracing Status** and **Tracing Date** fields need to be updated. See below.
      TRACING ***Note on proper use of tracing codes***:
      - Tracing status 18 means the address is invalid.
      - Tracing status 19 means all available phone numbers are invalid.
      - Tracing status 13 means both the address AND all available phone numbers are invalid.
      - Tracing status 81 (on the case record) means the address is invalid, and information came from a newsletter returned to sender. This code (81) does not exist for the Sibling **Permission** situation.

Current tracing Status	Outcome of effort	Change Tracing Status TO
13	Now have at least one good phone number, but address is still bad	18
13	Have a good address, but none of the phone numbers are good	82 (resend), update case record to 19
19	All phone numbers are still bad, and now the address is also bad	13
19	Have a good phone number (and address is still good)	Clear Tracing Status
18	Address is still bad, and now the phone numbers are also bad	13
18	Have a good address (and at least one phone is still good)	82
Blank	None of phone numbers are good; address still appears good	19
Blank	At least one phone number is good but address is bad	18
Blank	All phone numbers AND the address are bad	13
Blank	Resend requested	82

      i. If the case asked us to resend the permission packet, update the **Tracing Status** field to "82-Resend Permission" and the **Tracing Date** field to the current date to request the resend. Make a dated note in the **Comments** field.
      NOTE: We MUST have a valid mailing address on the Permission tab to resend the permission packet.
      NOTE: Do NOT use tracing code "82-Resend Permission" with an **Outcome** code indicating a hold.
      ii. If all numbers for the case and his/her associates are found to be bad, put the permission effort in Tracing for phone numbers:
         1. Check the **Tracing Status** field. If it is currently blank, update the **Tracing Status** field to "19-Disconnect/Wrong Num". If it is currently set to "18-Undeliverable", update the **Tracing Status** field to "13-Tracing".
         2. Update the **Tracing Date** field to the current date.

3. Make a dated note in the **Comments** field.
4. Remember that the blue case record also needs to be put in Tracing.

iii. If it is determined during a permission call that the documented address for the case is incorrect and no corrected address information can be obtained, put the permission effort in Tracing for an address:
   1. Check the **Tracing Status** field. If it is currently blank, update the **Tracing Status** field to "18-Undeliverable". If it is currently set to "19-Disconnect/Wrong Num", update the **Tracing Status** field to "13-Tracing".
   2. Update the **Tracing Date** field to the current date.
   3. Make a dated note in the **Comments** field.
   4. Remember that the blue case record also needs to be put in Tracing.

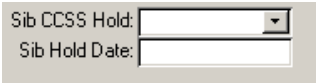
iv. If the permission effort was already in tracing for phone numbers (**Tracing Status** = "19-Disconnect/Wrong Num"), address (**Tracing Status** = "18-Undeliverable"), or both (**Tracing Status** = "13-Tracing"), and updated contact information is gained:
   1. If only needed contact phone numbers for the case (or his/her legal representative) are gained:
      a. And the permission effort is resolved, clear the **Tracing Status** and **Tracing Date** fields in the Permission Tracking box. Make a note in the **Comments** field regarding the change. Determine if the blue case record's Tracing fields should be updated.
      b. But the permission effort is not resolved: if **Tracing Status** = "13-Tracing", update **Tracing Status** to be "18-Undeliverable" and **Tracing Date** to the current date. Make a note in the **Comments** field about the change. Determine if the blue case record's Tracing fields should be updated.
      c. But the permission effort is not resolved: if **Tracing Status** = "19-Disconnect/Wrong Num", update **Tracing Status** and **Tracing Date** to be blank. Make a note in the **Comments** field about the change. Determine if the blue record's Tracing fields should be updated.
   2. If only the needed address for the case (or his/her representative) is gained:
      a. And the permission effort is resolved, clear the **Tracing Status** and **Tracing Date** fields in the Permission Tracking box. Make a note in the **Comments** field regarding the change. Determine if the blue case record's Tracing fields should be updated.
      b. But the permission effort is not resolved: if **Tracing Status** = "13-Tracing", update **Tracing Status** to be "82-Resend Permission" and **Tracing Date** to be the current Date. Make a note in the **Comments** field about the change. In the blue case record update the **Tracing Status** to be "19-Disconnect" and the **Tracing Date** to be the current date. Make a note in the **Comments** field about the change.
      c. But the permission effort is not resolved: if **Tracing Status** = "18-Undeliverable", update **Tracing Status** to be "82-Resend Permission" and **Tracing Date** to be the current Date. Make a note in the **Comments** field about the change. Determine if the blue case record's Tracing fields should be updated.
   3. If both the needed address and phone numbers for the case (or his/her representative) are gained:
      a. And the permission effort is resolved, clear the **Tracing Status** and **Tracing Date** fields in the Permission Tracking box. Make a note in the **Comments** field regarding the change. Determine if the blue case record's Tracing fields should be updated.

b. And the permission effort is not resolved: update **Tracing Status** to be "82-Resend Permission" and **Tracing Date** to be the current Date. Make a note in the **Comments** field about the change. Determine if the blue case record's Tracing status should be updated.

c. Record following information in the Permission Tracking box to reflect permission outcomes:

Call Outcome	Database fields to populate for each outcome. NOTE: If a field is not listed in this table, leave it BLANK.
Permission was GRANTED	• **PERMISSION Dt**: the current date • **Interviewer ID**: your SI ID • **Permitting Entity**: Select the drop-down option that best identifies the person who gave the permission. • **Source**: Verbal • **Outcome**: 1-Received • **Outcome Dt**: the permission call date • **Date Sent**: IF this field is blank, enter the permission call date. • CLEAR any values in **Tracing Status** and **Tracing Date**.
Permission was DENIED	• **Interviewer ID**: your SI ID • **Source**: Verbal • **Outcome code**: 2-Denied • **Outcome Dt**: the current date • **Denied Reason**: Select the drop-down option that best identifies the denial reason. Do not leave this field blank. • **Permission Denied Explanation:** Type a detailed explanation of the denial reason. Specify the name and relationship of the person denying permission. • CLEAR any values in **Tracing Status** and **Tracing Date**.
Permission was placed ON HOLD	• **Interviewer ID**: your SI ID • **Outcome Code:** 3, 4, or 5, as appropriate for the time of the requested hold • **Outcome Dt: the** current date • **Comments:** Document why the permission effort was placed on hold, who requested it, why it was requested, and how long the hold will be. **NOTE:** Be sure we have valid contact information to use once the hold expires. Do NOT use a Resend code if a permission hold is applied.
Sib in Jail – *Refer to a LSI for final determination on using this code. A hold may be more appropriate*.	• **Interviewer ID**: your SI ID • **Outcome Code:** 6-Sib In Jail • **Outcome Dt: the** current date • **Comments:** Document the known circumstances. NOTE: If there is an expected release date, it may be advisable to put the permission effort on hold instead of using this outcome code. Confer with a LSI for a final determination.
If information gained during the permission call leads you to believe that the case or sibling is INELIGIBLE (e.g. you learn that the sibling did not live to be five years of age or lives permanently outside of the US and Canada), report this to the LSI for a determination by making an entry in the *Call Outcomes Log*. Thoroughly document the circumstances in the **Comments** field and all call notes. *DO NOT* post outcome code 10-Ineligible (or anything else) in the Permission Tracking **Outcome** field. This will be done by the LSI.	

3. ONLY IF permission was GAINED, enter the sibling's information in the green sibling record:
   *Important Note: The following sibling information needs to be entered in the database **in a specific order** to successfully update the print tables (which impacts both the print and online versions of the survey).*
   a. Click the **Edit Header** button. Record sibling's legal **First Name, Last Name, Date of Birth**, **gender** (if known), and **Spanish Status**. (We are not currently entering data into the **Race** field, and the **SIBINITIALS** field is optional.) Click the **SAVE and CLOSE** button.
   NOTE: If the sibling's name, DOB, or gender is modified in the green sibling header AFTER the original permission entry, please notify the LSI team. It is important that the LSI team notify the 5th floor team that changes have been made.
   b. Record the *sibling's* contact information on the Sib Info tab:
      i. Select appropriate option for the **Send Q-aire To** field based on the sibling's vital status, current age, and any information we have about their independence.
      ii. Record the sibling's contact information (name, address, phone numbers, email addresses) and the address/phone/email **date** and **source**. The **Sibling Name** field should be recorded as Firstname Lastname unless:
         1. The sibling goes by his/her middle name. Then the field should be recorded as F. Middlename Lastname. (*Example: C. Renée Massey*)
         2. The sibling goes by his/her first and middle name. Then the field should be recorded as Firstname Middlename Lastname. (*Example: Billy Bob Thornton*)
         3. The sibling goes by a name that is not part of his/her legal name. Then the field should be recorded as Preferredname Lastname. (*Example: Douglas Ryan Winfield goes by "Dirk". Record the **Sibling Name** field as "Dirk Winfield" while the **First Name** field in the header will still be recorded as "Douglas".*)
      iii. Use "Phone Contact w/ Family" as the data source when information as confirmed by the case or another family member. Remember that unless the information was actually confirmed by the case's sibling, "phone contact w/sibling" is not appropriate.
      iv. When using the **Care of** field, begin the data with "C/O" in front of the name. See the SOP titled **Use of "Care of" Field** for details.
      v. For any appropriate notes, enter a dated message with your SI ID in the **Comments** field.
      vi. Move to a new field, and click the **Save** icon on the Access ribbon (Home tab).
      vii. IMPORTANT: Click the **Update Sibling Print Table** button on the Sib Info tab.
   c. If the permitting entity granted permission to contact the sibling but asked us to WAIT before making the contact, we can put the *sibling* on CCSS Hold. On the Sib Info tab:
      i. Select the appropriate hold period in the **Sib CCSS Hold** field.
      ii. Enter the current date in the **Sib Hold Date** field.
      iii. Provide additional explanation by entering a dated note with your SI ID in the **Comments** field.



4. Record the sibling parent information:
   a. Add any confirmed sibling parent information to the green Sib Reg tab. Enter the appropriate source.
   b. The **OK to Contact FATHER** or **OK to Contact MOTHER** fields on the green Sib Reg tab document whether or not the *sibling participant* has authorized his/her parent as the Additional Contact. Do not mark these fields as "1-Yes" unless the parent has been authorized as the Additional Contact by the sibling participant. NOTE: This will be an exceptional circumstance during the

permission process. It may happen if, for example, the case and the sibling are together at the time of permission and the SI is able to speak to both in the same call.

5. If the sibling is expired:
   a. Annotate the expired status with a dated note in the **Comments** field on the Permission tab and the **Comments** field of the Sib Info tab. Include your SI ID.
   b. Add a request in the **Call Outcomes Log** to update the vital status for the sibling.

Revision Record Printed 1/7/2014 9:08 AM

[245] Current Filename:		Expansion Sibling Cohort Permission Calls ver 2_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	4/25/2013	C. Lee, A. Oyuela, P. Ludwig, D. Rinehart, D. Bowen, B. Carson, R. Massey	Initial Development
1.2	5/20/2013	R. Massey, D. Rinehart	Content revision
1.3	5/21/2013	J.Bates, D. Rinehart, R. Massey	Content revision
1.4	5/22/2013	J.Bates, D. Rinehart, R. Massey	Content revision
1.5	5/23/15	J.Bates	Reorganize flow
1.6	6/4/13	R. Massey	Content Revision
1.7	6/12/13	J.Bates, L.Harrison, J.Ford	Reorganization
2.0	1/6/14	R. Massey	Format revision, content revision

Expansion Sibling Cohort Survey Calls

Background

After a survivor participant (or his/her legal representative) has given the LTFU Study permission to contact the nearest-in-age full-blood sibling, we provide information to the sibling about participating in the LTFU Study. The sibling is asked to complete a sibling baseline questionnaire. The sibling may complete the questionnaire via a paper format, online, or by telephone with a Survey Interviewer. Spanish-speaking sibling participants and representatives for deceased sibling participants only have the option to complete the survey by phone with an interviewer. We make follow-up phone calls to non-responders beginning approximately 3-weeks after the date the survey is mailed.

If the eligible sibling participant is a minor, the parents or legally authorized representative (LAR) are contacted to complete the informed consent and survey. If the minor participant turns 18 before the consent and sibling survey are completed with the parents/LAR and if the sibling can represent himself (i.e., is not cognitively impaired), then we contact the now-adult sibling participant to obtain the informed consent and adult sibling survey.

Procedures

Tools you will need:

1. **Sibling Cohort Recruitment Call Assignments** workbook
2. Expansion Tracking database
3. MS Word **Phone Contact Logs**
4. **Call Outcomes Log**
5. **New Contact Data Form** (optional)
6. **Expired Participant Information Sheet**
7. Survey stage support materials:
    a. **Informed Consent Expansion Sibling** form
    b. The Survey Date Range table
    c. Sibling-Baseline Expansion Adult Survey for SI
    d. Sibling-Baseline Expansion Minor for SI
    e. Sibling-Baseline Expansion Expired for SI

PRE-CALL PROCEDURES

1. Open the **Sibling Cohort Recruitment Call Assignments** workbook, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Call Assignments*
2. Select the appropriate SIBID, ensuring that the **Call Purpose** column is populated with Survey for the participant in question.
3. Open the Expansion Tracking database, and select “Siblings” from the main switchboard.
4. Locate the sibling record in question using the Find feature in Access.
5. Build a profile of the sibling by reviewing all appropriate fields in the database and by reviewing any previous call history. See **Pre-Post Checklist - Sibling Survey Calls**, located in the SOP library, for details.
6. Be prepared to complete the Expansion sibling baseline survey:
    a. Have ready a blank copy of the **Informed Consent Expansion Sibling**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Letters and Forms*.
    b. Review the Survey Date Range table.

c. Have a blank paper copy of the appropriate paper survey ready in case of technical issues with the online survey.

DURING THE CALL PROCEDURES: General

1. Use the appropriate script(s) during the call. See **Sibling Baseline Questionnaire** scripts located here: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Scripts*
2. Verify the names of the parents with the sibling and obtain contact information. Ask if we may use either or both parents as additional contacts.
3. If the sibling participant does not want to complete the baseline survey (=REFUSAL to participate in LTFU):
    a. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so.
    b. Ensure he/she understands that choosing not to complete the baseline survey means refusing all further participation in the study. Offer a hold if this is more appropriate.
4. If the sibling participant states he has completed and returned the survey, ask the participant for the approximate date of return. If the date is within the last month, thank him for participating in the study, and end the call. If the return date is greater than one month ago, the survey may be lost in the mail. Suggest a telephone survey to eliminate the opportunity for lost mail.
5. If we find that a LTFU Study sibling participant is now deceased:
    a. Complete the **Expired Participant Information Sheet** with as much information as the person you are speaking with is able to supply.
    b. If appropriate and the proxy is willing to complete the survey, proceed to the steps outlined in the section of this document titled *DURING THE CALL PROCEDURES: Completing the Survey Over the Phone* or schedule an appointment to complete the telephone survey at a later time.
    c. Remember that expired sibling expansion baseline surveys must be completed with a Survey Interviewer over the telephone. Paper and online versions are not available.
6. When we find a LTFU Study sibling participant prefers to do the expansion baseline survey in Spanish:
    a. Refer the sibling to a Spanish-speaking interviewer. If possible, try to secure an appointment with the sibling participant at a time when a Spanish-speaking interviewer is available. See Call Center work schedule located here: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Work schedules*.
    b. Remember that Spanish sibling expansion baseline surveys must be completed with a Survey Interviewer over the telephone. Paper and online versions are not available.
7. If the sibling participant wants to complete the survey over the phone, proceed to the section of this document titled *DURING THE CALL PROCEDURES: Completing the Survey Over the Phone*.

DURING THE CALL PROCEDURES: Completing the Survey Over the Phone

Click the link to the appropriate survey. There are three versions of the survey: Adult (sibling participants 18 and older), Minor (sibling participants younger than 18) and Expired (deceased sibling participants). Use the links below and/or add the shortcuts to your Windows Desktop or Internet Explorer Favorites list for ease and speed:

- MINOR: https://live.datstathost.com/stjude-Collector/Survey.ashx?Name=CCSS_Expansion_Baseline_Minor_Sibling
- ADULT: https://live.datstathost.com/stjude-Collector/Survey.ashx?Name=CCSS_Expansion_Baseline_Sibling
- EXPIRED: https://live.datstathost.com/stjude-Collector/Survey.ashx?Name=DECEASED_CCSS_Expansion_Baseline_Sibling

1. On the login page for the appropriate survey, enter the sibling participant's password (confirmation number) and date of birth into the survey form.
    a. The password is displayed in the sibling record's header in the **PW** field. Copy the password from the database and paste it into the survey login page to ensure accuracy.

b. If the sibling participant's DOB has ever been changed, you may have to use the ORIGINALLY RECORDED DOB to login, even if that DOB was incorrect. This should be documented in the **Comments** field of the Sib Info tab in the sibling participant's record.
c. If the sibling survey was previously started by either the sibling participant or a SI, you will get options to "Start Over" or "Restore" the survey after logging on. In general, you should click Restore to pick-up where the survey was left off. You can always review prior answers by using the "back" button after Restoring.

2. Before starting the sibling survey, read the **Informed Consent Expansion Sibling** to the sibling participant.
3. Document answers to the two questions on the last page of the printed **Informed Consent Expansion Sibling** form.
4. Determine if a copy of the informed consent should be sent to the participant, as described in the SOP **Requesting Participant Copies of Informed Consent**.
5. Read the opening statement on the first page of the online sibling survey. You must also document the consent in the online survey form.
6. If the sibling participant consents to join the study, then proceed with the sibling survey. Read the questions and answers exactly as they appear.
7. ADDITIONAL NOTES REGARDING DECEASED SIBLING PARTICIPANTS:
   a. When completing the sibling survey with a proxy for the deceased sibling participant, fill out an **Expired Participant Information Sheet**. (Find this document in *Z:\SJShare\SJCOMMON\ECC \Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Letters and Forms*.)
   b. Find out if the family member would like to receive the LTFU newsletters. (They will not receive them automatically). If they indicate an interest, note this on the **Expired Participant Information Sheet** (described above) by checking the appropriate box at the top of the form.

AFTER THE CALL PROCEDURES: General

Based on the call outcome, follow the appropriate call outcome procedure below.

1. Record the call outcome in the **Sibling Cohort Recruitment Call Assignments** workbook.
2. Update the sibling Call Log in the green sibling record of the Expansion Tracking database.
3. For information that has been confirmed on the telephone with a live person (e.g. participant, LAR, or family member), update the green sibling record as outlined in the section of this document titled *AFTER THE CALL PROCEDURES: Updating Sibling Database*.
   NOTE: ***NEVER*** update the database with unconfirmed information.
4. For completed surveys, proceed to the section of this document titled *AFTER THE CALL PROCEDURES: Completed Surveys*.
5. For partial surveys, proceed to the section of this document titled *AFTER THE CALL PROCEDURES: Partial Surveys*.
6. For all other outcomes, proceed to the section of this document titled *AFTER THE CALL PROCEDURES: All Other Outcomes*.

AFTER THE CALL PROCEDURES: Updating Sibling Database

1. If there is a change needed for **Date of Birth**, **Gender**, or **Spanish Status:**
   a. Use the **Edit Header** button to open the header form. Make the needed changes, then save and close the form.
   b. Add a dated note with your SI ID to the **Comments** field fully explaining the change made.
   c. If you have changed the **Date of Birth** or **Gender**, notify the LSI team of what has been changed and why. The LSIs will notify the 5th floor team.

2. Special Note Regarding Former St. Jude Patients (institution 15): If the sibling participant advised you of a change in the survivor/case's contact information (for cases whose CCSSID # begins with 15), send screen shots highlighting the changes made to the CRAII in charge of St. Jude Life Recruitment.

3. Choose the appropriate option from the drop-down list for the **Send Q-aire To** field on the Sib Info tab.

IMPORTANT: If updating *any* information (name, address, phone, email) on the Sib Info tab, click on the **Archive Information** button ***first***. Then, and only then, proceed to make the updates on the Sib Info tab.

4. Sibling Name (located on the Sib Info tab and in the Header) - If the participant has had a change in name:
    a. Click the **Archive Information** button.
    b. Click the **Edit Header** button, update the name fields, the save and close the form.
        i. Do not record preferred names in the header.
        ii. For name changes due to marriage, put parentheses around the maiden name, enter a space, and then type the married name in the **Last Name** field.
        Example: "(Jones) Smith" where Jones is the maiden name and Smith is the married name.
        iii. For name changes due to divorce, do not keep the married name in the **Last Name** field. *Example: The **Last Name** field will change from "(Jones) Smith" to "Jones" if the participant divorces Mr. Smith.*
        iv. For name changes due to adoption, we do not keep the birth surname in the **Last Name** field. *Example: The **Last Name** field will change from "Johnson" to "Simpson" if the participant's birth surname is Johnson but he or she is adopted by the Simpson family.*
    c. Update the **Sibling Name** field in the body of the Sib Info tab.
        i. We ***do not*** keep the maiden name in the **Sibling Name** field when the sibling marries. *Example: When Mary Jones marries Dedrick Smith, the **Sibling Name** field is updated to "Mary Smith".*
        ii. The standard format for the **Sibling Name** field is Firstname Lastname. If the participant goes by his or her middle name, the format is F. Middlename Lastname. If the participant goes by his or her full name (e.g. Billy Bob Thornton), type the full name. Preferred names can be indicated in the **Sibling Name** field (i.e. Preferredname Lastname).
    d. Add a dated note with your SI ID to the **Comments** field fully explaining name change and/or any preferred name.
    e. Save changes: Either (1) go to a new field, then click the **Save** button in the Access ribbon, OR (2) navigate to next record in database and then move back to record you updated.
    f. Click on the **Update Sibling Print Table** button.
    g. Notify the LSI team what has been changed and why. The LSIs will notify the 5th floor team.

5. Sibling Participant Mailing Address (located on the Sib Info tab):
    a. If the existing data has been confirmed (i.e. there is no NEW information to enter):
        i. Update the **Addr Date** field with the date it was confirmed and update the **Addr Source** field with appropriate source.
        ii. Click on the **Update Sibling Print Table** button.

b. If there is new address information:
   i. Click the **Archive Information** button.
   ii. Enter the new address. If the **Sibling Name** field is in all CAPS, the rest of address should also be in all CAPS. See the **Use of Care of Field** SOP for instructions on using this field.
   iii. Update the **Addr Date** field with the date it was confirmed and update the **Addr Source** field with appropriate source.
   iv. Save the changes: Either (1) go to a new field, then click the **Save** button in the Access ribbon, OR (2) move to next record in database and then move back to record you updated. Omitting this step causes the Update Print Tables operation to fail.
   v. Click on the **Update Sibling Print Table** button.

6. Sibling Participant Telephone Numbers (located on Sib Info tab):
   a. If an existing telephone number has been confirmed:
      i. Update the phone **Date** field with the date it was confirmed, and update the phone **Source** field with the appropriate source.
      ii. Update the phone **Rank** fields, if necessary. See below for information about ranking telephone numbers.
   b. If there is a new sibling participant telephone number to enter:
      i. Enter the new number in the top-most empty row. Populate the phone **Rank** field, the **PhoneNumber** field, the **Type** field, the phone **Date** field with the date the number was confirmed, and the phone **Source** field.
      ii. If all phone slots are taken and you need to enter a new number, see the SOP **Handling Additional Phone Numbers**.
   c. Rank telephone numbers according to your best judgment using the drop-down menu in the appropriate phone **Rank** field.
      i. Rank 9 is used for disconnected numbers.
      ii. Rank 37 is used for numbers that should NOT be called again. If a number is ranked "37", add a note in the **Comments** field explaining why the rank was used.
         1. Format the note with a leading double-asterisk, the date, THE MESSAGE IN ALL-CAPS, [your SI ID].
         2. *Example: **5/7/2014: DO NOT CALL 901-321-1231. SIBLING'S FATHER REQUESTED NO FURTHER CALLS. [158]*

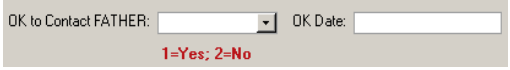
7. Sibling Participant Email Address (located on the Sib Info tab): Follow the same protocol used for updating sibling participant telephone numbers including the **Email #, Rank**, **Email**, email **Date**, and **Source** fields.

8. Sibling Parent Names (located on the Sib Reg tab) should be recorded as the legal name, when known. If the parent has a preferred name that is known to be different than the legal name, record the preferred name in quotes after the legal name in the **Father first name** or **Mother first name** field. Add a dated note in the **Parent Comments** field explaining the preferred name.

9. Sibling Parent Mailing Address (located on the Sib Reg tab):
    a. If updating any information on the Sib Reg tab where data would otherwise be lost:
        i. Since there is no archiving feature available, make a dated note in the **Parent Comments** field of the Sib Reg tab documenting the data being removed, the source of the change, and your SI ID.
        Example: 11/17/2013: Sibling provided new address for mother, Lucy Liu. Updated address from 1111 Main St, Anytown, NM 11111, to 2323 Union St, Anytown, TN 89111. [152]
        ii. Once the outdated information has been documented per the previous example, update the appropriate parent address fields in the Sib Reg tab. Move to a new field; click Save.
        iii. Click the **Refresh ZipCode Time Zones** button to update the data.
    b. Go to the Case tab, then click the **Open Sibling's Case** button.
        i. If the sibling parent names match the case parent names, update the parent address(es) for the parents on the Reg tab in the blue case record. (For detailed instructions, see the SOP titled **Expansion Baseline Survey Calls**.)
        ii. If the sibling parent names do not match the case parent names, do not update the parent address(es) on the Reg tab of the blue case record.

10. Parent Telephone Numbers (located on the Sib Reg tab):
    a. If an existing parent telephone number located on Sib Reg tab is confirmed, update the corresponding **PhoneDate** and **Phone Source** fields.
    b. If a new parent telephone number is gathered:
        i. Add the new number to top-most empty slot for the parent in the Sib Reg tab.
        ii. Populate the corresponding **PhoneDate** and **Phone Source** fields.
        iii. If all phone slots are taken and you need to enter a new number, see the SOP **Handling Additional Phone Numbers**. See a member of the LSI team if you need assistance.
    c. For disconnected numbers, add a dated note with your SI ID in the **Parent Comments** field of the Sib Reg tab documenting the disconnected number.
    d. If a number is a wrong or "Do Not Call" number, add a note to the **Parent Comments** field of the Sib Reg tab using the note format described in the section of this document, above, for Sibling Participant Telephone Numbers that should not be called again (rank 37).
    e. Click the **Open Sibling's Case** button on the Case tab.
        i. If the sibling parent names match the case parent names, update the applicable phone numbers, dates, and sources for the parents on the Reg tab in the blue case record. For detailed instructions, see the SOP **Expansion Baseline Survey Calls**.
        ii. If the sibling parent names do not match the case parent names, do not update the parent phone information on the Reg tab of the blue case record.

11. Additional Contact Information: (Sib AddlContact Info tab, *unless* contact is a parent)
    a. If the sibling participant specifically asks to use either parent as their additional contact, update the Sib Reg tab ***instead of*** the Sib AddlContact tab, as follows:
        i. Verify and update, if appropriate, the parent contact information on the Sib Reg tab using the instructions for parent address/phone information, above.
        ii. Update the **OK to Contact FATHER** and/or **OK to Contact MOTHER** field to 1-Yes and enter the authorization date in the **OK Date** field.



    b. Sib AddlContact tab (*Do NOT use for parents.)*:

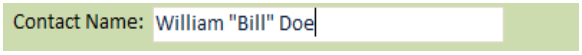
i. NOTE: If the additional contact is the case/survivor, also update the blue case record with any contact information provided and/or confirmed. Access the blue case record by choosing Cases at the main switchboard rather than through the **Open Sibling's Case** button on the Case tab. The **Archive Contact Info** button in the blue case record *will not work* if accessed through the **Open Sibling's Case** button.

ii. If the (non-parent) additional contact person and additional contact information have not changed, update the date in **Last Updated On** field of the appropriate record in Sib AddlContact tab.

iii. If the contact person is the same but has new contact information:

1. Document the outdated contact information by adding a dated note with your SI ID in the **Additional Contact Comments** field of the Sib AddlContact tab. *Example: 6/21/2014: Updated address for additional contact, Jada P. Smith, from 123 4th Street, Anytown, TN, 38123 to 234 5th Avenue, Anytown, TN 38234 and ph# from 901-234-5678 to 901-345-6789. [81]*
2. Enter the new contact information in appropriate record of the Sib AddlContact tab and update date in **Last Updated On** field.

iv. If the contact person is different, create a new contact entry in the Sib AddlContact tab without deleting the old one. If the additional contact has a preferred name that is known to be different than the legal name, record the preferred name in quotes after the legal name in the **Contact Name** field. Add a note in the **Additional Contact Comments** field explaining the preferred name.



12. Death Status:
    a. Log the change in vital status in the **Call Outcomes Log**.
    b. File the **Expired Participant Information Sheet** completed during the call in the appropriate folder of the short file cabinet.
    c. The Lead SI will be responsible for entering the death status on the Death Data Form.

13. Adding Sibling Participant To Tracing:
    a. If all available *phone numbers* in the database are disconnected and/or wrong, enter the appropriate tracing code:
        i. If the **Tracing Status** field on the Sib Info tab is blank, select 19 from the drop-down list. If this field is already populated with 18, select 13 from the list.
        ii. Enter the current date in the **Tracing Date** field.
        iii. Enter a dated note in the **Comments** field documenting the change.
    b. If we are notified that the *mailing address* is incorrect, enter the appropriate tracing code:
        i. If **Tracing Status** field on the Sib Info tab is blank, select 18 from the drop-down list. If this field is already populated with 19, select 13 from the list.
        ii. Enter the current date in the **Tracing Date** field.
        iii. Enter a dated note in the **Comments** field documenting the change.
    c. For all other Tracing questions, refer to the **Outcome and Tracing Code Guidelines** SOP or consult with a LSI or the Call Center Coordinator.

14. Sibling Participant Stated Survey Previously Returned - Make an appointment in your Outlook calendar to follow up in 4 weeks. Surveys returned via mail should be received within 4 weeks of the date mailed.

15. Participant Prefers or Requires Spanish-Speaking Representative – If a non-Spanish-speaking SI encounters a sibling participant who prefers or requires a Spanish-speaking interviewer, the SI should email the Coordinator (copying the LSI team) to reassign the case, then update the **Spanish Status** field in the header using the **Edit Header** button to:
    a. "1" if sibling participant speaks only Spanish OR
    b. "2" if sibling participant speaks both English and Spanish OR
    c. "3" if sibling participant speaks both English and Spanish but prefers Spanish.

16. Appointment Made
    a. Write the appointment on the Call Center appointment calendar. See the SOP titled **Call Center Appointment Calendar** for details.
    b. If YOU will be covering the appointment, add the appointment to your Outlook calendar.
    c. If the appointment needs to be assigned to another interviewer, send an email to the LSI team (cc the Coordinator) for assignment. If there is no time to follow the above procedure (i.e. scheduled for the same day and the LSIs and Coordinator are not in):
        i. Coordinate with another interviewer to handle the scheduled survey.
        ii. Put the information about the appointment on the Call Center appointment calendar.
        iii. Send an email to the LSI team (cc the Coordinator and the covering Survey Interviewer) with details about the appointment and who will cover it.
    d. If the sibling participant gave us a valid email address and approved sending an email reminder for the survey appointment, follow the instructions for emailing the appointment reminder. See the SOP titled **Email Appointment Reminders for Baseline Surveys**.

17. Sibling Participant Requests A Resend Of The Paper Survey
    a. IMPORTANT: Remember that deceased and Spanish surveys must be done with a Survey Interviewer over the telephone. Do NOT request a survey resend to a deceased sibling's proxy or to a Spanish-speaking sibling participant.
    b. Update the **Tracing Status** field on the Sib Info tab to code 82 using the drop-down menu.
    c. Update the **Tracing Date** field on the Sib Info tab with the current date.
    d. Enter a dated note in the **Comments** field explaining the change.

18. Sibling Participant Requests Email Link To Complete Sibling Survey Online
    a. IMPORTANT: Remember that deceased and Spanish surveys must be done with a Survey Interviewer over the telephone. Do NOT send the survey link to a deceased sibling's proxy or to a Spanish-speaking sibling participant.
    b. Follow the procedure to send the appropriate email. (See email templates in *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Email Templates, Expansion Sibling Recruitment* and SOP titled **Emailing LTFU Internet Links to Expanded Cohort Participants**.).
    c. After sending the email, document the send in the sibling database:
        i. On the Sib Baseline tab, check the appropriate **Sent Email#** box, and enter the **Email# Date** as the date the email was sent. (If all 3 fields are already used, skip this step.)
        ii. Enter a brief note in the **Tracking Comments** field (even if all 3 fields were used).
        Example: "1/1/2011: emailed survey link to onecutegirl@email.com, as requested by pt [123]"
        iii. Copy the **Tracking Comments** note to the **Comments** field of the Sib Info tab.

19. Sibling Participant Does Not Want To Complete Survey (=REFUSAL to Participate in the LTFU Study)
    a. Update the **Call Outcomes Log** noting the refusal.
    b. Update the green sibling record in the Expansion Tracking database with the refusal:
        i. On the Sib Info tab, enter a dated note with your SI ID in the **Comments** field documenting the refusal.
        ii. Copy this note to the **Tracking Comments** field of the Sib Baseline tab.
        iii. Also on the Sib Baseline tab, code the **Baseline Outcome** field as 7 and enter or update the **Baseline Outcome Date** field to the date the information is being entered.
        iv. On the Sib Reg tab, code the **Sibling Outcome** field to 37, and enter or update the **Sibling Outcome Date** field to the date the information is entered.

20. Sibling Participant Requests To Be On Hold
    a. On the Sib Info tab, update the **Sib CCSS Hold** field with the appropriate value using the drop-down menu, and update the **Sib Hold Date** field with the current date.
    NOTE: As with all special outcomes, the "calls" hold, a hold for outgoing calls but not mailings, should be authorized by a member of the LSI team or by the Coordinator. This hold will be assigned on a case-by-case basis only.
    b. Enter a dated note in the **Comments** field of the Sib Info tab with your SI ID.
    Example: "1/22/2013: Due to father's illness, sibling pt requests a six-month hold. [111]"
    c. Do NOT put the participant on your Outlook calendar to be called back when the hold expires. A LSI will assign the participant to a Survey Interviewer upon expiration of the hold.

21. Participant Is Believed To Be Ineligible – Make an entry in the **Call Outcomes Log** explaining why the participant is believed to be ineligible. A LSI will address this with the Call Center Coordinator for an eligibility determination.

AFTER THE CALL PROCEDURES: Completed Surveys

1. After thanking the sibling participant and ending the call, go back through each page of the online survey. This must be done using the Previous and Next buttons on the survey form; NEVER use the back/forward arrows from your internet browser.
2. Complete any information that was not entered during the interview, and check for missing information or any fields mistakenly left blank.
3. AFTER the sibling survey information is checked for accuracy and completion and AFTER the sibling database has been updated (See step 3 in the section of this document titled *AFTER THE CALL PROCEDURES: General*.), click the **Submit** button on the last page of the survey. Be sure to click Yes at the next prompt.
4. For a completed *scheduled* sibling survey, place a check mark on the Call Center appointment calendar to indicate the kept appointment.
5. Note the completed sibling survey on the Call Center dry erase board (DEB).
6. If the participant needs a copy of the informed consent, update the **Informed Consent Copy Request Log**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls*, as described in the SOP **Requesting Participant Copies of Informed Consent**.
7. Ensure **Informed Consent Expansion Sibling** form is completely filled out with your Survey Interviewer ID number, the date the consent was obtained, the sibling participant's SIBID number, and the answers to the two questions.

8. Place the **Informed Consent Expansion Sibling** form in the hanging file labeled "Sibling Consent - Completed Surveys" in the short file cabinet.
9. Email the closing monitor to include any *unscheduled* sibling survey in the closing report.
10. Deceased Sibling Participants - If the sibling survey was completed with the proxy for a deceased sibling participant:
    a. Complete all online and database entry, as instructed above. Ensure your call notes include the first and last name of the proxy as well as the proxy's relationship to the deceased sibling.
    b. Place **Expired Participant Information Sheet** in the "Sibling Consent - Completed Surveys" file folder along with the **Informed Consent Expansion Sibling** form.
11. Spanish Surveys - If the sibling survey was completed over the phone in Spanish:
    a. Complete all online and database data entry, as instructed above.
    b. Send an email to the Lead CRAs (cc: the LSI team and Call Center Coordinator) that a *sibling* survey has been completed in Spanish and include the SIBID in the Subject line and body of the email.
    c. Produce a personalized thank-you card insert in Spanish to the sibling participant, per the **Sending Spanish Thank You Notes** SOP.
    d. Update the sibling database Call Log and the **Call Outcomes Log** indicating that the survey was completed in Spanish.
    e. Deliver the thank-you card insert to the lead CRAs. (If neither is available, give the insert to either a LSI or to the Coordinator for delivery when the CRAs are available.)

AFTER THE CALL PROCEDURES: Partial Surveys (Consented But Did NOT Complete Survey)

1. Follow all steps outlined in the **Partially Completed Survey Tracking Log** SOP.
2. On the Sib Info tab, enter a dated note with your SI ID in **Comments** field.
   Example: "12/9/2013: gathered informed consent, completed partial survey with pt [110]"
3. Update the **Call Outcomes Log** noting a partially completed survey.
4. File completed **Informed Consent Expansion Sibling** form in the "Partially Completed Surveys" file folder (located in top drawer of the file cabinet).
5. Email the Closing Monitor to include an *unscheduled* partial sibling survey in the Closing Report.
6. Update the dry erase board (DEB) tally to indicate the partial sibling survey.
7. Log time spent on the partial sibling survey in your **Journal**. (See the SOP **Survey Interviewer Journal Data Entry**.)
8. Proofread all data entry to be sure all information has been properly documented. (See the **Pre-Post Checklist - Sibling Survey Calls**, located in the SOP library.)
9.

AFTER THE CALL PROCEDURES: ALL OTHER OUTCOMES

Consult with a LSI or the Call Center Coordinator for assistance.

Revision Record Printed 4/28/2014 9:21 AM

[241] Current Filename:		Expansion Sibling Cohort Survey Calls ver 1_4.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	5/21/2013	R. Massey, D. Bowen, D. Rinehart	Initial Development
1.1	5/22/2013	J. Bates, D. Rinehart, R. Massey	Content revision
1.2	10/1/2013	R. Massey	Content Revision: Making edits to sibling record header, No longer need to add completed expired surveys to Call Outcomes Log
1.3	12/2/2013	R. Massey	Content rev: handling ineligibles, "calls" hold, accessing case record to update, sibling name field updates, pt informed consent copies
1.4	4/26/2014	R. Massey	Content Revision – death status and preferred names

Experian Searches

Background

Experian is a fee-based service that can be used to search for current address and phone numbers. This service is periodically used as part of the tracing efforts to contact participants. Experian searches can only be run for U.S. addresses. International addresses cannot be included in an Experian search.

Procedure

1. Run a query in the applicable database to gather needed information for the participants that you would like to include in the search. Needed information includes
    a. CCSSID (or SIBID)
    b. Send Name
    c. Send Address
    d. Send City
    e. Send State
    f. Zip sort
    g. All available phone numbers
    h. SSN
2. Export the query results to Excel
    a. Tools/Office Links/Analyze It with Excel
    b. Save the file in the following path…\ECC\CCSS\Tracking\(Month and Year of Request)
3. Use "Find and Replace"
    a. To remove hyphens from the SSN field
    b. Parentheses and hyphens from phone number fields
    c. Commas, asterisks, or any other unnecessary punctuation
4. Open the Metronet Database in the following path: …:\ECC\CCSS\Tracking
5. Import the Excel file into the Metronet database
    a. Click the New button while in the Table object view
    b. Import Table with headings
    c. OK
    d. Change the Files of Type at the bottom of the import screen to Microsoft Excel
    e. Select the Excel file from step #2
6. The table called INPUT is the master table (template). Make a copy of the table, and then name it InputCopy
    a. There may already be a table named this, which is ready to use (it will be blank when you open it – if it isn't don't use this and make a new copy of INPUT).
7. Run an append query to input the data from the table you created (with the names, addresses, etc.) into the InputCopy table
    a. Click the Queries button in the objects list
    b. New/Design View
    c. Add the Table that contains the names, addresses, etc. that you created and imported into the current database
    d. Close the dialog box that allows you to choose tables to add to your query
    e. On the menu bar, choose Query→Append query
    f. When prompted with the dialog box titled "Append", add InputCopy as the table you are appending to

g. Add all the variables from the table that you created that you need for the Experian search
h. In the row titled "Append To", choose these fields to populate from your name/address table to InputCopy
    i. AccountInformation = CCSSID (or SIBID)
    ii. Name = Send Name
    iii. Address = Send Address
    iv. City = Send City
    v. State = Send State
    vi. Zip = Zip Sort
    vii. SSN = SSN
    viii. Phone2 = Phone 1 (or first phone field you have)
    ix. Phone3 = Phone 2
    x. Phone4 = Phone 3 (if applicable)
i. Run the query, and all the information from your table should now be in InputCopy – renamed to the reflect the names Experian requires

8. Run the update query called qupExperianVariables to populate the other required fields in InputCopy. In case the query has been deleted, these are the fields that need to be updated.
    a. Search Type = Y
    b. Reserved1 = Y
    c. NeighborSearch = N
    d. EchoedInput = Y
    e. Reserved2 = Blank
    f. SearchLogicPass = 2
    g. Reserved3 = Blank
    h. SurnameSearch = B
    i. NumSurnameSearch = 00
    j. SurnameSearchRegion = Blank
    k. OptionalSearchFlag = 3
    l. USPSNCOAoption = Y
    m. DapVerifyFlag = N
    n. Reserved4 = Blank
    o. StandardizedAddressReturn = 1
    p. EDABestPickScore = Blank
    q. RadiusSearch = Blank
    r. Reserved5 = Blank
    s. NumOfNeighbors = Blank
    t. InputRecordformat = N
    u. OutputRecordFormat = C
    v. Reserved6 = Blank
    w. SurnameSearchDelimiter = N
    x. Reserved7 = Blank
    y. NumofEDAListings = 03
    z. UserProfileID = SJMNAB0
    aa. Phone1 = Blank
    bb. Reserved8 = Blank
    cc. Unknown = Y
    dd. Reserved9 = Blank

9. With your newly updated table open
    a. Click File/Export
    b. Change the save as type to Text Files
    c. Click Export All button
    d. Click Fixed Width radio button in Export Text Wizard/Next
    e. Next
    f. Save the file as CEM250.TXT
    g. Finish
10. Upload the text file to Experian
    a. Go to www.expbdt.com
    b. Click Logon button in left hand menu bar
    c. User ID: MBMDECC
    d. Password: rug13rat
    e. Click gray logon button at bottom
    f. After logging on, Click Send button
    g. Click ASCII button in Data Format
    h. Click Browse button to import Text file
    i. Click gray Send button at bottom of screen
11. Retrieve Search Results
    a. Logon using steps 10 a – e
    b. Click the Directory button on the left hand side menu bar
    c. Click the gray Directory button on the bottom of the screen
    d. Your files should appear with a hyperlink
    e. Click on each one – AND MAKE SURE YOU SAVE IT AS A TEXT FILE BEFORE YOU CLOSE IT – once you click on the hyperlink, it will disappear if you try to access it again.
12. Upload the text file into Metronet database
    a. Open the database
    b. New/Import Table (you may need to rename the table before starting - Access didn't recognize the name/pathway Experian gave it)
    c. Change Files of Type to text files to find your file
    d. Click Import
    e. Click fixed width/Next
    f. Make sure "Comma" is the option selected
    g. In the box titled "Text Qualifier" choose the quotation (")
    h. Check the box "First Row Contains Field Names"
    i. Next
    j. In a New Table/Next
    k. Next
    l. No primary key (or account information if you think you'll ever need to link it to something in one of the databases)
    m. Finish – now you can export to Excel or other database (make sure the formatting looks right, though)

Revision Record Printed 7/16/2012 12:35 PM

Current Filename:		Experian Searches ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	4/2/09	A. McDonald/B. Benavides	Initial Development

Extracting and Processing Expansion Baseline DatStat Refusals

Background

When Expansion cohort participants (or their representatives) access the online baseline survey, they are prompted to read a consent statement and indicate whether or not they agree to participate in the Long-Term Follow-Up Study. If a participant selects "no," then they have declined consent and may not go any further in the survey process. Also, they are in effect refusing all further participation in the Long-Term Follow-Up Study since they have declined to complete the baseline survey.

These refusals have to be extracted from the appropriate table and coded correctly in the Expansion Tracking database. The tables should be checked *at least* every other day.

Procedure

1. Open the appropriate tables in the Expansion Tracking database. For both cases and sibling participants, there are three separate tables for adult, minor, and deceased participants.

   For cases:
   Lnk_DatStat_ExpBase_Adult_Refusals_Results
   Lnk_DatStat_ExpBase_Deceased_Refusals_Results
   Lnk_DatStat_ExpBase_Minor_Refusals_Results

   For sibling participants:
   Lnk_DatStat_Exp_Sibling_Adult_Refusals_Results
   Lnk_DatStat_Exp_Sibling_ Deceased_Refusals_Results
   Lnk_DatStat_Exp_Sibling_ Minor_Refusals_Results

2. Evaluate the results of each table for any new entries based on the listed date.

3. If there are any new entries, open the record for that participant in the Expansion Tracking database using either the "Cases" or "Siblings" option at the main database switchboard.

4. In the Quest tab (for cases) or Sib Info tab (for sibling participants):
   A. Enter a dated note in the **Comments** field noting the online refusal.
      Example: 8/1/2014: Participant has REFUSED per DatStat. [137]
   B. Copy the note in the **Comments** field.

5. In the Baseline tab (for cases) or of the Sib Baseline tab (for sibling participants)
   A. Paste the note copied from the Quest/Sib Info tab **Comments** field, above, to the **Tracking Comments** field.
   B. Select 7-Refused from the drop-down menu in the **Baseline Outcome** field.

C. Enter the current date in the **Baseline Outcome Date** field.

6. In the Reg tab (for cases) or Sib Reg tab (for sibling participants):
   A. Select 37-Refused All Else from the drop-down menu in the **Outcome** field (for cases) or **Sibling Outcome** field (for sibling participants).
   B. Enter the current date in the **Outcome Date** field (for cases) or **Sibling Outcome Date** field (for sibling participants).

Revision Record Printed 7/28/2014 12:19 PM

[240] Current Filename:		Extracting and Processing Expansion Baseline DatStat Refusals ver 1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	9/17/2012	M. Jackson	Initial Development
1.2	5/20/2013	R. Massey, D. Rinehart	Content Revision To Include Expansion Sibling Cohort
1.3	7/28/2014	R. Massey, A. Oyuela	Content Revision to remove reference to MS Word Phone Contact Log

Extracting Online Expansion Survey Data

Background

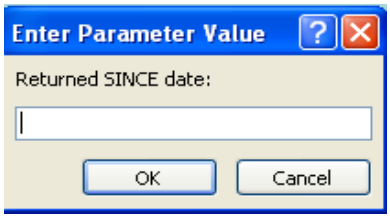
When a participant/parent/LAR completes the online Expansion Baseline survey (either themselves or via the telephone with a Survey Interviewer), certain elements have to be entered in the Expansion Tracking database. The following steps must be taken by a Lead Survey Interviewer (LSI), the Call Center Coordinator, or the Coordinator's designee to collect the information for later data entry. This procedure details the steps taken to gather the information needed to update the tracking database. There are separate steps for adult participants and minor participants for both cases and siblings. The basic process is the same for each group but the queries, file names, etc., are different. See the SOPs entitled **Daily Expansion Tracking Data Entry – Cases** and **Daily Expansion Tracking Data Entry - Siblings** for guidance on how to update the database.

Procedure

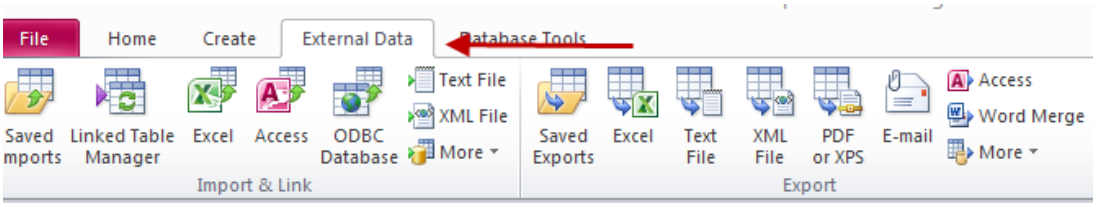
Use this procedure for surveys completed using the online form. Complete the process entirely for the ADULT CASE surveys, then repeat the process for the MINOR CASE surveys, the ADULT SIBLING surveys, and the MINOR SIBLING surveys.

1. Open the folder labeled "Data Entry" in the Interviewers folder On the Z-drive, located here: ***Z:\SJShare\SJCOMMON\ECC\Interviewers\data entry***
2. Find the workbook with the most recent date, and note the date the workbook was created. Workbook file name:
    a. For ADULT CASES: "daily download adult mm-dd-yyyy"
    b. For MINOR CASES: "daily download minor mm-dd-yyyy"
    c. For DECEASED CASES: "daily download deceased mm-dd-yyyy"
    d. For ADULT SIBLINGS: "sib daily download adult mm-dd-yyyy"
    e. For MINOR SIBLINGS: "sib daily download minor mm-dd-yyyy"
    f. For DECEASED SIBLINGS: "sib daily download deceased mm-dd-yyyy"
3. Open the Expansion Tracking database.
4. Use the double arrows in the upper left-hand corner to open the Navigation Pane.
5. In the Navigation Pane, select "Queries" from the drop-down menu.
6. Select:
    a. For ADULT CASES - "qryBlaireOnlineCompletesAdult-promptedForDate"
    b. For MINOR CASES - "qryBlaireOnlineCompletesMinor-promptedForDate"
    c. For DECEASED CASES – "qryBlairOnlineCompletesExpired-promptedForDate"
    d. For ADULT SIBLINGS – "qry_Exp_Sib_Online_Complete_Adult_promptedForDate"
    e. For MINOR SIBLINGS – "qry_Exp_Sib_Online_Complete_Minor_PromptedForDate"
    f. For DECEASED SIBLINGS – "qry_Exp_Sib_Online_Complete_Expired_PromptedForDate"

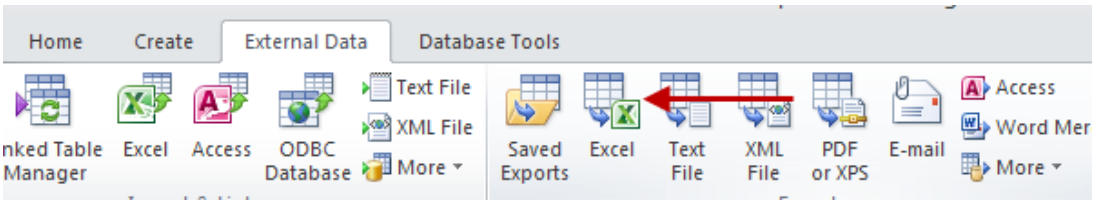
7. The prompt "Returned SINCE date" appears. Enter the date *one day prior* to the date of the last query (as noted by looking at the previous adult workbook) and click "OK." For example, if the last adult case workbook is titled "daily download 6-18-2012," enter 6-17-2012 in the dialogue box.



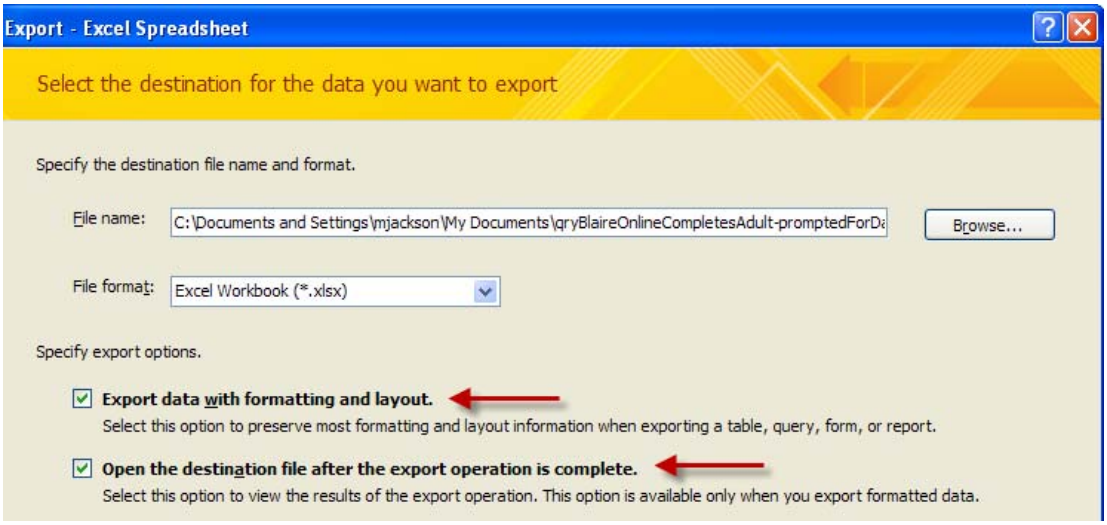
8. Once the results of the query populate, click on the "External Data" tab at the top of the Expansion Tracking database.



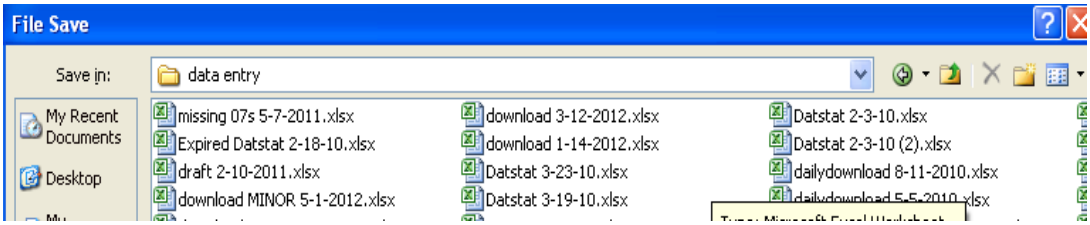
9. In the "Export" group, select "Excel".



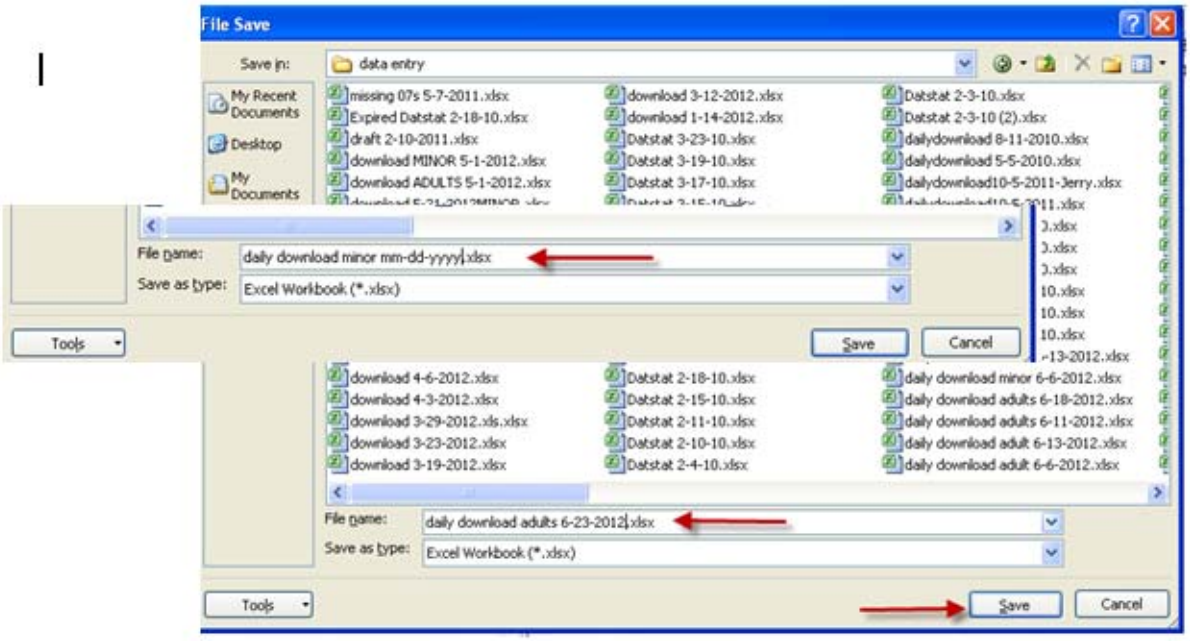
10. When the Export box appears, check the boxes labeled "Export data with formatting and layout" and "Open the destination file after the export operation is complete."



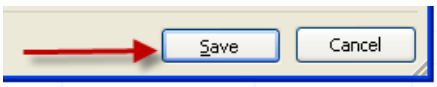
11. For "File name:" click the "Browse" button, and drill down to save the file in ***Z:\SJShare\SJCOMMON\ECC\Interviewers\data entry***



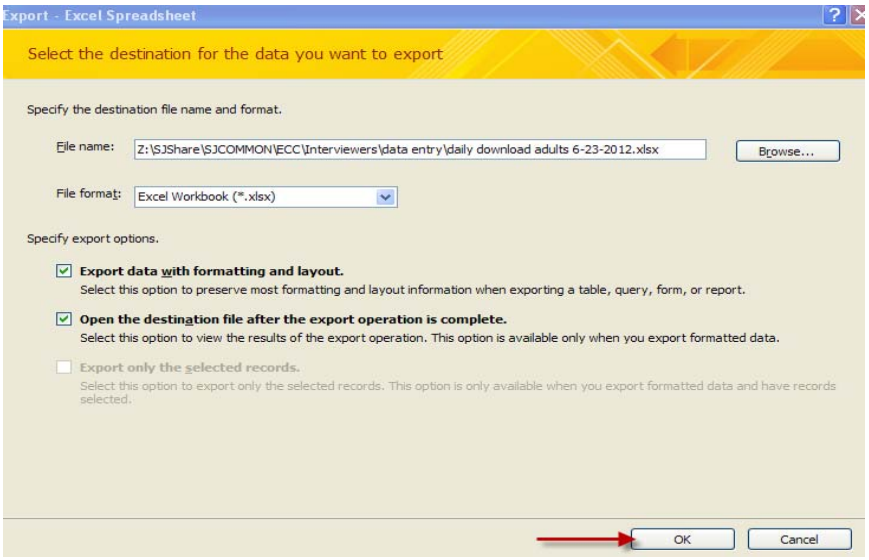
12. Then, in the box labeled "file name" type in
    a. For ADULT CASES:
       "daily download adult mm-dd-yyyy" using the current month, day, and year.
    b. For MINOR CASES:
       "daily download minor mm-dd-yyyy" using the current month, day, and year.
    c. For DECEASED CASES:
       "daily download deceased mm-dd-yyyy" using the current month, day, and year.
    d. For ADULT SIBLINGS:
       "sib daily download adult mm-dd-yyyy" using the current month, day, and year.
    e. For MINOR SIBLINGS:
       "sib daily download minor mm-dd-yyyy" using the current month, day, and year.
    f. For DECEASED SIBLINGS:
       "sib daily download deceased mm-dd-yyyy" using the current month, day, and year.



13. Click "save"



14. Click “OK” when the export dialogue box re-appears.



15. The Excel spreadsheet will open in another window.

16. Exit out of the query results in the Expansion Tracking database. Click “close” when the dialogue box appears. **Do not** check the box labeled “Save export steps”

17. The Excel spreadsheet is now ready for formatting and printing, if desired. For best results:
    a. Use narrow margins.
    b. Use an easy-to-read font.
    c. Use the maximum “row height” and “font size” that will fit on one page.
    d. Use “landscape” orientation.
    e. Use “legal” for paper size.
    f. Select “one page” for width and height of document.

Revision Record
Printed 7/26/2013 12:17 PM

[259] Current Filename:		Extracting Online Expansion Survey Data ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/25/2013	R. Massey, D. Rinehart	Replacing archived SOP, Extracting Data from Online Expansion Baseline Surveys to Update the Tracking Database ver 1.2, adding Adult and Minor Sibling Queries (call number 204)

FedEx Institution Recruitment Resends

Background

In recruiting cases to the LTFU study, we may use FedEx to ship recruitment materials to non-responding eligible participants. We do this in batches by institutions. We use a series of **FedEx_InstResend** queries to assist in this process. These queries are maintained in the CRA2's QTO database and are ported to the Z-drive version for multi-user access. This document delineates those queries and outlines the cycle of procedures used to resend recruitment packets via FedEx. (NOTE: As of April, 2012, the institutions selected for the FedEx resend batches are 15, 19, 2, 26, 4, 1, 21, 20, 24, 3, 22, and 9.) At any one time, we will have several institutions at different stages in the FedEx InstResend process. Be sure to verify that the institution you query is the institution identified in the "SELECT" query.

Procedures

Background/Reference queries

1. **Qry_JB_FedEx_InstResend-ALL** . This query identifies non-responder eligible cases from all the *selected* institutions, pulls needed fields, and builds appropriate variables (rundate, ageToday, sendcareof, needsTracing, POBoxFlag, Adult, Deceased, Minor, NeedsSpanish). Selects regardless of tracingcode or pobox flag. No need to export to excel as it is for global reference.

2. **Qry_JB_FedEx_InstResend-COUNTS** queries the RecruitmentMain table and COUNTS eligible cases with no outcome code, by specified Instcod.

   a. We can manipulate the tracingcode/POBoxFlag criteria to get a quick count of all cases

   b. E.g., the query currently selects only those where tracingcode is 13 or 18 (used to get the count of cases that will need to be traced) and POBoxFlag is NOT "YES". Manipulate the criteria as needed for specific counts.

PRODUCTION Process / queries

1. **Select records for the specified institution.** Run **Qry_JB_FedEx_InstResend-SELECT**. Queries RecruitmentMain (same as …-ALL) but pulls only the specified institution.

   a. TO USE: set value for InstCod. RUN this query. ***EXPORT Select query to Excel*** and indicate instcod in excel file name. (e.g., *qry_JB_FedEx_InstResend-SELECT 20_CHOP.xlsx*)

2. **Build the TRACING list** using **Qry_JB_FedEx_InstResend-TRACING**.

   a. Selects from the –SELECT query the cases with tracingcode 13 or 18. Shows TracingDate, CCSSID, SSNum, Fname, Lname,tracingCode, name, and rundate (and from the Recruitment table) [updated 7/23/12 to add fields needed by LSI]

b. Run this immediately after the SELECT query and ***export to Excel***. Send to tracing team. Indicate the "need by" date. File name *qry_JB_FedEx_InstResend-SELECT ##-InstName*

c. ***IMPORT Tracing excel file into an Access table*** _TEMP_Trace_Inst##-NAME_FedEx so you can query against it to get the current status of the tracing efforts. Recommend keeping each inst's tracing table in the QTO version of the database (not in the public version).

3. **Review tracing status of the cases sent to tracing** before the tracing deadline, (**qry_JB_FedEx_InstResend-ReviewTracingStatus**).

   a. In design view, swap out the TEMP_Trace_Inst##-XXXX_FedEx table to the tracing table for the institution. Save and run.

   b. Send inquiry to the tracing team for status update. Include the list. Presumably these cases are still being worked. (If an older TracingDate displays, this should mean tracing is still in process.)

4. **Generate the PRODUCTION data** file after the designated tracing period, using **qry_JB_FedEx_InstResend-PRODUCTON** (Recheck instcod in SELECT query as it may have been changed to a different institution.) You must wait until tracing is completed before running the production list. It is possible that some traced cases that originally had a street address will now have a POBox address. POBox addresses are excluded from production.

   a. This query uses the previous -SELECT query (which contains the instcod criterion for the currently selected institution). It connects to the qry_JB_SpanishPktList.
      i. Builds GROUP (concatenates the adult, deceased, minor fields from the SELECT query so these will appear in the same column.)
      ii. Builds NeedsSpanish **(NeedsSpanish: IIf([qry_JB_SpanishPktList].[CCSSID] Is Not Null,"SpPacket","")**
      iii. SORTS descending by adult, then minor, then deceased; and ascending by PTLast, to get list alphabetical by last name, within each specific group. This facilitates stuffing the packets with the airbills (also in alphabetical order) once they are ready.
      iv. FILTERS OUT those still in tracing or flagged because the address is a POBox

   b. ***EXPORT* Production query to excel**. AFTER making a copy of the file to use for the Airbill document (see below), color code the rows in the PRODUCTION file for the assigned production person.

5. Generate/distribute the Airbill production file

   a. COPY the PRODUCTION excel file, rename copy with AIRBILLS instead of PRODUCTION

   b. Keep only the following columns in the AIRBILL file: CCSSID, Sendcareof, Careof, Add1, City_1, State_1, ZIP, Country, and the 5 telephone fields.

   c. Send Excel file to airbill production team (admins; cc Abbe) together with institution-specific information showing Institution name, PI, shipping date, and "need by" date. (Complete Summary of Shipping LTFU Recruitment Packets via FedEx-GENERIC for institution; save w/

Inst name; copy/paste Pg1 into email body.) (Pg2 contains Task Tracking Checklist useful in logging progress through the 3 week timespan this process can take.)

d. If admins notify us during airbill production that FedEx rejects an address, investigate to find another source to verify the address.

   i. If it is a simple and obvious address correction, make the correction with a note in the database and ask the admin to generate the airbill with the corrected address.
   ii. If we find separate verification that the address we provided is viable, ask admin to generate the airbill anyway. Document in database record for the CCSSID.
   iii. If we cannot verify the address, pull the record from production. In the PRODUCTION Excel file, start a tab to list DoNotMail cases, and key in the CCSSID (column header CCSSID). Document with comment in the database, enter tracing code 18 (or change to 13 if current code is 19) and post the tracing date.

6. **Create a reference list of the CCSSIDs** identified for production

   a. In the Excel Production file, copy the CCSSID column and all ccssids onto a new sheet named **_TEMP_ResendFedEx_Inst##** (insert Instcod for ##),

   b. Import this TEMP tab from the Production excel file into the database for posting cross reference.

7. **ADDRESSING the POBOX cases.** Since FedEx cannot deliver to a post office box address, we cannot include these cases in the FedEx resend production. However, we CAN send a packet by US Mail to those individuals. We do this by including them in the next scheduled "requested resend."

   a. **qry_JB_FedEx_InstResend_POBOX** identifies the POBox cases for the institution while it is still in the SELECT query. Run this query after you generate the production file. Use the list as a reference.

   b. Locate each identified case in the Recruitment database form.

   c. BEFORE posting the request, review the tracing and recruit notes (Tracking tab) and comments on the Quest tab, to see if there is anything that indicates we should NOT send a packet.

   d. Post the resend request. (RESEND REQUEST 2 (Packet); DATE RESEND REQUEST (current date); annotate in Recruit notes "**mm/dd/yy: Excluded from FedEx resend batch due to POBox address; posted standard resend request [inits]"**

   e. After posting the resend requests on the Tracking form, you can refresh the Resend_POBOX query to view the resend codes (to be sure you got them all).

8. **Identify the DO NOT MAIL list** when the airbills are ready, using **Qry_JB_FedEx_InstResend_DOnotMAIL .** This query lists cases from the imported Resend list that have an outcome code or are ineligible.

    a. MODIFY the existing DOnotMAIL query: Swap out the _TEMP_ResendFedEx_Inst## table with the table that belongs to THIS institution.

    b. Run the query to identify any cases that have been *recruited* or found *ineligible* since the original production list was generated. **Print**.

    c. In the PRODUCTION Excel file,
        i. Copy and paste the DO NOT MAIL query results onto a new tab called DO NOT MAIL (if this tab already exists because FedEx bounced an address, add the query to the tab.)
        ii. On both the Production sheet and the TEMP_Resend sheet, locate each DoNotMail cases and change font to strikeout

    d. Locate the packet for each listed person. REMOVE packet and do not mail. When the airbills are ready, pull airbills and notify admins with the tracking # indicating we did NOT mail.

    e. Locate each record's CCSSID in the database **_TEMP_ResendFedEx_Inst##** table and DELETE the record. (You will use this TEMP table to post the mailouts.)

POST PRODUCTION procedures: Post the RESENDS (in the QTO version of the database or Z drive version) and File

1. Post

    a. Open the _TEMP_ResendFedEx_Inst## data file you imported earlier. Double-check to be sure records NOT mailed have been deleted.

    b. Create **an ad hoc query** linking the TEMP_Resend table with the Recruitment Main table. Display CCSSID, RESEND# and matching RESEND#MODE fields, and both RESENDREQUEST and DATERESENDREQ.

    c. Run the query to find out how many of the resend fields you need in order to post a resend date. (E.g., if the case with the most resends on record had 5 resends, you will need 6 resend fields in your query in order to be able to post resends.) If you only need 6 resend fields, you can remove the higher fields from the query.

d. Set criteria to identify the cases with the MOST resends by setting criteria for all previous resend fields to NOT NULL. (E.g., resend1, resend2, resend3, resend4, and resend5 are NOT NULL, but resend6 IS NULL). Record the resend date and mode (use mode 5 for FedEx Packet) in the IS NULL field. (NOTE: ASK to see this in action if you have ANY QUESTIONS. For small numbers of resends, manually entering the date/mode is fine. But for large numbers, you will want to use the update query type.)

e. Check for any ResendRequests posted to these cases. Clear the requests and resendRequestDate

f. Determine whether this was the FIRST mailing for any cases: Add DATEPACKETSENT and and DATEHIPAAONLYSENT to the query and filter for cases where BOTH fields are blank. If there ARE any records, then clear the resend1 date/mode and post the mailing date in the DATEHIPAAONLYSENT field (for Michigan, use DATEPACKETSENT).

g. As you post, make note of how many you post at each stage (how many resend6's, resend5's, etc.)

2. File

a. The excel production files in the institution's !xxxx-Mailings folder after adding the ship date to the end of the excel file name.

b. The production schedule in the institution's main recruitment folder.

Revision Record Printed 7/23/2012 12:58 PM

Current Filename:		FedEx Institution Recruitment Resends ver 1_5.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	4/27/12	J.Bates	Initial Development
1.1	5/10/12	J.Bates	POBox, mode clarification, production colors
1.2	5/17/12	J.Bates	FedEx rejects
1.3	6/14/12	J.Bates	Clear resend requests
1.4	7/20/12	J.Bates	Clarifications
1.5	7/23/12	J.Bates	Rev TRACING qry: add SSN f/lname for LSI convenience

File Storage in Bruner Building

Background

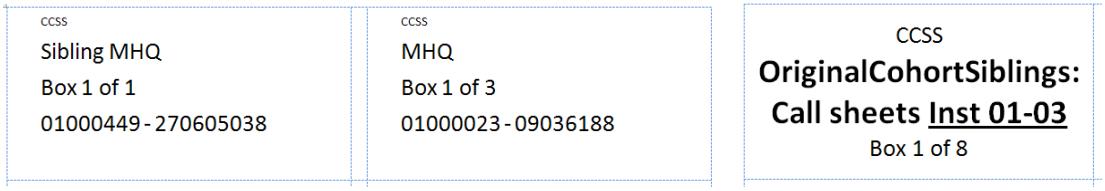
When paper files need to be moved to on-site storage, we label the storage boxes, record each box in the Storage Site spreadsheet, contact the appropriate parties, and oversee the actual pickup of the materials. To request boxes to be RETURNED to us, submit the request via email to ChartRequest@stjude.org.

Procedure

1. Sort materials in banker boxes by CCSSID or some other logical, identifiable sequence.
2. Record the description from the label in the spreadsheet **CCSSstoragesort.xls** (Z:\SJShare\SJCOMMON\ECC\CCSS)

DateSen	Int.R	Description	Notes/Comments	from BarryCenter Location
10/21/2010	520	FU 2007: Box 23 of 26: 23136966-24081841	surveys	5th floor workroom
10/21/2010	521	FU 2007: Box 24 of 26: 24081866-26016991	surveys	5th floor workroom
10/21/2010	522	FU 2007: Box 25 of 26: 26017011-26158503	surveys	5th floor workroom
10/21/2010	523	FU 2007: Box 26 of 26: 26158542-27208022	surveys	5th floor workroom
	524	CCSS OriginalCohortSiblings: call sheets Inst 01-03. Box 1 of 8	Call worksheets	4th floor
	525	CCSS OriginalCohortSiblings: call sheets Inst 04-05. Box 2 of 8	Call worksheets	4th floor
	526	CCSS OriginalCohortSiblings: call sheets Inst 06-10. Box 3 of 8	Call worksheets	4th floor
	527	CCSS OriginalCohortSiblings: call sheets Inst 10-13. Box 4 of 8	Call worksheets	4th floor
	528	CCSS OriginalCohortSiblings: call sheets Inst 15-16. Box 5 of 8	Call worksheets	4th floor
	529	CCSS OriginalCohortSiblings: call sheets Inst 17-20. Box 6 of 8	Call worksheets	4th floor
	530	CCSS OriginalCohortSiblings: call sheets Inst 21-24. Box 7 of 8	Call worksheets	4th floor
	531	CCSS OriginalCohortSiblings: call sheets Inst 25-27. Box 8 of 8	Call worksheets	4th floor
	532	CCSS Original Cases and Siblings: buccal consents Accno 1-301. Box 1 of 15	Buccal Consent Forms	4th floor
	533	CCSS Original Cases and Siblings: buccal consents Accno 302-601. Box 2 of 15	Buccal Consent Forms	4th floor
	534	CCSS Original Cases and Siblings: buccal consents Accno 602-888. Box 3 of 15	Buccal Consent Forms	4th floor
	535	CCSS Original Cases and Siblings: buccal consents Accno 889-1166. Box 4 of 15	Buccal Consent Forms	4th floor
	536	CCSS Original Cases and Siblings: buccal consents Accno 1167-1447. Box 5 of 15	Buccal Consent Forms	4th floor
	537	CCSS Original Cases and Siblings: buccal consents Accno 1448-1739. Box 6 of 15	Buccal Consent Forms	4th floor
	538	CCSS Original Cases and Siblings: buccal consents Accno 1740-2033. Box 7 of 15	Buccal Consent Forms	4th floor

3. Label each box with the description in the spreadsheet. If there are multiple boxes with the same description, be sure the label indicates “Box x of y” (Samples below)



4. After the boxes are inventoried (on the xls file) and labeled:
    a. Email the "Director of HIMS (currently Patti Gust), and copy Abbe Anderson, that we have boxes that need to be moved to the Bruner Building. Tell her how many boxes and where they are located.
    b. Abbe Anderson contacts Derrick Steward (Materials management) to schedule movers to pick up and deliver the boxes. She indicates how many, where, and what account code.
    c. Derrick notifies Abbe what the pickup schedule will be. Someone will need to meet the movers when they arrive.

   d. Once we know the pickup schedule, notify Gracie Hobson in HIMS so the HIMS department will have someone available at the loading dock when the movers deliver the boxes.
   e. At the scheduled pickup time, someone meets the movers.
   f. When the movers leave with the materials, contact Gracie again to let her know they are on their way.
5. Go back to the inventory list and record the date the boxes were picked up (use the DateSent column).

Retrieving Boxes

1. When we need to RETRIEVE materials from the Bruner building, consult the inventory list to identify which box(es) are needed. This is where the description on the label becomes critical. First, it lets you find which box may have what you need, and second it is how to tell HIMS exactly which box(es) you need….. by using the description you placed on the label.

2. To request boxes RETURNED to you, send the email request to ChartRequest@Stjude.org

Revision Record Printed 6/18/2013 12:19 PM

[117] Current Filename:		File Storage in Bruner Building ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	2/16/11	J.Bates	Initial Development
1.1	6/18/13	J.Bates	Requesting boxes RETURNED

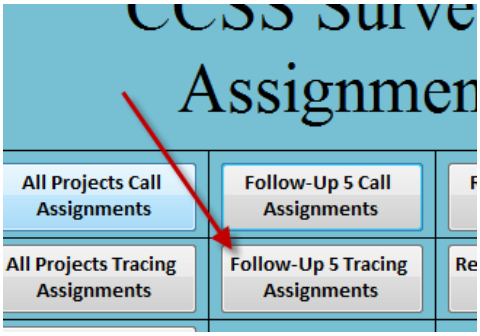
Follow-Up 5 Tracing Procedures

Background

Follow-Up 5 tracing procedures occur in two stages, Intro (iPad) Letter Stage and Paper Survey Stage, as outlined in this procedure. At the Intro (iPad) Letter Stage, tracing is performed only on those participants identified to have a bad mailing address, with tracing codes 13, 18, 81 and 85. At the Paper Survey Stage, tracing is performed only on those participants identified to have a bad telephone number, with tracing codes 13, 19 and 86. Paper Survey Stage tracing begins three weeks after the paper survey has been mailed, to allow the participant time to respond with an updated telephone number(s) in the course of survey completion.

Procedures

1. Tracers **access tracing assignments** in the CCSS SI Assignments database, located at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.



2. Each tracing assignment should be evaluated to determine the current FU5 stage.
   A. **Intro (iPad) Letter Stage** – The "intro (iPad) letter" stage occurs prior to the paper survey mailing.
      i. No Tracing Code – No action required by Tracers.
      ii. Tracing Code 19 – No action required by Tracers. The participant may provide updated telephone number information when completing the survey.
      iii. Tracing Code 13, 18, 81, 85 or 86 and:
         a. The intro letter has not been mailed – No action required by Tracers. The study will mail the intro (iPad) letter to the best address provided in the Lexis-Nexis batch results.
         b. The intro letter was mailed and was returned to sender:
            1) Tracers should trace these participants using standard tracing procedures. See the SOP titled **Tracing Lost Participants** for details.
            2) When an email address is available, the 5th floor team will send an email to these participants. Tracers should review the contact log in the LTFU Participant database as one component of the full tracing scenario for the participant in question.
   B. **Paper Survey Stage** – The "paper survey" stage occurs after the paper survey has been mailed.
      i. No Tracing Code – No action required by Tracers.

ii. Tracing Code 13 and 86 - Tracers should trace these participants using standard tracing procedures. See the SOP titled **Tracing Lost Participants** for details.

iii. Tracing Code 19 – Tracers should trace these participants using standard tracing procedures *after the participant becomes eligible for outgoing FU5 calls* (i.e. 3 weeks after the paper survey is mailed). See the SOP titled **Tracing Lost Participants** for details.

iv. Tracing Code 18, 81, 85 – No action required by Tracers. Once the participant is eligible for outgoing FU5 calls (i.e. 3 weeks after the paper survey is mailed), the non-tracing SIs should call these participants using the telephone numbers on file. If no contact is made after making the minimum number of telephone calls (determined on a case-by-case basis), the SI will update the tracing code from 18, 81 or 85 to a 13 or 86, and the participant will then be eligible for review by the Tracing team.

3. If during the course of standard tracing procedures, outlined in the SOP titled **Tracing Lost Participants**:

A. The Tracer **reaches an associate** of the participant, s/he should:

i. Attempt to obtain current contact information for the participant.

ii. Click the **Add Record to Call Log** button in the trace log after logging the tracing call. This will add an identical record in the contact log.

iii. Update the LTFU Participant database with the associate's contact information and status. See the SOP titled **LTFU Participant Database Data Entry** for details.

iv. Update the LTFU Participant database with any contact information for the participant confirmed by the associate. See the SOP titled **LTFU Participant Database Data Entry** for details.

v. If there is an indication that the previous mailing was returned to sender, request a resend. If there is not an indication that the previous mailing was returned to sender, the Tracer will use his/her discretion regarding a resend.

B. The Tracer **reaches the participant**, s/he should:

i. Attempt to obtain current contact information for the participant.

ii. Explain the FU5 project to the participant.

a. For tracing at the intro letter stage, use the **FU5 iPad Letter Return to Sender Tracing Script** located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\FU5\Scripts*.

b. If appropriate, advise the participant of the incentive. Unlike non-tracing SIs, Tracers may use their own discretion in resetting the incentive period when the participant provides a new mailing address and expresses that s/he did not receive any prior FU5 mailings. This option should be used conservatively.

1) Keep in mind that resetting the incentive period creates additional workload for the 5th floor team.

2) If the participant confirms his/her email address is valid and if the 5th floor team has sent an incentive reminder to that email

address, the incentive period should *not* be reset, even if the participant did not check his/her email or junk mail.

iii. Determine if the participant would like to complete the survey on the telephone. If not, determine how the participant would like to receive written information regarding FU5 (i.e. hard copy or email).

iv. Click the **Add Record to Call Log** button in the trace log after logging the tracing call. This will add an identical record in the contact log.

v. Update the LTFU Participant database with any contact information for the participant or his/her associates. See the SOP titled **LTFU Participant Database Data Entry** for details.

vi. If the participant did NOT choose to complete the survey via telephone, resend FU5 information to the participant in the format requested:

a. **Email** – See the SOP titled **Emailing Follow-Up 5 Survey Links** for instructions on sending FU5 emails. IF the Tracer used his/her special discretion to reset the incentive period outside the guidelines in the SOP:

1) Send the survey link using the incentive template, as described in the SOP.

2) Document the sent link in the LTFU Participant database:

A) Contact Log – Specify that the incentive template was used and why. See the SOP titled **LTFU Participant Database Data Entry** for instructions on using the contact log to document an email communication.

B) **Notes** field in FU5 Tracking tab – Document the sent link in a dated comment with SI ID. Specify that the incentive template was used and why.

C) **Intro Letter Resend #** field in FU5 Tracking tab – Enter the date of the email in the next available field.

D) **Date Intro Letter Sent** field in FU5 Tracking tab – Do NOT overwrite the date in this field.

E) **IPad Due Date** field in FU5 Tracking tab – Do NOT overwrite the date in this field. The 5th floor team will re-populate this field.

F) Do NOT populate the **Request Date** or the **Resend Request** fields in FU5 Tracking tab except in the rare event that the participant wants a paper copy of the iPad letter in addition to the email link.

b. **Paper Resend** of the:

1) Intro (iPad) Letter – On the FU5 Tracking tab:

A) **Request Date** – Populate with the current date.

B) **Resend Request** – Populate with 1-Intro Letter.

C) **Notes** – Add a dated comment with SI ID indicating the changes in the **Request Date** and **Resend Request** fields and why the changes were made.

2) Paper Survey – See the SOP titled **Follow Up 5 Survey – Outgoing Calls** for paper survey resend procedures.

4. Lexis Nexis Address Source and Tracing Codes

A. For information regarding Lexis Nexis (LN) participant and associate contact info, see **Tracing Database Data Entry**.

B. The study will use the unconfirmed addresses from LN batches for specified mailings to certain participants with a bad address-related Tracing Code, but because this data is unconfirmed, the 5th floor team will leave the Tracing Code in place, update the **Address Source** to a new value, "Lexis Nexis", and mail the materials to these select participants. Until the LN address has been confirmed, the Tracing Code will not be removed.

C. If the materials mailed to these participants should come back "Returned to Sender" or if a SI discovers during follow-up calls that the LN address isn't valid, the Tracing Code should be updated using the chart below for guidance:

No:	Scenario	Current Tracing Code Field	Update Tracing Code to:
1	A mailing has been sent, not returned, no tracing codes, and the SI determines that all phone numbers are "bad"	<null>	19
2	A mailing has been sent, not returned, no tracing codes, and the SI determines that address for the pt is "bad"	<null>	18
3	A mailing has been sent, not returned, no tracing codes, and the SI determines that both the address and the phone numbers for the pt are "bad"	<null>	13
4	A mailing is returned to sender, and there are phone numbers in the database for the pt that *HAVE NOT* yet been confirmed to be "bad"	<null>	18
5	A mailing is returned to sender, and there are phone numbers in the database for the pt that *HAVE* been previously confirmed to be "bad"	19	13
6	A mailing is returned to sender after being mailed to a new unconfirmed Lexis Nexis address, and there are phone numbers in the database for the pt that *HAVE NOT* yet been confirmed to be "bad"	18	85
7	A mailing is returned to sender after being mailed to a new unconfirmed Lexis Nexis address, and there are phone numbers in the database for the pt that *HAVE* previously been confirmed to be "bad"	13	86

No:	Scenario	Current Tracing Code Field	Update Tracing Code to:
8	A mailing is returned to sender after being mailed to a new unconfirmed Lexis Nexis address, and then we subsequently determine that the phone numbers in the database for the pt that we thought were "good" numbers, *HAVE* then been confirmed to be "bad"	85	86
9	An associate of the pt confirms updated mailing address information, but does not provide the pt's phone number, and there are phone numbers in the database for the pt that *HAVE* been previously confirmed to be "bad"	13	19
10	A mailing is returned to sender after being mailed to a new unconfirmed Lexis Nexis address, and an associate of the pt provides confirmed updated address information for the pt, but does not provide the pt's phone number, and the phone numbers in the database *HAVE* then been confirmed to be "bad"	86	19
11	A mailing is returned to sender after being mailed to a new unconfirmed Lexis Nexis address and the phone numbers in the database HAVE then been confirmed to be "bad", and an associate of the pt provides confirmed updated phone number for the pt, but does not provide and updated address for the pt	86	85

5. Unforeseen Situations

A. Situations requiring direction not covered herein will be handled on a case-by-case basis, by contacting the LSI team or Coordinator.

Revision Record
Printed 5/19/2016 2:59 PM

Current Filename: [284]		Follow Up 5 Tracing Procedures ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	1/14/15	R. Massey, D. Rinehart, A. McDonald	Initial Development
1.1	5/17/2016	A. DiScenza, D. Rinehart, A. Cobble. J. Ford	Content revision. Updated tracing codes and formatting

Follow-Up 5 Survey – Incoming Calls

Background

The first follow-up survey sent simultaneously to both the original and expanded cohorts, referred to as "Follow-Up 5", was initiated in 2014. The Follow-Up 5 (FU5) survey is pursued for alive English- and Spanish-speaking adult and minor cases and sibling participants. There will be no expired participant FU5 survey. All FU5 data entry will be recorded in the LTFU Participant database.

In an effort to enhance response rate, an advance letter is sent to participants to notify them that if they complete their survey online or with a Survey Interviewer (SI) before a specified date, they will be entered into a drawing to win an iPad. Participants with a documented email address will also receive a reminder email during the incentive period. Approximately 500 advance letters will be mailed per week, and a total of 12 iPads (one per month for a year) will be awarded.

About three weeks following the advance letter mailing and one week before the incentive due date, surveys will be mailed to all non-responders. Incoming calls may be received in response to the advance letters, in response to tracing calls, in response to outgoing calls following the survey mailings, or as participant-initiated calls.

For many participants, this will be the first time the LTFU Study has asked them to complete a new survey in several years. SIs should be prepared to reintroduce the study, its mission, purpose, and goals; overcome barriers; and answer questions. In some circumstances participants will need to be reconsented to the LTFU Study. Consult with a Lead Survey Interviewer (LSI) or with the Coordinator with any questions.

Procedures

Tools Needed:

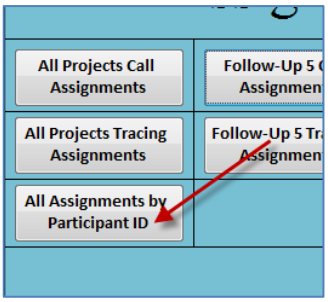
1. CCSS LTFU Participant database (located on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
2. **FU5 iPad Letter Master List_mm-dd-yyyy** (located at *Z:\Departments\ECC\common\Interviewers\FU5*)
3. CCSS SI Assignments database (located on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
4. **Expired Participant Information Sheet** (located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*)
5. Paper copies of the Follow-Up 5 surveys (located at *Z:\Departments\ECC\common\Interviewers\FU5\Surveys*)
6. **Script for Incoming Calls from the Follow-Up 5 iPad Incentive Letter** (located at *Z:\Departments\ECC\common\Interviewers\FU5\Scripts*)
7. Accessory SOPs (located in the SOP Library, found on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*):
    A. **Incoming Call Triage and Documentation**
    B. **LTFU Participant Database Data Entry**
    C. **Call Center Appointment Calendar**
    D. **Emailing Follow-Up 5 Survey Links**
    E. **Sending Spanish Thank You Notes**
    F. **Reconsenting During Follow-Up 5 Survey Calls**

INCOMING CALLS

DURING THE CALL PROCEDURES – General

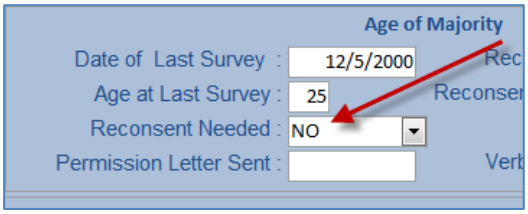
Verify the identity of the caller using standard procedures (name, DOB, etc.) and identify the purpose of their call. Reference the SOP titled **Incoming Call Triage and Documentation**. If you determine the call is regarding the FU5 survey:

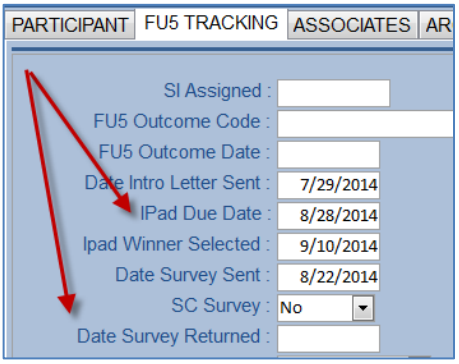
1. Locate the participant in the LTFU Participant database, and open the participant's record. See the SOP titled **LTFU Participant Database Data Entry** for details on using the search screen. NOTE: If the LTFU Participant database is unavailable, locate the participant on the **FU5 iPad Letter Master List_mm-dd-yyyy**.



2. Use the LTFU Participant database contact log and the CCSS SI Assignments database to determine if the participant is assigned to an SI.
   A. If so and the assigned SI is available, transfer the incoming call to the SI.
   B. If not assigned or if the assigned SI is unavailable, take ownership of the call.

3. Review the appropriate fields on the FU5 TRACKING tab:
   A. Review the **Reconsent Needed** field to determine the appropriate action. See the SOP titled **Reconsenting During Follow-Up 5 Survey Calls** for full details.
   B. Review the **IPad Due Date** field to determine the window of eligibility for the incentive.
   C. Review the **Date Survey Returned** field to confirm the survey has not been received.





4. Follow the script as outlined in the document titled **Script for Incoming Calls from the Follow-Up 5 iPad Incentive Letter**.

5. If the participant **refuses** to complete the FU5 survey:
   A. Clarify if the participant is refusing FU5 only or refusing all further participation in the LTFU Study.
   B. Try to capture a reason for the refusal. If the participant's concerns can be addressed, do so. Offer a hold if more appropriate.

6. If we learn the participant is now **incarcerated**:
   A. Attempt to obtain the anticipated release date. (In a few months? Several years?)
   B. If the participant is expected to be available again in a reasonable period of time, ask what the best number will be to reach him/her when s/he is released.

7. If the caller advises that the participant is now **deceased**:
   A. Offer condolences, as directed in the **Script for Incoming Calls from the Follow-Up 5 iPad Incentive Letter**.
   B. Complete the **Expired Participant Information Sheet** with as much information as the caller is able/willing to provide.
   C. Obtain contact information for an appropriate proxy.
   D. NOTE: There is not a FU5 survey for deceased participants. Thank the caller for providing the information, but do not pursue a FU5 survey.

8. If we learn that the participant has a Legally Authorized Representative (**LAR**) or proxy (See a member of the LSI team or the Coordinator for assistance determining an authorized proxy for a non-deceased adult participant.):
   A. Gather the name(s) and contact information for the LAR(s)/proxy.
   B. Determine if the participant has a disability and if the participant is able to legally represent himself or herself (e.g. Mother is a legal representative due to participant's hearing disability, but the participant is a cognitively able adult).

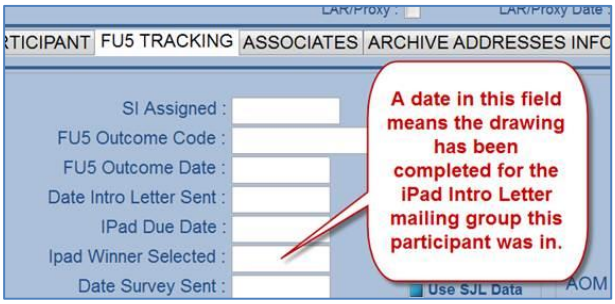
9. If the participant prefers to do the FU5 survey in **Spanish**, non-Spanish-speaking SIs should refer the participant to a Spanish-speaking SI. If there is not a Spanish-speaking SI available:
   A. Whenever possible, the non-Spanish-speaking SI should attempt to secure a survey appointment with the participant at a time when a Spanish-speaking SI will be available.
   B. Non-Spanish-speaking SIs can refer to the document titled **Basic Spanish Words**, located at *Z:\Departments\ECC\common\Interviewers\Spanish*.

10. If the participant wants to **complete the survey on the telephone**, proceed to the section of this document titled *DURING THE CALL PROCEDURES – Completing the FU5 Survey*.

11. If the participant indicates s/he has **already returned** the FU5 survey:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. If a paper copy was returned more than one month ago, it may be lost in the mail. Offer to complete the survey over the telephone to avoid further losses.
      ii. If a paper copy was returned less than one month ago, it may still be in route. Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.
      iii. If an online survey was returned before today but the **Date Survey Returned** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday and Saturday will have the **Date Survey Returned** field populated the following Monday.
         a. Confirm the participant is referring to the LTFU Study's FU5 survey. The participant could be thinking of another study in which s/he participates.
         b. Try logging in to the online survey to determine the survey status. It may be that the participant neglected to click the **Submit** button.
      iv. If an online survey was returned today, the **Date Survey Returned** field will be populated on the next business day (Monday through Friday). Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.

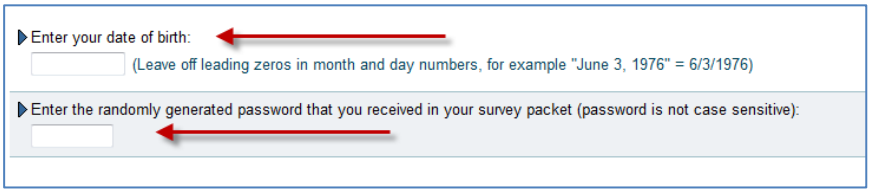
C. Confirm all contact information (address, phone numbers, email address, additional contacts).

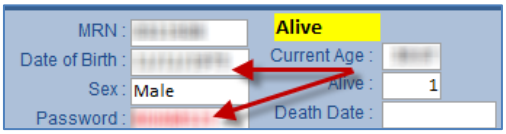
12. If the participant inquires about the iPad drawing, check the **Ipad Winner Selected** field on the FU5 Tracking tab. If this field is populated with a date, the drawing for this participant's mailing group was completed on that date.



DURING THE CALL PROCEDURES – Completing the FU5 Survey

1. Make a note of the time the incoming call began.
2. Click on the link to the appropriate survey. There will be four versions of the FU5 survey:
   A. Adult case survey (for survivor participants 18 years old and older): www.stjude.org/LTFUsurveyA OR https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name=CCSS_FU5
   B. Minor case survey (for survivor participants younger than 18 years old): link to be determined
   C. Adult sibling survey (for sibling participants 18 years old and older): www.stjude.org/LTFUsurveyS OR https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name=CCSS_FU5_Sibling
   D. Minor sibling survey (for sibling participants younger than 18 years old): https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name=CCSS_FU5_Minor&_RS_=1
   E. NOTE: There is no expired version of the FU5 survey. SIs should not pursue a FU5 survey with the proxy of a deceased participant.
3. On the survey login page, enter:
   A. The participant's DOB, found in the **Date of Birth** field of the LTFU Participant database header
   B. The participant's confirmation code, located in the **Password** field of the LTFU Participant database header





4. If the survey was previously started, either by the participant or by an SI, DatStat will display the options to **Start Over** or **Restore** the survey. In general, click on the **Restore** button to start the survey where it was previously closed.
5. Complete the survey with the appropriate party, reading all instructions and questions as written and including all possible answers. Carefully record responses accurately in the online survey.

POST-CALL PROCEDURES - General

1. **Create a contact log record** to document the incoming call. See the SOP titled **LTFU Participant Database Data Entry** for details on entering a call record.
2. If **contact information** for the participant or his/her associate(s) was **confirmed or updated** during the incoming call, update the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for details on documenting participant and associate contact information.
3. For updates to the **participant's name**, **Spanish status**, **date of birth**, **gender**, **incarceration status**, **vital status**, **LAR status**, **hold status**, **tracing status**, **preferred contact time**, or **eligibility status**, see the SOP titled **LTFU Participant Database Data Entry** for details on documenting the changes.
4. For changes in **associate contact status** or **associate vital status**, see the SOP titled **LTFU Participant Database Data Entry** for details on documenting the changes.

5. For survey outcomes, continue to the section of this document titled *POST-CALL PROCEDURES – FU5 Survey Outcomes*.

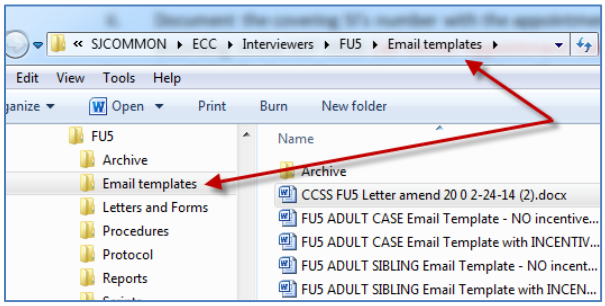
POST-CALL PROCEDURES – FU5 Survey Outcomes

1. **Appointment Made** –
   A. Write the appointment on the Call Center appointment calendar. See the SOP titled **Call Center Appointment Calendar** for details on how to document the appointment.
   B. If you scheduled the appointment and will be covering the appointment, add the appointment to your personal MS Outlook calendar on the appropriate date/time.
   C. If the appointment needs to be assigned to another SI, email with the CCSSID/SIBID and the appointment type/date/time to the LSI team, copying the Coordinator, requesting that the appointment be reassigned. If there is no time to follow this procedure (e.g. The appointment is scheduled for the same day, and the LSI team and Coordinator are out or unavailable before the appointment.), the scheduling SI should:
      i. Coordinate with another SI to handle the appointment.
      ii. Document the covering SI's number with the appointment on the Call Center calendar according to the SOP titled **Call Center Appointment Calendar**.
      iii. Email details about the appointment and who will cover it to the LSI team, the Coordinator, and the covering SI.

2. **Request for Paper Survey Resend** – Note that Spanish-language surveys must be done on the telephone with an SI. Please check the **Spanish Status** field in the participant's header prior to requesting a resend of the paper survey.

   A. NOTE: If the participant requests a paper survey:
      i. In response to the incentive letter, no action is required to initiate the paper survey mailing. Paper surveys will automatically be mailed to non-responders approximately 3 weeks after the incentive letter.
      ii. When the incentive letter has never been mailed, actively request the survey resend as instructed, below.
   B. **Resend Request** (FU5 Tracking tab) – Populate with 2-Survey.
   C. **Request Date** (FU5 Tracking tab) – Populate with the current date.
   D. **Notes** (FU5 Tracking tab) - Add a dated comment with your SI ID documenting the field changes.

3. **Request for FU5 Survey Link** – Note that Spanish-language surveys must be done on the telephone with an SI. Please check the **Spanish Status** field in the participant's header prior to sending a survey link.
   A. Send the survey link using the appropriate email template (adult vs. minor, case vs. sibling, incentive vs. non-incentive) located at



Z:\Departments\ECC\common\Interviewers\FU5\Email templates. See the SOP titled **Emailing Follow-Up 5 Survey Links** for details on this procedure.

B. Document the email communication in the database's contact log. The email sent to the participant should be documented separately from the telephone call. See the SOP titled **LTFU participant Database Data Entry** for details on this procedure.

4. **Refusal** –

A. Refused FU5 but agreed to stay in the LTFU Study:

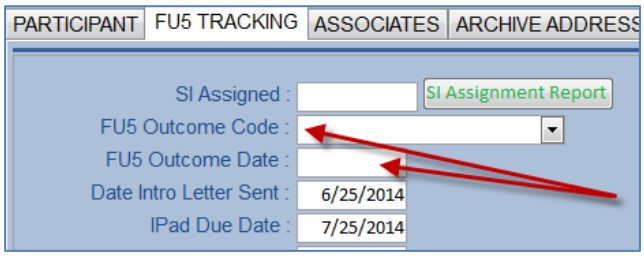
i. **Outcome** and **Notes** (contact or trace log) – Document the FU5 refusal in both fields. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.

ii. **Notes** (Participant tab) – Enter a dated note with your SI ID documenting the "FU5 only" refusal. Click on the **Notes** button to access this field. Before closing the **Notes** window, copy the entire note.

iii. On the FU5 Tracking tab:

a. **Notes** – Paste the refusal note into the field.

b. **FU5 Outcome Code** – Populate with 1-Refused FU5. If this field is already populated, consult a member of the LSI team before changing.



c. **FU5 Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team before changing.

B. Refused All Else:

i. **Outcome** and **Notes** (contact or trace log) – Document the refusal in both fields. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.

ii. **Notes** (Participant tab) – Enter a dated note with your SI ID documenting the "all else" refusal. Click on the **Notes** button to access this field. Before closing the **Notes** window, copy the entire note.

iii. On the FU5 Tracking tab.

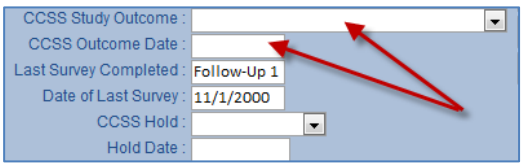
a. **Notes** – Paste the refusal note into the field.

b. **FU5 Outcome Code** – Populate with 2-Refused All Else (CCSS). If this field is already populated, consult a member of the LSI team before changing.

c. **FU5 Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team before changing.

iv. In the header:

a. **CCSS Study Outcome** – Populate with 37-Refused all else. If this field is already populated, consult a member of the LSI team before changing.



b. **CCSS Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team before changing.

5. **Partial FU5 Surveys**
   A. Using the **Previous** and **Next** buttons on the online survey (NEVER use the back/forward buttons in the internet browser.), review every completed page of the online survey for accuracy and check for missing information or fields erroneously left blank. Complete any missing information on these pages before closing the survey.
   B. **Complete the contact or trace log** for the call specifying 8-Partially Complete in the **DB Change** field.
   C. Update the LTFU Participant database with any **confirmed** information using the SOP titled **LTFU Participant Database Data Entry**.
   D. On the FU5 Tracking tab:
      i. **Notes** – Enter a dated note with your SI ID documenting the partially completed survey. If Spanish was used, specify this in the note. *Example: 8/4/2014: Partially completed FU5 survey through question R2 with Martha Stewart, mother and LAR of adult case. [162]*
      ii. **Survey Source**, **Survey Interviewer ID**, or **Interview Status** – Do not populate these fields. The database update team will populate these fields when appropriate.
   E. For **scheduled** surveys, note the partial survey outcome on the Call Center appointment calendar according to the SOP titled **Call Center Appointment Calendar**.
   F. For **unscheduled** partial surveys, email the closing monitor to include the partially completed survey in the closing report.
   G. Update the Dry Erase Board (DEB) FU5 survey tally to indicate the partial survey by writing a "p" instead of a tally mark.

6. **Completed FU5 Surveys**
   A. Using the **Previous** and **Next** buttons on the online survey (NEVER use the back/forward buttons in the internet browser.), review every page of the online survey for accuracy and check for missing information or fields erroneously left blank. Complete any missing information.
   B. Update the LTFU Participant database with any **confirmed** information using the SOP titled **LTFU Participant Database Data Entry**.
   C. Click the **Submit** button on the last page of the survey. Click the **Close** button on the next page, and then choose **Yes** at the next prompt to close the browser instance.
   D. On the FU5 Tracking tab:
      i. **Survey Interviewer ID** – Populate with your SI ID.
      ii. **Notes** – Add a dated note with your SI ID documenting completion of the FU5 survey. If the survey was completed in Spanish, specify this.
      iii. **Date Survey Returned**, **Survey Source**, or **Interview Status** – Do NOT populate these fields.
   E. For a completed **scheduled** survey, place a check mark on the Call Center appointment calendar to indicate the kept appointment. See the SOP titled **Call Center Appointment Calendar** for full details.
   F. For a completed **unscheduled** survey, email the closing monitor to include the completed survey in the closing report.
   G. Note the completed survey with a tally mark on the Dry Erase Board (DEB).
   H. If the participant has **requested to NOT receive LTFU Study newsletters**, document the request in the **DB Change** field of the contact or trace log, and an LSI or designee will make the appropriate entries in the record. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.
   I. If the survey was completed with the participant in **Spanish**:

i. Document the Spanish survey completion in the **DB Change** field of the contact or trace log, and an LSI or designee will make the appropriate entries in the record. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.

ii. Complete all online and database data entry, as indicated above.

iii. **Spanish Status** (header) – Confirm the field is properly updated. See the SOP titled **LTFU Participant Database Data Entry** for details.

iv. Send an email to CRA2s in charge of the study, copying the LSI team and the Call Center Coordinator, that a FU5 survey has been completed in Spanish. Include the CCSSID or SIBID in the **Subject** line and in the body of the email.

v. Create a personalized Spanish thank-you card insert to the participant. See the SOP titled **Sending Spanish Thank You Notes** for details.

vi. Deliver the thank-you card insert to the CRA2 team. See the SOP titled **Sending Spanish Thank You Notes** for details.

Revision Record Printed 10/31/2016 9:08 AM

[274] Current Filename:		Follow Up 5 Survey Incoming Calls ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/25/14	R. Massey, A. McDonald, D. Rinehart, A. Oyuela	Initial Development
1.1	10/9/2014	R. Massey, D. Rinehart	Content Revision
1.2	4/24/2015	R. Massey	Content Revision
1.3	10/20/2016	A. Cobble	Content Revision

Follow-Up 5 Survey – Outgoing Calls

Background

The first follow-up survey sent simultaneously to both the original and expanded cohorts, referred to as "Follow-Up 5", was initiated in 2014. In an effort to enhance response rate, an advance letter is sent to each participant to notify them that if they complete their survey online or with a Survey Interviewer (SI) before a specified date, then they will be entered in a drawing to win an iPad. Approximately 500 advance letters will be mailed per week. Participants with a documented email address will also receive a reminder email during the incentive period.

About three weeks following the advance letter mailing and one week before the incentive due date, surveys will be mailed to all non-responders. Three weeks following the survey mailing, outgoing calls begin. All Follow-Up 5 (FU5) data entry will be recorded in the LTFU Participant database.

The FU5 survey will be pursued for alive English- and Spanish-speaking adult and minor cases and sibling participants. There will be no expired participant FU5 survey.

For many participants, this will be the first time the Long-Term Follow-Up (LTFU) Study has asked them to complete a new survey in several years. SIs should be prepared to reintroduce the study, its mission, purpose, and goals; overcome barriers; and answer questions. In some circumstances participants will need to be re-consented to the LTFU Study. Consult with a Lead Survey Interviewer (LSI) or the Coordinator with any questions.

Procedures

Tools Needed:

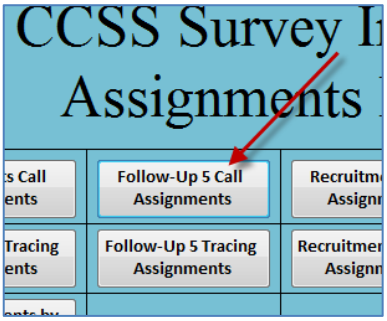
1. CCSS SI Assignments database (located on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
2. LTFU Participant database (located on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
3. MS Word **Phone Contact Log**, if applicable
   A. Original Cohort (located at *Z:\Departments\ECC\common\Interviewers\Original Cohort Call Logs - Reg db*)
   B. Expanded Cohort (located at *Z:\Departments\ECC\common\Interviewers\Expansion Survey Calls\Participant call logs*)
4. Call scripts (located at *Z:\Departments\ECC\common\Interviewers\FU5\Scripts*)
5. **Expired Participant Information Sheet** (located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*)
6. Paper copies of the Follow-Up 5 surveys (located at *Z:\Departments\ECC\common\Interviewers\FU5\Surveys*)
7. Accessory SOPs (located in the SOP Library, found on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*):
   A. **Pre-Post Call Checklist – Follow Up 5 Survey Calls**
   B. **Reconsenting During Follow-Up 5 Survey Calls**
   C. **LTFU Participant Database Data Entry**
   D. **Call Center Appointment Calendar**
   E. **Emailing Follow-Up 5 Survey Links**
   F. **Sending Spanish Thank You Notes**

OUTGOING CALLS

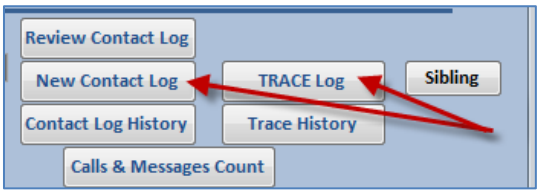
Outgoing calls begin three weeks following the mailing of the paper FU5 survey (approximately 6 weeks following the advance letter mailing). *SIs should NOT mention the iPad incentive during outgoing calls.* If an SI feels a particular situation warrants revisiting the incentive for the participant, s/he should email the participant's ID and circumstances to the Coordinator but still should not mention the incentive to the participant.

PRE-CALL PROCEDURES

1. Open the CCSS SI Assignments database and the LTFU Participant database.
2. Locate the first assigned participant in the CCSS SI Assignments database:
   A. Click on the **Follow-Up 5 Call Assignments** button.
   B. At the **SI ID:** prompt, enter your ID and click the **OK** button.
   C. The assignments display. The first participant to call will display at the top of the list, based on the date of the last FU5 call.



3. Review all appropriate fields in the LTFU Participant database to build a pre-call profile of the participant. See the **Pre-Post Call Checklist – Follow Up 5 Survey Calls**, located in the SOP library, for full details. If the participant will need to be reconsented, see the SOP titled **Reconsenting During Follow-Up 5 Survey Calls**.
4. Review any previous call history:
   A. In the MS Word **Phone Contact Log**, if available
   B. In the database call history – Click on the **Review Contact Log** button or the **Contact Log History** button.
5. Click the **Calls & Messages Count** button to see the number of calls and messages previously recorded in the LTFU Participant database for each telephone number in the past 60 days.
6. Initiate a new contact entry:
   A. If calling a previously confirmed number:
      i. Click on the **New Contact Log** button in the header of the participant's record.
      ii. Populate the **Time START** field with the time the call is dialed.
      iii. Populate the **Phone** field with the telephone number being dialed.



   B. If calling an unconfirmed number from Tracing:
      i. Click on the **Trace Log** button, then on the **New Record** button.
      ii. Populate the **Time START** field with the time the call is dialed.
      iii. Populate the **Phone** field with the telephone number being dialed.

DURING THE CALL PROCEDURES - General

1. Verify the identity of the person to whom you are speaking using standard procedures (name, DOB, etc.). Do NOT provide protected information to anyone other than the participant (case or sibling) or his/her legally authorized representative (LAR).

2. Follow the **FU5 Outgoing Calls Script**, located at *Z:\Departments\ECC\common\Interviewers\FU5\Scripts*.

3. If the participant **refuses** to complete the FU5 survey:
   A. Clarify if the participant is refusing only FU5 or refusing all further participation in the LTFU Study.
   B. Try to capture a reason for the refusal. If the participant's concerns can be addressed, do so. Offer a hold if more appropriate.

4. If the participant indicates s/he has **already returned the FU5 survey**:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. If a paper copy was returned more than one month ago, it may be lost in the mail. Offer to complete the survey over the telephone to avoid further losses.
      ii. If a paper copy was returned less than one month ago, it may still be in route. Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.
      iii. If an online survey was returned before today but the **Date Survey Returned** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday and Saturday will have the **Date Survey Returned** field populated the following Monday.
         a. Confirm the participant is referring to the LTFU Study's FU5 survey. The participant could be thinking of another study in which s/he participates.
         b. Try logging in to the online survey to determine the survey status. It may be that the participant neglected to click the **Submit** button.
      iv. If an online survey was returned today, the **Date Survey Returned** field will be populated on the next business day (Monday through Friday). Thank the participant for his/her involvement and advise that the study team will follow up if the survey is not received.
   C. Confirm all contact information (address, phone numbers, email address, additional contacts).

5. If we learn the participant is now **incarcerated**:
   A. Attempt to obtain the anticipated release date. (In a few months? Several years?)
   B. If the participant is expected to be available again in a reasonable period of time, ask what the best number will be to reach him/her when s/he is released.

6. If we learn that the case or sibling is now **deceased**:
   A. Offer condolences.
   B. Complete the **Expired Participant Information Sheet** with as much information as the party is able/willing to provide.
   C. Obtain contact information for an appropriate proxy.
   D. Thank the party for providing the information.
   E. NOTE: There is not a FU5 survey for deceased participants. Do not pursue a FU5 survey with the proxy.

7. If we learn that the participant has a legally authorized representative (**LAR**) or proxy (See a member of the LSI team or the Coordinator for assistance determining an authorized proxy for a non-deceased adult participant.):
   A. Gather the name(s) and contact information for the LAR(s)/proxy.

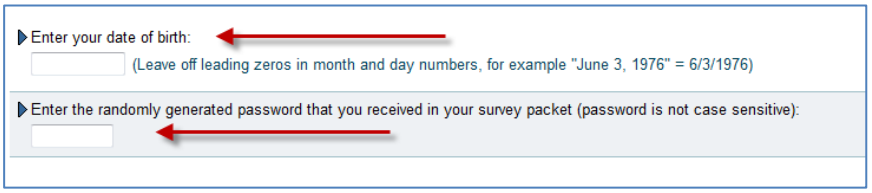
B. Determine if the participant has a disability and if the participant is able to legally represent himself or herself (e.g. Mother is a legal representative due to participant's hearing disability, but the participant is a cognitively able adult).

8. If the participant prefers to do the FU5 survey in **Spanish**, non-Spanish-speaking SIs should refer the participant to a Spanish-speaking SI. If there is not a Spanish-speaking SI available:
   A. Whenever possible, the non-Spanish-speaking SI should attempt to secure a survey appointment with the participant at a time when a Spanish-speaking SI will be available.
   B. Non-Spanish-speaking SIs can refer to the document titled **Basic Spanish Words**, located at *Z:\Departments\ECC\common\Interviewers\Spanish*.

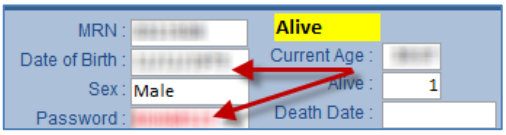
9. If the participant wants to **complete the survey on the telephone**, proceed to the section of this document titled *DURING THE CALL PROCEDURES – Completing the FU5 Survey*.

DURING THE CALL PROCEDURES – Completing the FU5 Survey

1. Click on the link to the appropriate survey. There will be four versions of the FU5 survey:
   A. Adult case survey (for survivor participants 18 years old and older): www.stjude.org/LTFUsurveyA OR https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name=CCSS_FU5
   B. Minor case survey (for survivor participants younger than 18 years old): link to be determined
   C. Adult sibling survey (for sibling participants 18 years old and older): www.stjude.org/LTFUsurveyS OR https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name=CCSS_FU5_Sibling
   D. Minor sibling survey (for sibling participants younger than 18 years old): https://live.datstathost.com/STJUDE-Collector/Survey.ashx?Name=CCSS_FU5_Minor&_RS_=1
   E. NOTE: There is no expired version of the FU5 survey. SIs should not pursue a FU5 survey with the proxy of a deceased participant.
2. On the survey login page, enter:
   A. The participant's DOB, found in the **Date of Birth** field of the LTFU Participant database header
   B. The participant's confirmation code, located in the **Password** field of the LTFU Participant database header



3. If the survey was previously started, either by the participant or by an SI, DatStat will display the options to **Start Over** or **Restore** the survey. In general, click on the **Restore** button to start the survey where it was previously closed.
4. Complete the survey with the appropriate party, reading all instructions and questions as written and including all possible answers. Carefully record responses accurately in the online survey.



POST-CALL PROCEDURES - General

1. **Complete the contact or trace log** record initiated in the pre-call procedures by populating the remaining fields. See the SOP titled **LTFU Participant Database Data Entry** for full details.

2. If **contact information** for the participant or his/her associate(s) was **confirmed or updated** during the call, update the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for details on documenting participant and associate contact information.
3. For confirmed updates to the **participant's name**, **Spanish status**, **date of birth**, **gender**, **incarceration status**, **vital status**, **LAR/proxy status** (including "no proxy available" situations), **hold status**, **tracing status**, **preferred contact time**, or **eligibility status**, see the SOP titled **LTFU Participant Database Data Entry** for details on documenting the changes.
4. For changes in **associate contact status** or **associate vital status**, see the SOP titled **LTFU Participant Database Data Entry** for details on documenting the changes.
5. For survey outcomes, continue to the section of this document titled *POST-CALL PROCEDURES – FU5 Survey Outcomes*.

POST-CALL PROCEDURES – FU5 Survey Outcomes

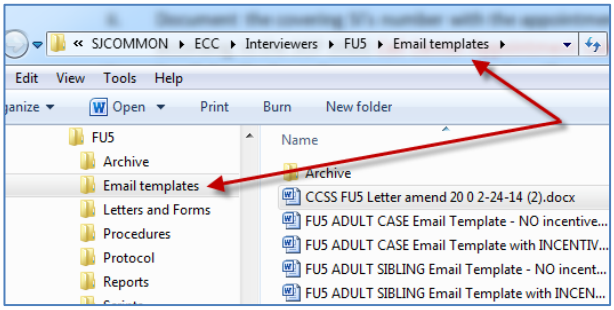
1. **Participant Indicated Paper Survey Previously Returned** – Enter a reminder in your MS Outlook calendar (*not* the Call Center appointment calendar) to follow-up with the participant 4 weeks from the approximate date of return.

2. **Appointment Made** –
   A. Write the appointment on the Call Center appointment calendar. See the SOP titled **Call Center Appointment Calendar** for details on how to document the appointment.
   B. If you will be covering the appointment, add the appointment to your personal MS Outlook calendar on the appropriate date/time.
   C. If the appointment needs to be assigned to another SI, the send an email with the CCSSID/SIBID and the appointment type/date/time to the LSI team, copying the Coordinator, requesting that the appointment be reassigned. If there is no time to follow this procedure (e.g. The appointment is scheduled for the same day, and the LSI team and Coordinator are out or unavailable before the appointment.):
      i. Coordinate with another SI to handle the appointment.
      ii. Document the covering SI's number with the appointment on the Call Center calendar according to the SOP titled **Call Center Appointment Calendar**.
      iii. Email details about the appointment and who will cover it to the LSI team, the Coordinator, and the covering SI.

3. **Request for Paper Survey Resend** –

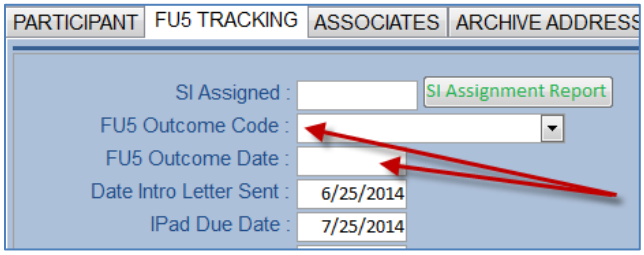
On the FU5 Tracking tab:
   A. **Resend Request** – Populate with 2-Survey.
   B. **Request Date** – Populate with the current date.
   C. **Notes** – Add a dated comment with your SI ID documenting the field changes.
   D. Note that Spanish-language surveys must be done on the telephone with an SI. Please check the **Spanish Status** field in the participant's header prior to requesting a resend of the paper survey.

4. **Request for FU5 Survey Link** – Note that Spanish-language surveys must be done on the telephone with an SI. Please check the **Spanish Status** field in the participant's header prior to sending a survey link.
   A. Send the survey link using the appropriate email template (adult vs. minor, case vs. sibling, incentive vs. non-incentive) located at



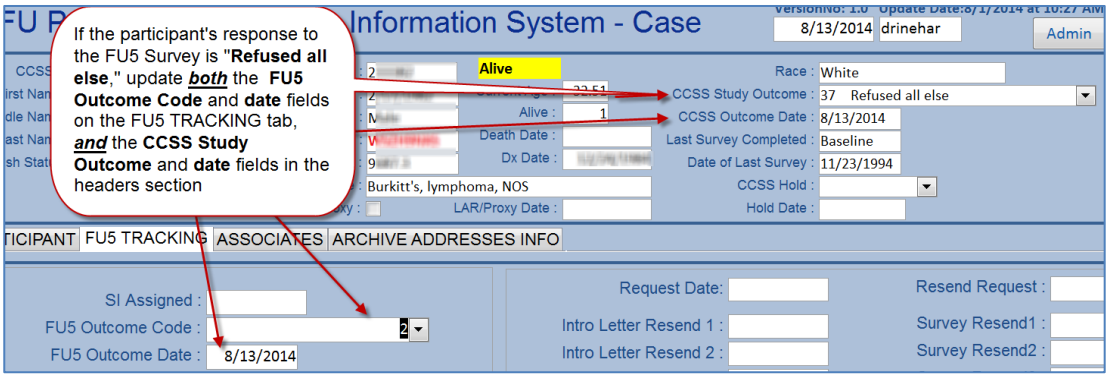
   Z:\Departments\ECC\common\Interviewers\FU5\Email templates. See the SOP titled **Emailing Follow-Up 5 Survey Links** for details on this procedure.
   B. Document the email communication in the contact log. The email sent to the participant should be documented separately from the telephone call. See the SOP titled **LTFU Participant Database Data Entry** for details on this procedure.

5. **Refusal** –
   A. Refused FU5 but agreed to stay in the LTFU Study:
      i. Document the FU5 refusal in the **Outcome** field of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.
      ii. Update the LTFU Participant database with the FU5 refusal:
         a. On the Participant tab, click on the **Notes** button. Enter a dated note with your SI ID documenting the refusal; specify that the participant refused FU5 only. Before closing the **Notes** form, copy the entire refusal note.
         b. On the FU5 Tracking tab:
            1. **Notes** – Paste the refusal note into the field at the bottom of the screen.
            2. **FU5 Outcome Code** – Populate with 1-Refused FU5. If this field is already populated, consult a member of the LSI team prior to modifying the value.
            3. **FU5 Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.



   B. Refused All Else:
      i. Document the refusal in the **Outcome** field of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.
      ii. Update the LTFU Participant database with the refusal:
         a. On the Participant tab, click on the **Notes** button. Enter a dated note with your SI ID documenting the refusal; specify that the participant refused all else. Before closing the **Notes** form, copy the entire refusal note.
         b. On the FU5 Tracking tab:

1. **Notes** – Paste the refusal note into the field at the bottom of the screen.
2. **FU5 Outcome Code** – Populate with 2-Refused All Else (CCSS). If this field is already populated, consult a member of the LSI team prior to modifying the value.
3. **FU5 Outcome Date** – Populate with the current date. If this field is already



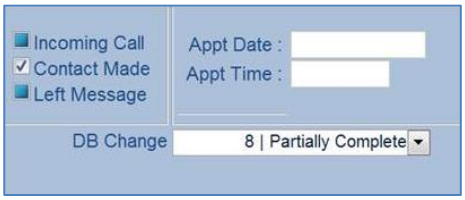
populated, consult a member of the LSI team prior to modifying the value.

c. In the header:
   1. **CCSS Study Outcome** – Populate with 37-Refused all else. If this field is already populated, consult a member of the LSI team prior to modifying the value.
   2. **CCSS Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.

6. **Partial FU5 Surveys**

A. Using the **Previous** and **Next** buttons on the online survey (NEVER use the back/forward buttons from your internet browser.), **review every completed page** of the online survey for accuracy and check for missing information or fields erroneously left blank. Complete any missing information on these pages before closing the survey.

B. **Complete the contact or trace log** for the call, specifying 8-Partially Complete in the **DB Change** field.



C. **Update the LTFU Participant database** with any confirmed contact information using the SOP titled **LTFU Participant Database Data Entry**.

D. On the FU5 Tracking tab:
   i. **Notes** – **Enter a dated note** with SI ID documenting the partial survey. Specify if Spanish was used. *Example: 6/16/2015: Partially completed FU5 survey through question R2 with Martha Stewart, mother and LAR of adult case. [162]*
   ii. **Survey Source**, **Survey Interviewer ID**, **Interview Status** – DO NOT populate these fields. The database update team will populate these fields when appropriate.

E. For **scheduled** surveys, note the partial survey outcome on the Call Center appointment calendar according to the SOP titled **Call Center Appointment Calendar**.

F. For **unscheduled** partial surveys, email the participant ID to the closing monitor to include the partially completed survey in the closing report.

G. **Update the Dry Erase Board** (DEB) FU5 survey tally to indicate the partial survey by writing a "p" instead of a tally mark.

7. **Completed FU5 Surveys**
   A. Using the **Previous** and **Next** buttons on the online survey (NEVER use the back/forward buttons from your internet browser.), **review every page of the online survey** for accuracy and check for missing information or fields erroneously left blank. Complete any missing information.
   B. **Complete the contact or trace log** for the call. If the participant has requested to NOT receive LTFU Study newsletters, document the request in the **DB Change** field of the contact or trace log, and an LSI or designee will make the appropriate entries in the record. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.
   C. **Update the LTFU Participant database** with any confirmed information using the SOP titled **LTFU Participant Database Data Entry**.
   D. Click the **Submit** button on the last page of the survey. Click the **Close** button on the next page, and then choose **Yes** at the next prompt to close the browser instance.
   E. On the **FU5 Tracking tab**:
      i. **Survey Interviewer ID** – Populate with your SI ID.
      ii. **Notes** – Add a dated note with your SI ID documenting completion of the FU5 survey. If the survey was completed in Spanish, specify this.
      iii. **Date Survey Returned**, **Survey Source**, **Interview Status** – DO NOT populate these fields.
   F. For a completed **scheduled** survey, place a check mark on the Call Center appointment calendar to indicate the kept appointment. See the SOP titled **Call Center Appointment Calendar** for full details.
   G. For a completed **unscheduled** survey, email the participant ID to the closing monitor to include the completed survey in the closing report.
   H. Note the completed FU5 survey with a tally mark on the **Dry Erase Board** (DEB).
   I. If the survey was completed with the participant over the phone in **Spanish**:
      i. Document the Spanish survey completion in the **DB Change** field of the database contact or trace log, and an LSI or designee will make the appropriate entries in the record. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.
      ii. Complete all online and database data entry, as indicated above.
      iii. Confirm the **Spanish Status** field in the header is properly updated. See the SOP titled **LTFU Participant Database Data Entry** for details.
      iv. Send an email to CRA2s in charge of the study, copying the LSI team and the Call Center Coordinator, that a FU5 survey has been completed in Spanish. Include the CCSSID or SIBID in the **Subject** line and in the body of the email.
      v. Create a personalized Spanish thank-you card insert to the participant. See the SOP titled **Sending Spanish Thank You Notes** for details.
      vi. Deliver the thank-you card insert to the CRA2 team. See the SOP titled **Sending Spanish Thank You Notes** for details.

Revision Record Printed 10/31/2016 9:05 AM

[279] Current Filename:		Follow Up 5 Survey Outgoing Calls ver 1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/13/14	R. Massey, A. Oyuela, D. Rinehart	Initial Development
1.1	10/2/14	R. Massey	Content Revision
1.2	4/21/15	R. Massey	Content Revision
1.3	10/20/2016	A. Cobble	Content Revision

Follow-Up 6 Survey Non-Responder Calls

Background

Approximately 500 FU6 surveys will be mailed per week. Participants that have not returned their survey and have a documented email address will be sent a reminder email 2 weeks after the initial mailing. Outgoing calls will begin to FU6 survey non-responders 3 weeks after the initial survey mailing.

SIs should be prepared to reintroduce the study, its mission, purpose, and goals; overcome barriers; and answer questions. In some circumstances participants will need to be re-consented to the LTFU Study. Consult with a Lead Survey Interviewer (LSI) or with the Coordinator with any questions.

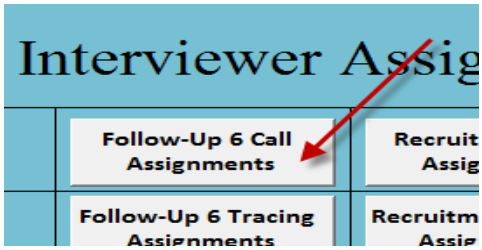
Procedures

Tools Needed:

1. CCSS SI Assignments database (located on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
2. LTFU Participant database (located on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
3. MS Word **Phone Contact Log**, if applicable
   A. Original Cohort (located at *Z:\...\Interviewers\Original Cohort Call Logs - Reg db*)
   B. Expanded Cohort (located at *Z:\...\Interviewers\Expansion Survey Calls\Participant call logs*)
4. Call scripts (located at *Z:\...\Interviewers\FU6\Scripts*)
5. **Expired Participant Information Sheet** (located at *Z:\...\Interviewers\Calling Tools*)
6. Paper copies of the Follow-Up 6 surveys (located at *Z:\...\Interviewers\FU6\Surveys*)
7. Accessory SOPs (located in the SOP Library, found on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*):
   A. **Pre-Post Call Checklist – Follow Up 6 Survey Calls**
   B. **Reconsenting During Follow-Up 6 Survey Calls**
   C. **LTFU Participant Database Data Entry**
   D. **Call Center Appointment Calendar**
   E. **Emailing Follow-Up 6 Survey Links**
   F. **Sending Spanish Thank You Notes**

OUTGOING CALLS

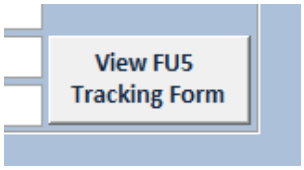
PRE-CALL PROCEDURES



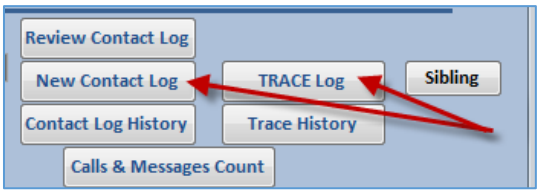
1. Open the CCSS SI Assignments database and the LTFU Participant database.
2. Locate the first assigned participant in the CCSS SI Assignments database:
   A. Click on the **Follow-Up 6 Call Assignments** button.
   B. At the **SI ID:** prompt, enter your ID and click the **OK** button.
   C. The assignments display. The first participant to call will display at the top of the list, based on the date of the last FU6 call.
3. Review all appropriate fields in the LTFU Participant database to build a pre-call profile of the participant. See the **Pre-Post Call Checklist – Follow-Up 6 Survey Calls**, located in the SOP library, for full details. If

the participant will need to be reconsented, see the SOP titled **Reconsenting During Follow-Up 6 Survey Calls**.

4. Review any previous call history:
   A. In the MS Word **Phone Contact Log**, if available
   B. In the database call history – Click on the **Review Contact Log** button or the **Contact Log History** button.
5. Review all **Notes:**
   i. Participant tab
   ii. Associates
   iii. HIPAA – Participation History (***View FU5 Tracking Form***)
   iv. FU6 Tracking



6. Click the **Calls & Messages Count** button to see the number of calls and messages previously recorded in the LTFU Participant database for each telephone number in the past 60 days.
7. Initiate a new contact entry:
   A. If calling a previously confirmed number:
      i. Click on the **New Contact Log** button in the header of the participant's record.
      ii. Populate the **Contact Mode** field with "1. Phone".
      iii. Populate the **Phone** field with the telephone number being dialed.



   B. If calling an unconfirmed number from Tracing:
      i. Click on the **Trace Log** button, then on the **New Record** button.
      ii. Populate the **Contact Mode** field with "1. Phone".
      iii. Populate the **Phone** field with the telephone number being dialed.

DURING THE CALL PROCEDURES - General

1. Verify the identity of the person to whom you are speaking using standard procedures (name, DOB, etc.). Do NOT provide protected information to anyone other than the participant (case or sibling) or his/her legally authorized representative (LAR).
2. Follow the **FU6 Outgoing Calls Script**, located at *Z:\...\Interviewers\FU6\Scripts*.
3. If the participant **refuses** to complete the FU6 survey:
   A. Clarify if the participant is refusing only FU6 or refusing all further participation in the LTFU Study.
   B. Try to capture a reason for the refusal. If the participant's concerns can be addressed, do so. Offer a hold if more appropriate.
4. If the participant indicates s/he has **already returned the FU6 survey**:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. If a paper copy was returned more than one month ago, it may be lost in the mail. Offer to complete the survey over the telephone to avoid further losses.
      ii. If a paper copy was returned less than one month ago, it may still be in route. Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.
      iii. If an online survey was returned before today but the **Date Survey Received** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday and Saturday will have the **Date Survey Received** field populated the following Monday.

a. Confirm the participant is referring to the LTFU Study's FU6 survey. The participant could be thinking of another study in which s/he participates.
b. Try logging in to the online survey to determine the survey status. It may be that the participant neglected to click the **Submit** button.

iv. If an online survey was returned today, the **Date Survey Received** field will be populated on the next business day (Monday through Friday). Thank the participant for his/her involvement and advise that the study team will follow up if the survey is not received.

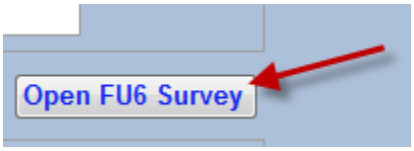
C. Confirm all contact information (address, phone numbers, email address, additional contacts).

5. If we learn the participant is now **incarcerated**:
   A. Attempt to obtain the anticipated release date. (In a few months? Several years?)
   B. If the participant is expected to be available again in a reasonable period of time, ask what the best number will be to reach him/her when s/he is released.
6. If we learn that the case or sibling is now **deceased**:
   A. Offer condolences.
   B. Complete the **Expired Participant Information Sheet** with as much information as the party is able/willing to provide.
   C. Obtain contact information for an appropriate proxy.
   D. Thank the party for providing the information.
   E. NOTE: There is not a FU6 survey for deceased participants. Do not pursue a FU6 survey with the proxy.
7. If we learn that the participant has a legally authorized representative (**LAR**) or proxy (See a member of the LSI team or the Coordinator for assistance determining an authorized proxy for a non-deceased adult participant.):
   A. Gather the name(s) and contact information for the LAR(s)/proxy.
   B. Determine if the participant has a disability and if the participant is able to legally represent himself or herself (e.g. Mother is a legal representative due to participant's hearing disability, but the participant is a cognitively able adult).
8. If the participant prefers to do the FU6 survey in **Spanish**, non-Spanish-speaking SIs should refer the participant to a Spanish-speaking SI. If there is not a Spanish-speaking SI available:
   A. Whenever possible, the non-Spanish-speaking SI should attempt to secure a survey appointment with the participant at a time when a Spanish-speaking SI will be available.
   B. Non-Spanish-speaking SIs can refer to the document titled **Basic Spanish Words**, located at *Z:\...\Interviewers\Spanish*.
9. If the participant wants to **complete the survey on the telephone**, proceed to the section of this document titled *DURING THE CALL PROCEDURES – Completing the FU6 Survey*.

DURING THE CALL PROCEDURES – Completing the FU6 Survey

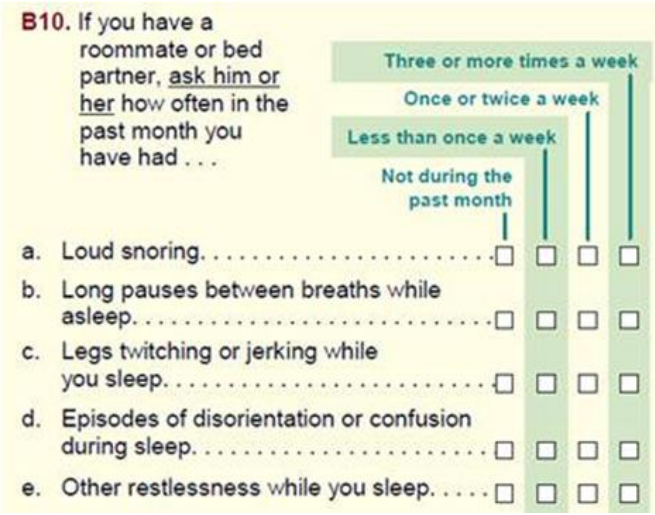
Note: there are 7 survey versions, FU6 Short, FU6 Medium, FU6 Long for Case and Sibling adults, and one Sibling minor survey. There is no FU6 survey for expired pts.

1. From the LTFU Pt Database, FU6 Tracking tab, click the button, "**Open FU6 Survey**", and begin the survey. **IMPORTANT NOTE:** *DO NOT* click this button *UNLESS* you have the pt on the phone and are ready to complete the survey, otherwise you will create a "Partial" survey, which may confuse the pt, if they decide to do the survey online themselves.



2. If the survey was previously started, either by the participant or by an SI, DatStat will display the options to "**Start Over"** or "**Restore"** the survey. In general, click on the "**Restore"** button to start the survey where it was previously closed.
3. **IMPORTANT NOTE REGARDING FU6 SURVEY QUESTION B10**:

   During the phone survey, if the pt says their partner is not available to ask this question, ask the pt, "What do you think your partner would say?" If they do not know, set a call-back appointment and continue with the survey. Do not submit the survey until after gaining the answer to this question: it will be a "Partial Survey" (see the section, "Partial FU6 Surveys")
4. Complete the survey with the appropriate party, reading all instructions and questions as written and including all possible answers. Carefully record responses accurately in the online survey.



POST-CALL PROCEDURES - General

1. **Complete the contact or trace log** record initiated in the pre-call procedures by populating the remaining fields. See the SOP titled **LTFU Participant Database Data Entry** for full details.
2. If **contact information** for the participant or his/her associate(s) was **confirmed or updated** during the call, update the LTFU Participant database. See the SOP titled **LTFU Participant Database Data Entry** for details on documenting participant and associate contact information.
3. For confirmed updates to the **participant's name**, **Spanish status**, **date of birth**, **gender**, **incarceration status**, **vital status**, **LAR/proxy status** (including "no proxy available" situations), **hold status**, **tracing status**, **preferred contact time**, or **eligibility status**, see the SOP titled **LTFU Participant Database Data Entry** for details on documenting the changes.
4. For changes in **associate contact status** or **associate vital status**, see the SOP titled **LTFU Participant Database Data Entry** for details on documenting the changes.
5. For survey outcomes, continue to the section of this document titled *POST-CALL PROCEDURES – FU6 Survey Outcomes*.

POST-CALL PROCEDURES – FU6 Survey Outcomes

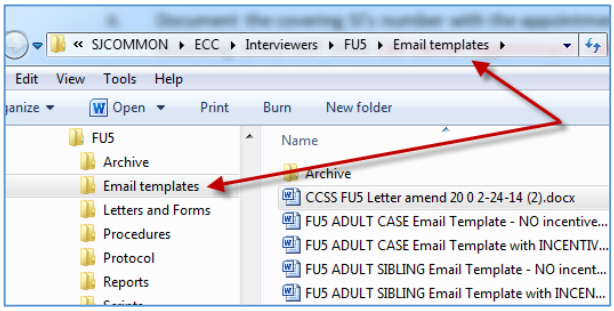
1. **Participant Indicated Paper Survey Previously Returned** – Enter a reminder in your MS Outlook calendar (*not* the Call Center appointment calendar) to follow-up with the participant 4 weeks from the approximate date of return.
2. **Appointment Made** –
   A. Write the appointment on the Call Center appointment calendar. See the SOP titled **Call Center Appointment Calendar** for details on how to document the appointment.
   B. If you will be covering the appointment, add the appointment to your personal MS Outlook calendar on the appropriate date/time.
   C. If the appointment needs to be assigned to another SI, the send an email with the CCSSID/SIBID and the appointment type/date/time to the LSI team, copying the Coordinator, requesting that the appointment be reassigned. If there is no time to follow this procedure (e.g. The appointment is scheduled for the same day, and the LSI team and Coordinator are out or unavailable before the appointment.):

i. Coordinate with another SI to handle the appointment.
ii. Document the covering SI's number with the appointment on the Call Center calendar according to the SOP titled **Call Center Appointment Calendar**.
iii. Email details about the appointment and who will cover it to the LSI team, the Coordinator, and the covering SI.

3. **Request for Paper Survey Resend** – On the FU6 Tracking tab:

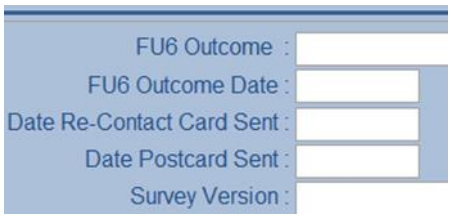
A. **Resend Request** – Populate with 3-Survey.
B. **Request Date** – Populate with the current date.
C. **Notes** – Add a dated comment with your SI ID documenting the field changes.
D. Note that Spanish-language surveys must be done on the telephone with an SI. Please check the **Spanish Status** field in the participant's header prior to requesting a resend of the paper survey.

4. **Request for FU6 Survey Link** – Note that Spanish-language surveys must be done on the telephone with an SI. Please check the **Spanish Status** field in the participant's header prior to sending a survey link.



A. Send the survey link using the appropriate email template (adult vs. minor, case vs. sibling) located at *Z:\...\Interviewers\FU6\Email templates*. See the SOP titled **Emailing Follow-Up 6 Survey Links** for details on this procedure.
B. Document the email communication in the contact log. The email sent to the participant should be documented separately from the telephone call. See the SOP titled **LTFU Participant Database Data Entry** for details on this procedure.

5. **Refusal** –
A. Refused FU6 but agreed to stay in the LTFU Study:
i. Document the FU6 refusal in the **Outcome** field of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.
ii. Update the LTFU Participant database with the FU6 refusal:
a. On the Participant tab, click on the **Notes** button. Enter a dated note with your SI ID documenting the refusal; specify that the participant refused FU6 only. Before closing the **Notes** form, copy the entire refusal note.
b. On the FU6 Tracking tab:
1. **Notes** – Paste the refusal note into the field at the bottom of the screen.
2. **FU6 Outcome Code** – Populate with 1-Refused FU6. If this field is already populated, consult a member of the LSI team prior to modifying the value.
3. **FU6 Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.



B. Refused All Else:
i. Document the refusal in the **Outcome** field of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.
ii. Update the LTFU Participant database with the refusal:

a. On the Participant tab, click on the **Notes** button. Enter a dated note with your SI ID documenting the refusal; specify that the participant refused all else. Before closing the **Notes** form, copy the entire refusal note.

b. On the FU6 Tracking tab:

1. **Notes** – Paste the refusal note into the field at the bottom of the screen.
2. **FU6 Outcome Code** – Populate with 2-Refused All Else (CCSS). If this field is already populated, consult a member of the LSI team prior to modifying the value.

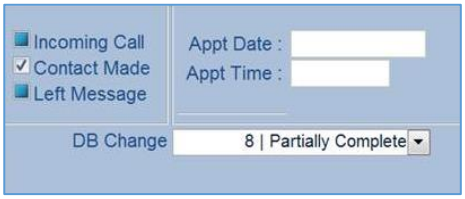
c. **FU6 Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.

In the header:

1. **CCSS Study Outcome** – Populate with 37-Refused all else. If this field is already populated, consult a member of the LSI team prior to modifying the value.
2. **CCSS Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.

6. **Partial FU6 Surveys** –

A. Using the **Previous** and **Next** buttons on the online survey (NEVER use the back/forward buttons from your internet browser.), **review every completed page** of the online survey for accuracy and check for missing information or fields erroneously left blank. Complete any missing information on these pages before closing the survey.



B. **Complete the contact or trace log** for the call, specifying 8-Partially Complete in the **DB Change** field.

C. **Update the LTFU Participant database** with any confirmed contact information using the SOP titled **LTFU Participant Database Data Entry**.

D. On the FU6 Tracking tab:

i. **Notes** – **Enter a dated note** with SI ID documenting the partial survey. Specify if Spanish was used. *Example: 6/7/2017: Partially completed FU6 survey through question C.4. with Martha Stewart, mother and LAR of adult case. [162]*

ii. **Survey Source**, **Survey Interviewer ID**, **Interview Status** – DO NOT populate these fields. The database update team will populate these fields when appropriate.

E. For **scheduled** surveys, note the partial survey outcome on the Call Center appointment calendar according to the SOP titled **Call Center Appointment Calendar**.

F. For **unscheduled** partial surveys, email the participant ID to the closing monitor to include the partially completed survey in the closing report.

G. **Update the Dry Erase Board** (DEB) FU6 survey tally to indicate the partial survey by writing a "p" instead of a tally mark.

7. **Completed FU6 Surveys** –

A. Using the **Previous** and **Next** buttons on the online survey (NEVER use the back/forward buttons from your internet browser.), **review every page of the online survey** for accuracy and check for missing information or fields erroneously left blank. Complete any missing information.

B. **Complete the contact or trace log** for the call. If the participant has requested to NOT receive LTFU Study newsletters, document the request in the **DB Change** field of the contact or trace log, and an LSI or designee will make the appropriate entries in the record. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.

C. **Update the LTFU Participant database** with any confirmed information using the SOP titled **LTFU Participant Database Data Entry**.

D. Click the **Submit** button on the last page of the survey. Click the **Close** button on the next page, and then choose **Yes** at the next prompt to close the browser instance.

E. On the **FU6 Tracking tab**:
   i. **Survey Interviewer ID** – Populate with your SI ID.
   ii. **Notes** – Add a dated note with your SI ID documenting completion of the FU6 survey. If the survey was completed in Spanish, specify this.
   iii. **Date Survey Returned**, **Survey Source**, **Interview Status** – DO NOT populate these fields.

F. For a completed **scheduled** survey, place a check mark on the Call Center appointment calendar to indicate the kept appointment. See the SOP titled **Call Center Appointment Calendar** for full details.

G. For a completed **unscheduled** survey, email the participant ID to the closing monitor to include the completed survey in the closing report.

H. Note the completed FU6 survey with a tally mark on the **Dry Erase Board** (DEB).

I. If the survey was completed with the participant over the phone in **Spanish**:
   i. Document the Spanish survey completion in the **DB Change** field of the database contact or trace log, and an LSI or designee will make the appropriate entries in the record. See the SOP titled **LTFU Participant Database Data Entry** for details on using the contact and trace logs.
   ii. Complete all online and database data entry, as indicated above.
   iii. Confirm the **Spanish Status** field in the header is properly updated. See the SOP titled **LTFU Participant Database Data Entry** for details.
   iv. Send an email to CRA2s in charge of the study, copying the LSI team and the Call Center Coordinator, that a FU6 survey has been completed in Spanish. Include the CCSSID or SIBID in the **Subject** line and in the body of the email.
   v. Create a personalized Spanish thank-you card insert to the participant. See the SOP titled **Sending Spanish Thank You Notes** for details.
   vi. Deliver the thank-you card insert to the CRA2 team. See the SOP titled **Sending Spanish Thank You Notes** for details.

Revision Record — Printed

[319] Current Filename:		Follow-Up 6 Survey Non-Responder Calls v1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/08/2017	A. Cobble, D. Rinehart, R. Daniels	Initial Development

Generating Weekly Recruitment Status Update Reports

Background

This document outlines steps to generate two status report updates of recruitment efforts conducted at St. Jude. Both reports are generated from an EXCEL spreadsheet which is updated weekly (on **Tuesday**), based on queries run from the Recruitment database. *Effective 5/21/12, still update reports weekly, but print/distribute only once a month.*

Weekly record of recruitment, across all institutions recruited at St.Jude

section 1					section 2			
Date	Total Eligible, in recruitment	Total Signed HIPAA	% Total Signed/ Eligible	wk's HIPAA gain	Total VH	% Total VH / HIPAA	wk's VH gain	% wk's VH/ HIPAA
2/22/2011	9,080	3,110	34.3%		351	11.3%		
3/1/2011	9,080	3,230	35.6%	120	391	12.1%	40	33.3%
3/8/2011	9,080	3,278	36.1%	48	427	13.0%	36	75.0%
3/15/2011	9,080	3,363	37.0%	85	458	13.6%	31	36.5%
3/22/2011	9,080	3,423	37.7%	60	509	14.9%	51	85.0%
3/29/2011	9,078	3,520	38.8%	97	552	15.7%	43	44.3%

The **ORANGE** report (orange and white alternating rows) contains 2 sections. Section 1 presents total eligible, the number of signed HIPAAs, the signed HIPAAs' percentage of total eligible, and the week's HIPAA gain. Section 2 presents information concerning **verbal** HIPAAs: total number of verbal HIPAAs, verbal HIPAAs' percentage of all HIPAAs, the week's Verbal HIPAA gain, and verbal HIPAAs' percentage of the week's HIPAA total.

The **GREEN** report (green and white alternating rows) presents a weekly summary of recruitments for EACH institution recruited by St. Jude. By institution, columns present the institution's cumulative number of recruits, the percentage recruited out of those eligible, the HIPAA gain for the week, and the number of verbal HIPAAs obtained for the week. The top of the institution's columns shows the date recruitment started and the total eligible for the institution.

	1/7/2010	Sloan (9)			2/2/2010	CHOP (20)		
wk#	∑ eligible:	657	%elig	+ VH	∑ eligible:	1014	%elig	+ VH
1	1/11/2010	7	1.07%		2/15/2010	25	2.47%	
2	1/18/2010	38	5.78%	31	2/22/2010	73	7.20%	48
3	1/25/2010	77	11.72%	39	3/1/2010	135	13.31%	62
4	2/1/2010	89	13.55%	12	3/8/2010	167	16.47%	32
5	2/8/2010	105	15.98%	16	3/15/2010	188	18.54%	21
6	2/15/2010	119	18.11%	14	3/22/2010	203	20.02%	15
7	2/22/2010	131	19.94%	12	3/29/2010	222	21.89%	19

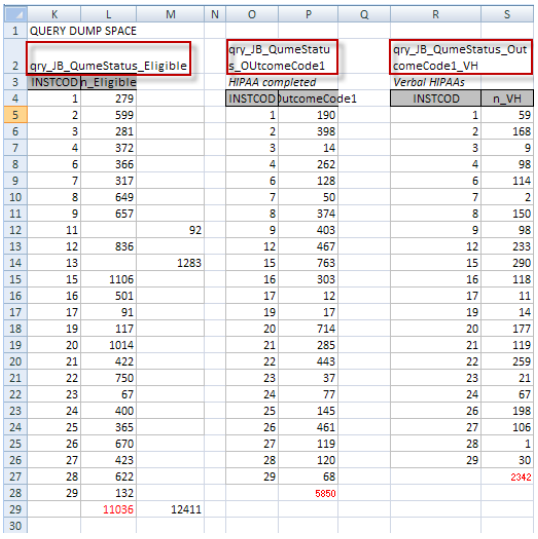
Procedures

Steps in Collecting Data for the ORANGE Report

Open the Excel spreadsheet: **Cumulative Receipt Log-PORTRAIT.xlsx**

- Go to the QUME tab.
- Rows 1-30 provide a place to "dump" the query results, as well as query names used.

*Note: Because you paste query results over the existing query dump, make sure you have a printed copy of the previous week's "dump space" for your records *before* proceeding!



	K	L	M	N	O	P	Q	R	S
1	QUERY DUMP SPACE								
2	qry_JB_QumeStatus_Eligible				qry_JB_QumeStatus_OUtcomeCode1			qry_JB_QumeStatus_OutcomeCode1_VH	
3	INSTCOD	n_Eligible			*HIPAA completed*			*Verbal HIPAAs*	
4	1	279			INSTCOD	utcomeCode1		INSTCOD	n_VH
5	2	599			1	190		1	59
6	3	281			2	398		2	168
7	4	372			3	14		3	9
8	6	366			4	262		4	98
9	7	317			6	128		6	114
10	8	649			7	50		7	2
11	9	657			8	374		8	150
12	11		92		9	403		9	98
13	12	836			12	467		12	233
14	13		1283		15	763		15	290
15	15	1106			16	303		16	118
16	16	501			17	12		17	11
17	17	91			19	17		19	14
18	19	117			20	714		20	177
19	20	1014			21	285		21	119
20	21	422			22	443		22	259
21	22	750			23	37		23	21
22	23	67			24	77		24	67
23	24	400			25	145		26	198
24	25	365			26	461		27	106
25	26	670			27	119		28	1
26	27	423			28	120		29	30
27	28	622			29	68			2342
28	29	132				5850			
29		11036	12411						
30									

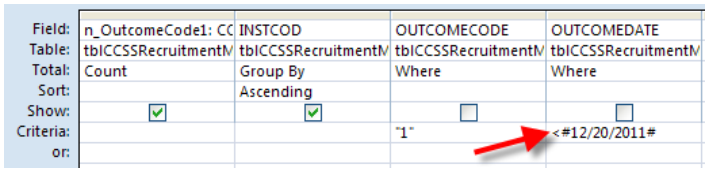
Open the **Recruitment database**. You will run 3 queries which show values for each institution:

- qry_JB_QumeStatus_Eligible: total eligible
  qry_JB_QumeStatus_OutcomeCode1: number of signed HIPAA's
- qry_JB_QumeStatus_OutcomeCode1_VH: number of verbal HIPAAs

1. Double click **qry_JB_QumeStatus_Eligible** to run the query. (This query does not need to have any criteria adjusted.) Use the mouse to select all, then copy and paste into the Excel file's QUME tab, over the prior results in the Columns K and L in the Query Dump Space. Since we are currently not recruiting Inst 11 and 13, enter those values in column M, and then clear them from column L. The number in red at the bottom of the n_Eligible column is the sum of the values and is the new number used in the Orange report. (The number in column M sums all cases, including institutions 11 and 13.)

2. Now run the query to check for all HIPAAs obtained to date. Open **qry_JB_QumeStatus_OutcomeCode1** in design view, so you can adjust the criteria.

   a. In the OUTCOMEDATE field, change the *less than date* to Tuesday's date. (Usually this report is run on a Tuesday, so the date will be less than "today's" date; however, if you run the report on a Wednesday, still use Tuesday's date).

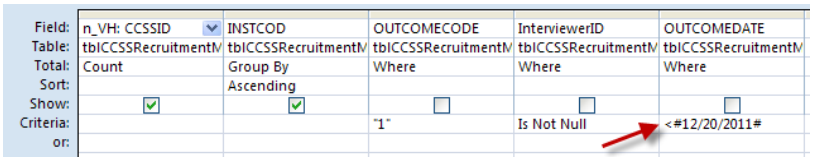


   b. Save and then run the query.

   c. Copy and paste the results to your spreadsheet, in Columns O and P.

3. Now run the query to check for number of verbal HIPAAs obtained to date. Open **qry_JB_QumeStatus_OutcomeCode1_VH** in design view, so you can adjust the criteria.

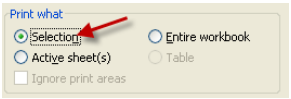
   a. In the OUTCOMEDATE field, change the *less than date* to Tuesday's date (as with the previous query).



   b. Save and then run the query.

   c. Copy and paste these results to the spreadsheet, in Columns R and S.

4. On the QUME tab, select the entire query dump space range (K1…S29), and then print one copy of the selected range. *Keep this in the Weekly Signed HIPAA notebook.*

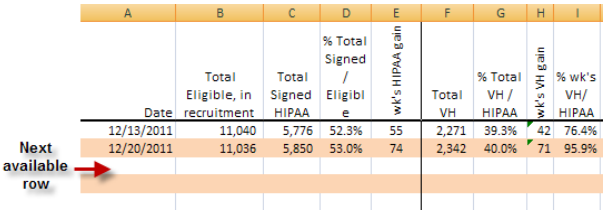


5. Compare each institution's eligible numbers from this week with the values on the previous week's print out. Note any changes in eligibility numbers. Circle the ones that changed per institution, as you will need to use this data for the Green report.

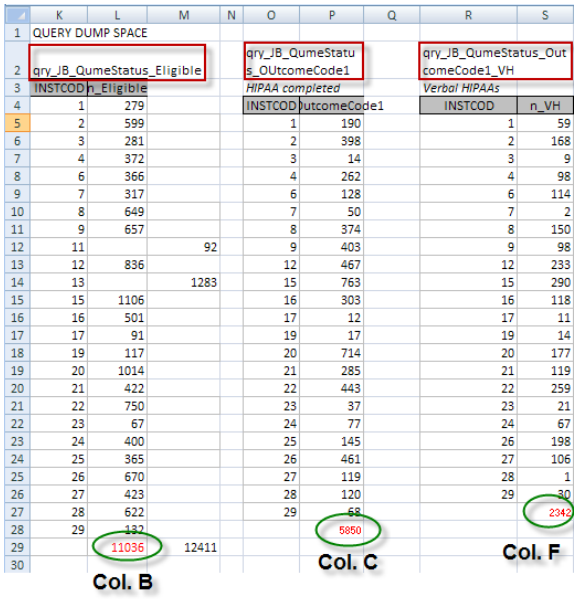
Updating the Orange Report

Now you are ready to add new data to the orange report.

1. Go to the next available row at the bottom of the report. Add the Tuesday date used in the Qume queries.



2. In Column B, enter the total value from the first query (total eligible in recruitment).
3. In Column C, enter the total value from the second query (Total signed HIPAAs).
4. Column D is automatically generated.
5. To get the value for Column E, copy and paste the formula from a prior cell in column E with similar formatting (same color row).
6. In Column F, enter the total value from the third query (Total verbal HIPAAs).
7. Column G is automatically calculated.
8. For Columns H and I, copy and paste from prior cells with similar formatting (see step 5).



Printing the Orange Report

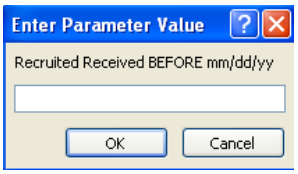
The print range for the QUME sheet is set to print the orange report's range. Print 8 copies of the sheet on a color printer.

Steps in Collecting Data for the GREEN Report

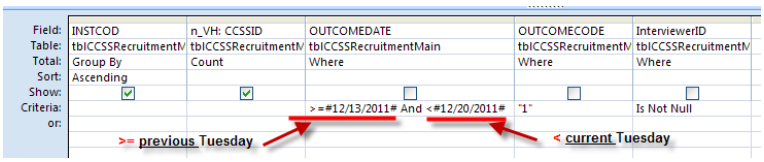
1. Open the Excel spreadsheet: **Cumulative Receipt Log-PORTRAIT.xlsx**
   - Go to the tab WKByWK-based on ELIGIBLE w VH.

2. Open the Recruitment database. You will need to run the following 2 queries:
   - qryStatus-CountInstHIPAA-byDate-OutcomeCode1: to total, by institution, the number of HIPAAs received before the data entered on input.
   - qryStatus-CountVerbalHIPAA-forWeek: to determine the number of Verbal HIPAAs, by institution, for a specified one week date range.

3. Double click on **qryStatus-CountInstHIPAA-byDate-OutcomeCode1** to run the query. You normally run this query on Tuesday morning each week in order to count cases recruited up to, but not including, Tuesday.
   a. At the prompt (Enter Parameter Value: Recruited Received BEFORE mm/dd/yy), enter Tuesday's date.
   b. Print the query output.
   c. NOTE: if you are running the report after Tuesday, you should still enter Tuesday's date at the prompt.



4. Next run **qryStatus-CountVerbalHIPAA-forWeek.** Open the query in Design View so you can modify the criteria.
   a. In the OUTCOMEDATE field, change the dates to reflect a range that is > or = to the *previous* Tuesday and less than the *current* Tuesday, (which is usually the day you run the query).
   b. Save the query and print the query output.



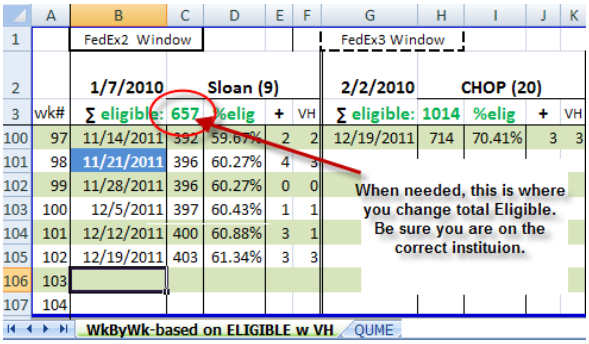
Lead CRA

Updating the Green Report

Now you are ready to add the new data to the cumulative green report. Use the results from the two "Status-Count…" queries as well as results from the **qry_JB_QumeStatus_Eligible** used for the Orange report.

1. Use **WKByWK-based on ELIGIBLE w VH** tab.

2. First update any changes in an institution's total number eligible. (Refer to the printed copy of the eligible query where you circled the institutions whose total eligible changed from the previous week.) Locate the institution's set of columns, then go to row 3. Enter the new total eligible number in the cell to the right of the ∑**eligible** label.



3. Now enter the total recruited and weekly VH counts, institution by institution. Begin with the institution farthest to the left (09).

   a. Go to the first blank Wk# row at the bottom of the institution's date column. Enter the date for the Monday of the week.
   b. Refer to the printed copy of **qryStatus-CountInstHIPAA-byDate-OutcomeCode1**. Locate the institution in the list. Enter the HIPAAreceived value in the institution's column to the right of the date you entered. Mark through the institution's instcod on the hard copy after you have entered its HIPAAreceived value in the report.
   c. The next column (% elig) contains a percent which will be automatically calculated.
   d. The next column (+) presents the number of HIPAAs gained during the week. The value is calculated with a formula. Copy and paste the formula from a prior cell with similar formatting (same color row).

HIPAAreceived	INSTC	instname
190	1	University of Minnesota
398	2	Denver Childrens
14	3	Pittsburgh
262	4	Children's Hospital at Stanford
128	6	Emory
50	7	Washington National
374	8	U.T.M.D. Anderson Cancer Center
403	9	Memorial Sloan Kettering Cancer Center
467	12	Seattle Children's Hospital
763	15	St. Jude Children's Research Hospital
303	16	Nationwide
12	17	Roswell Park
17	19	Minneapolis
714	20	Children's Hospital of Philadelphia
285	21	StLouis Childrens
443	22	Childrens Los Angeles
37	23	UCLA
77	24	Riley
145	25	UAB
461	26	Michigan
119	27	UT SW
120	28	Texas Childrens
68	29	City of Hope

   e. The next column (VH) presents the number of Verbal HIPAAs gained for the institution during the week. Refer to the printed copy of **qryStatus-CountVerbalHIPAA-forWeek**. Locate the institution (by instcod) in the list. Then enter its n_VH value in the "VH" column on the green report. Mark through the institution's instcod on the hard copy after you have entered its n_VH value in the report. *Note: The number of VH for the week should not be greater than the total number of HIPAAs gained for the week.*

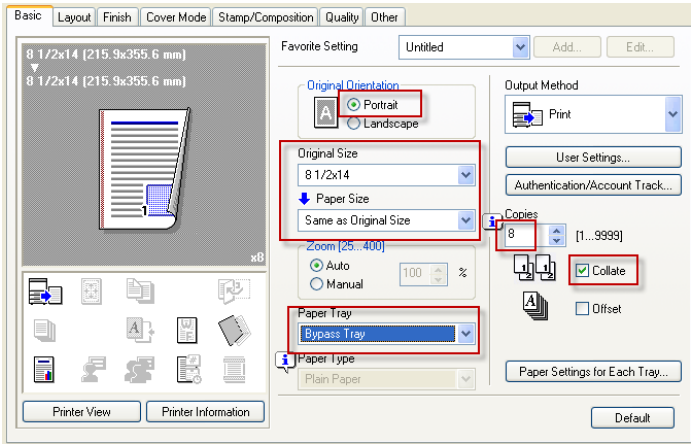
INSTCOD	n_VH
1	4
2	4
3	9
4	2
6	6
8	5
9	3
12	2
15	2
16	2
20	3
21	3
22	8
24	4
26	2
27	7
29	4

4. Proceed to the next institution, working your way from left to right in the green report.
5. *Keep the annotated copies of both queries with the Weekly Signed HIPAA notebook.*
6. Be sure to save your worksheet when you are finished. (You will be adding to it each week.)

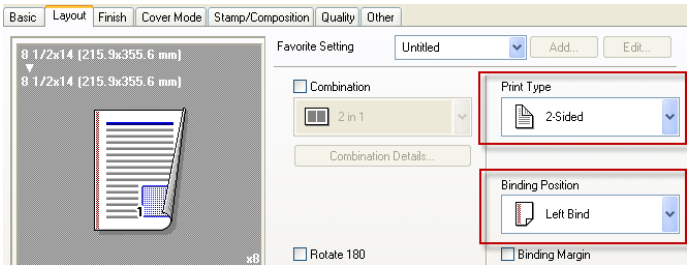
Printing the Green Report

Print 8 copies in color, on legal paper, on both sides of the paper. Use the printer's bypass tray.

1. Use the Properties button on the Print screen to make the following settings:
   a. Basic tab
      i. Paper Tray: Bypass Tray
      ii. Copies: 8
      iii. Collate (yes)
      iv. Original Size 8 ½ x 14
      v. Paper Size: Same as Original Size



   b. Layout tab
      i. Print Type: 2-Sided
      ii. Binding Position: Left Bind



2. Print after setting print job properties. If there is no paper in bypass tray, printer will hold the job until there is; then once you place legal paper in the bypass tray, the print job should start. (If you send the job to the printer *before* putting the paper in the bypass, it is best to check and make sure there is no other paper in the bypass tray before printing!)

Assembling Reports

Assemble the two reports, placing the orange report on top of the green report. Staple the reports together in the upper left corner.

Revision Record Printed 7/10/2012 1:37 PM

Current Filename:		Generating Weekly Recruitment Status Update Reports ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	12/21/11	L. Harrison	Initial Development
1.1	5/22/12	J.Bates	Print once a month

Guide to CCSS Expansion Baseline "Print Tables"

Background

When we print surveys using the Teleform Automerge Publisher program, the publisher program merges information about each person specified in the production list, in order to individualize each survey. The merged information always includes the CCSSID of the individual, and will also include other information, based the requirements of the specific survey. The Automerge Publisher program gets the merge information from a special "print table" in the database. Each survey version necessarily has its own unique print table. Print tables are separate from the table that "feeds" the data entry forms we see on screen. The print tables are "loaded" with their contents when the individual is first added to the study and are NOT automatically updated when data are changed using the data entry form.

Guide

Expansion Baseline Print Tables

For the Expansion Baseline survey for cases, we currently have 7 active print tables. The main print tables are those for Adults and for those Under18 (minors) (CCSSExpansionAdult and CCSSExpansionUnder18 respectively). In addition, adult and minor cases from Minnesota (instcod 01) and Toronto (instcod 13) each have their own separate print tables. Finally, there is a print table for deceased cases from Dana Farber (instcod 05). Table names are as follows:

1. tblPrintQuestionnaireCCSSExpansionAdult
2. tblPrintQuestionnaireCCSSExpansionUnder18
3. tblPrintAdultMN
4. tblPrintMinorMN
5. tblPrintAdultToronto13
6. tblPrintMinorToronto13
7. tblPrintQuestionnaireCCSSExpansionDFDeceased

Print Table Contents

For the Expansion Baseline survey, these print tables contain the following pieces of information:

1. NameImport (full name, built from first name and last name)
2. FirstNameImport (adult print table only)
3. CCSSID
4. Name in ALL CAPS (as ImportNameBoldCaps)
5. Birth date (as DOB_HIPAA)
6. Mailing address information:
    a. Sendcareof (for MINORS, this will be "THE PARENTS OF" followed by the person's name)
    b. Sendaddr
    c. Sendcity, sendstate, zipsort
    d. Sendphone

Lead CRA; LSI

Updating Participant Information in Print Tables

Whenever we update a person's name, address, or phone numbers, we have to synchronize the print table with the information we updated on the data entry form. Two buttons on the Quest tab take care of this**: Update Print Table Names**, and **Update Print Table Address**. The person who updates the record in the database is expected to use the Update Print Table button(s) after saving the changes that were made on the form. The buttons are "smart" buttons, as they attempt to find and update the appropriate print table for the case.

Three Age-Related Issues with Print Tables

1. ***Automatic "Grown up" function for people turning 18.*** When an individual is about to turn 18 (based on the birthdate displayed on the database form), the procedures we use each morning will move the individual from the minor (under 18) print table into the adult print table. *This automated function depends on the database having a (correct) date of birth on file for the individual*.

2. ***Missing or incorrect date of birth.*** If we did NOT have any date of birth on file, or if the date of birth we do have is found to be incorrect, then we must manually make the correction in (a) the main database table and in (b) the appropriate print table. This is outlined in the procedure ***Updating Date of Birth***. Take care to ensure that the correct print table is updated manually. If any questions arise, or the case is not in the print table where you expect it to be, the situation should be referred to the project CRA2 for resolution.

3. ***Dana Farber cases (instcod 05).*** When we add cases from Dana Farber (instcod 05) to the study, we are not given the individual's date of birth (or gender). Thus, when we make contact with the individual, we are to obtain the date of birth as well as gender. We then use a special form to enter the information into the main table. While this process is outlined in ***Processing LTFU Expansion Baseline Dana Farber***, the section about Dana Farber cases should be used by the LSI whenever an SI obtains undated information about a Dana Farber case. Although updating the Dana Farber age and gender in the main table is form-driven, updating the age (DOB_HIPAA) in the print table is not. Therefore, we still need to manually update the print table DOB_HIPAA (date of birth) for the Dana Farber case in the appropriate print table. It may be necessary to check BOTH print tables (Under18 and Adult) to locate the Dana Farber individual. Refer any problems you have with this to the CRA2 for resolution.

Revision Record Printed 12/12/2012 3:12 PM

Current Filename:		Guide to CCSS Expansion Baseline Print Tables ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/12/2012	J.Bates	Initial Development

Handling Additional Phone Numbers

Background

When we obtain a new phone number for a participant, we enter the new number in any of the available (empty) phone fields in the appropriate database. When there are no empty fields, the following procedure outlines what to do. This procedure illustrates the process for the Recruitment database, the Expansion Tracking (cases and siblings) database, and the Reg (cases and siblings) database. Both Survey Interviewers and CRAs update information in both databases. Consistent use of the numerous phone fields and ranking (when available) is critical to ensure our data are reliable.

Why this is important:

- Each primary CCSS/LTFU database supports multiple phone numbers for a participant. Some also support multiple numbers for additional contacts and parents.
- While tracking databases for ancillary studies reflect phone numbers from the primary database, the ancillary tracking databases do NOT display **Comments** from the primary database.
- For older ancillary studies you will only be able to view the phone number from the primary database. For these older ancillary studies, you must update the phone number in the primary database.
- Ancillary tracking databases for newer ancillary studies let you update the phone number in the primary database right from the ancillary study database. Newer ancillary study tracking databases also incorporate a **Call Log** system.
- *Changing phone number order (rearranging from one slot to another) or deleting numbers DISRUPTS Call Log functioning. For this reason, remove phone numbers ONLY when absolutely necessary using the procedure outlined below and NEVER rearrange the order.*

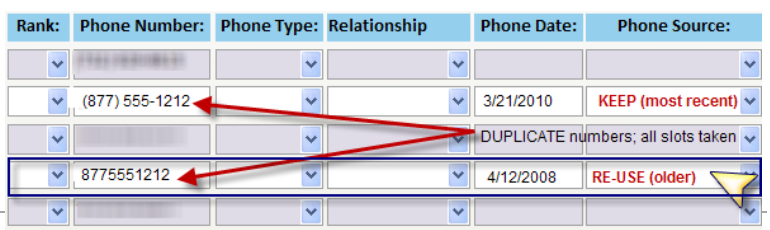
Procedures

Expansion RECRUITMENT Database Procedures

1. Verify that the "new" phone number is not listed. If it IS listed, update **Phone Date** and **Phone Source** fields.

2. OTHERWISE, use the following procedures:
   a. If we do not have the new phone number in the database, and ***there is an AVAILABLE (EMPTY) PHONE ROW***:
      i. Enter the new phone number in first *empty* phone row.
      ii. Select an active Phone **Rank** (not 9 or 37).
      iii. Record the **Phone Type** (if known), **Phone Date**, and **Phone Source**.
      iv. If you need to log a call to the new phone number, move to the next CCSSID record and then back again *before* opening the New Contact Log.

   b. If we do not have the new phone number in the database and ***there is no available (empty) phone row*** but ***a DUPLICATE number is listed***:
      i. Keep the row with the MOST RECENT date and make sure the **Phone Source** is indicated (if known). (If no



date or source is given for either number, keep either one.)

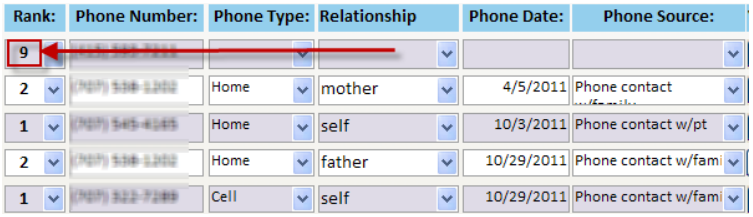
ii. In the **Comments** field, document your action. (EXAMPLE: *10/10/2013: Cleared Phone 4, 877-555-1212 which duplicated Phone 2, to make room for new number 877-805-2635. [jb]*)

iii. Clear the values (**Rank**, **Phone Number**, **Phone Type**, **Relationship**, **Phone Date**, and **Phone Source**) for the number not being kept. (See step i.)

iv. Put the NEW phone number in the row you cleared (in this example, Phone 4). Indicate **Phone Type** (if known), **Phone Date**, and **Phone Source**. Select an active **Rank** (<u>not</u> 9 or 37).

v. If you need to log a call to the new phone number, move to the next CCSSID record and then back again *before* opening the New Contact Log.

c. If we do not have the new phone number in the database, and ***<u>there is no available (empty) phone row and no duplicate phone numbers</u>***, but there is ***<u>a number RANKED "9" (disconnect)</u>***:



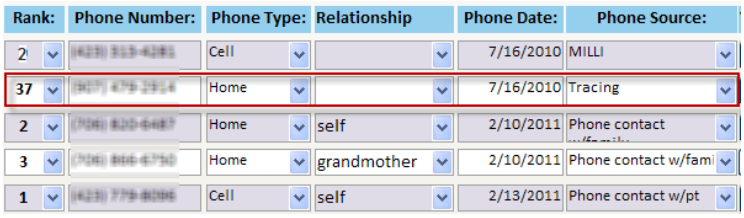
i. In the **Comments** field, document your action. (EX: *7/5/2013: Cleared Phone 1, 999-555-1212 ranked 9, to make room for new number, 800-775-2167 [jb]*).

ii. Clear the values (**Rank**, **Phone Number**, **Phone Type**, **Relationship**, **Phone Date**, **Phone Source**) for that phone number.

iii. Enter the new number in the row you cleared. Indicate **Phone Type** (if known), **Phone Date**, and **Phone Source**. Select an active **Rank** (<u>not</u> 9 or 37).

iv. If you need to log a call to this new phone number, move to the next CCSSID record and then back again *before* opening the New Contact Log.

d. If we do not have the new phone number in the database, and ***<u>there is no available (empty) phone row, no duplicate numbers, no numbers ranked "9" (disconnect)</u>***, but there is ***<u>a number RANKED "37" (Do Not Call)</u>***.



i. It is VERY IMPORTANT to retain the phone number and the fact that it was ranked 37-Do Not Call

ii. Therefore, in the **Comments** field, CLEARLY document your action. (EXAMPLE: *2/14/13: DO NOT CALL ###-###-####; previously ranked 37-Do Not Call. Cleared from Phone 2 to make room for new number, 901-555-1234. [89]*)

iii. Clear the values (**Rank**, **Phone Number**,**Source, etc.**) for that phone number.

iv. Enter the new number in the row you cleared. Indicate **Phone Type** (if known), **Phone Date**, and **Phone Source**. Select an active **Rank** (<u>not</u> 9 or 37).

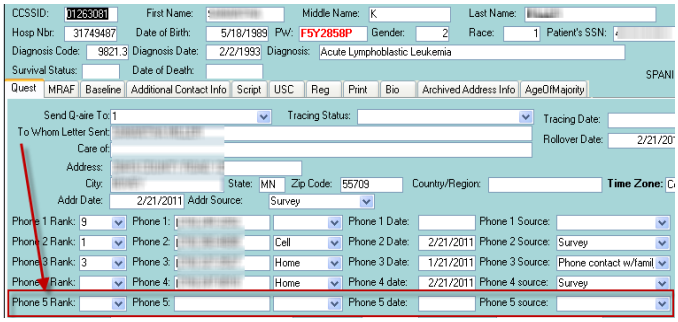
v. If you need to log a call to this new phone number, move to the next CCSSID record and then back again *before* opening the New Contact Log.

<u>Expansion Tracking Database – Cases (blue records)</u>

1. Verify that the "new" phone number is not listed. <u>If it is listed</u>, update **Phone Date** and **Phone Source** fields.
2. OTHERWISE, use the following procedures:

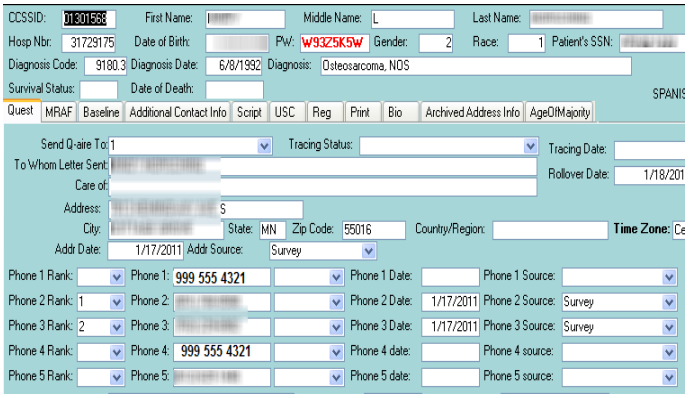
Everyone

a. If we do not have the new phone number in the database, and ***there is an AVAILABLE (EMPTY) PHONE ROW***:
   i. Enter the number in first *empty* phone row.
   ii. Select an active Phone **Rank** (not 9 or 37).
   iii. Record the **Phone Type** (if known), **Phone # Date**, and **Phone # Source**.

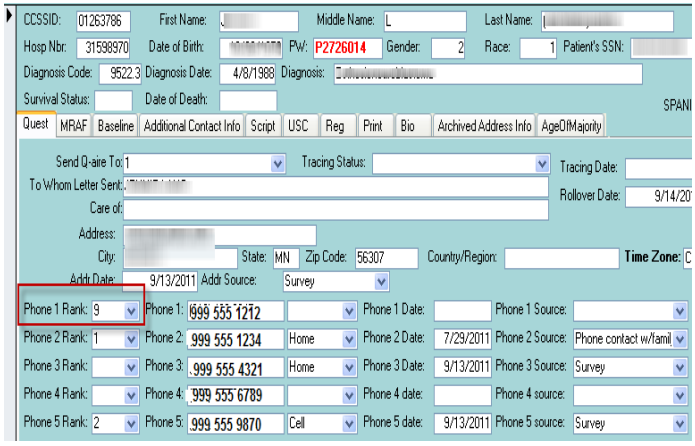


b. If we do not have the new phone number in the database and ***there is no available (empty) phone row*** but ***a DUPLICATE number is listed***:
   i. Click the **Archive Contact Info** button.

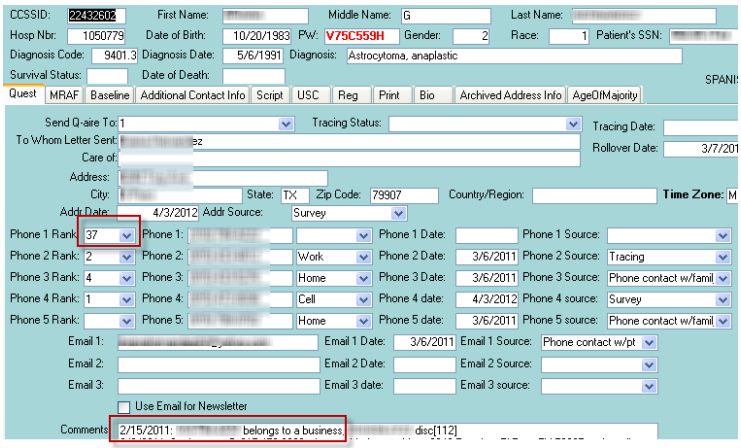
   ii. Keep the row with the MOST RECENT date and make sure the **Phone # Source** is indicated (if known). (If no date or source is given on either, keep either one.)
   iii. In the **Comments** field, document your action. (EX: *10/10/2013: Cleared Phone 1, 999-555-4321 which duplicated Phone 4, to make room for new number 877-805-2635. [jb]*)
   iv. Clear the values (**Phone # Rank**, **Phone #**, **Phone Type**, **Phone # Date**, and **Phone # Source**) for the number not being kept.
   v. Put the NEW phone number in the row you cleared (in this example, Phone 1). Indicate **Phone Type** (if known), **Phone # Date**, and **Phone # Source**. Select an active **Phone # Rank** (not 9 or 37).



c. If we do not have the new phone number in the database, and ***there is no available (empty) phone row and no duplicate phone numbers***, but there is ***a number RANKED "9" (disconnect)***:
   i. Click the **Archive Contact Info** button.
   ii. In the **Comments** field, document your action. (EX: *7/5/2013: Cleared Phone 1, 999-555-1212 ranked 9, to make room for new number, 800-775-2167 [jb]*).
   vi. Clear the values (**Phone # Rank**, **Phone #**, **etc**) for that phone number.
   vii. Enter the new number in the row you cleared. Indicate **Phone Type** (if known), **Phone # Date**, and **Phone # Source**. Select an active **Phone Rank** (not 9 or 37).



d. If we do not have the new phone number in the database, and ***there is no available (empty) phone row, no duplicate phone numbers, no numbers ranked "9" (disconnect)***, but there is ***a number RANKED "37" (Do Not Call)***:



i. Click the **Archive Contact Info** button.

ii. It is VERY IMPORTANT to retain the phone number and the fact that it was ranked 37-Do Not Call.

iii. Therefore, in the **Comments** field, CLEARLY document your action. (EXAMPLE: *2/14/13: DO NOT CALL ###-###-####; previously ranked 37-Do Not Call. Cleared from Phone 1 to make room for new number, 901-555-1234. [89]*)

iv. Clear the values (**Phone # Rank**, **Phone #, etc.)** for that phone number.

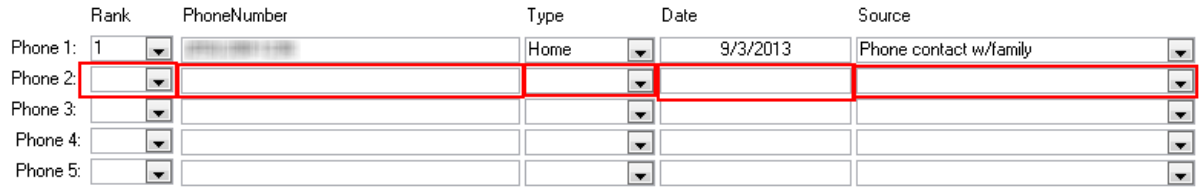
v. Enter the new number in the row you cleared. Indicate **Phone Type** (if known), **Phone # Date**, and **Phone # Source**. Select an active **Phone # Rank** (not 9 or 37).

Expansion Tracking Database – Siblings (green records)

1. Verify the "new" phone number is not already listed. If it IS listed, update the **Date** and **Source** fields.

2. OTHERWISE, use the following procedures:

a. If we do not have the phone number in the database, and ***there is an AVAILABLE (EMPTY) PHONE ROW***:



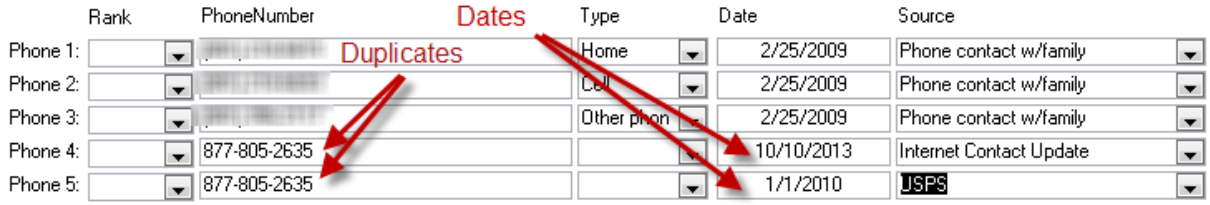
i. Enter the new phone number in first *empty* phone row.

ii. Select an active Phone **Rank** (not 9 or 37).

iii. Record the **Type** (if known), **Date**, and **Source**.

b. If we do not have the new phone number in the database and ***there is no available (empty) phone row*** but ***a DUPLICATE number is listed***:

Everyone



i. For the Sib Info tab, click the **Archive Information** button. For the Permission tab, be sure to carefully document the number being removed in step iii, below, as there is no Archive feature.

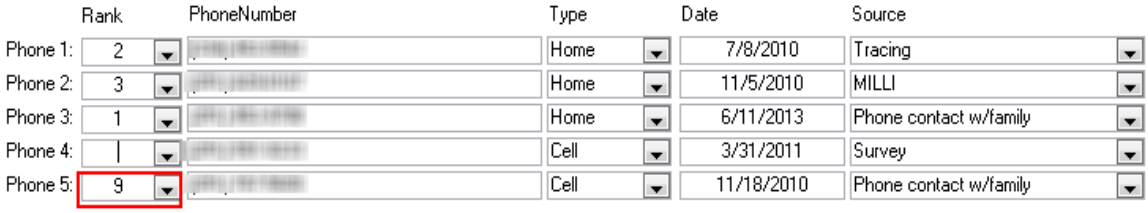
ii. Plan to keep the row with the MOST RECENT date (see image, above) and make sure the **Source** is indicated (if known). (If no date or source is given on either, keep either one.)

iii. In the **Comments** field, document your action.

iv. Clear the values (**Rank**, **PhoneNumber**, **Type**, **Date**, and **Source**) for the number not being kept.

v. Put the NEW phone number in the row you cleared (in this example, Phone 5). Be sure to indicate **Type** (if known), **Date**, and **Source**. Select an active **Rank** (not 9 or 37).

c. If we do not have the new phone number in the database, and ***there is no available (empty) phone row and no duplicate phone numbers***, but there is ***a number RANKED "9' (disconnect)***:



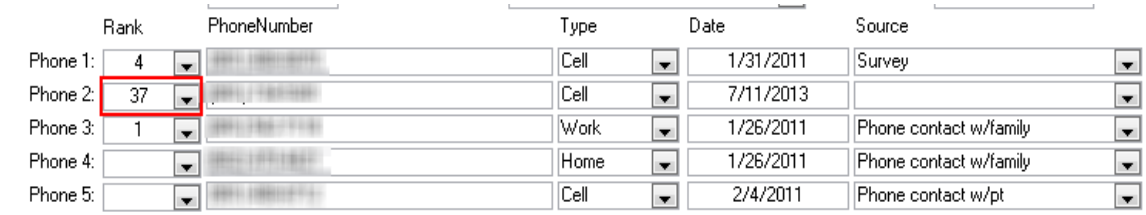
i. For the Sib Info tab, click the **Archive Information** button. For the Permission tab, be sure to carefully document the number being removed in step ii, below, as there is no Archive feature.

ii. In the **Comments** field, document your action.

iii. Clear the values (**Rank**, **PhoneNumber**, **Type**, **Date**, **Source**) for that phone number.

iv. Enter the new number in the row you cleared. Indicate **Type** (if known), **Date**, and **Source**. Select an active **Rank** (not 9 or 37).

d. If we do not have the new phone number in the database, and ***there is no available (empty) phone row, no duplicate phone numbers, no numbers ranked "9" (disconnect)***, but there is ***a number RANKED "37" (Do Not Call)***:



i. For the Sib Info tab, click the **Archive Information** button. For the Permission tab, be sure to carefully document the number being removed in step iii, below, as there is no Archive feature.

ii. It is VERY IMPORTANT to retain the phone number and the fact that it was ranked 37-Do Not Call .

iii. Therefore, in the **Comments** field, CLEARLY document your action. (EX: *2/14/13: DO NOT CALL ###-###-####; previously ranked 37-Do Not Call. Cleared from Phone 2 to make room for new number, 901-555-1234. [89])*

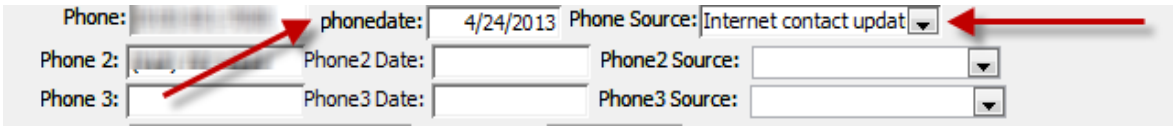
iv. Clear the values (**Rank**, **PhoneNumber**, **Type**, **Date**, **Source**) for that phone number.

v. Enter the new number in the row you cleared. Indicate **Type** (if known), **Date**, and **Source**. Select an active **Phone # Rank** (not 9 or 37).

REG database – Cases

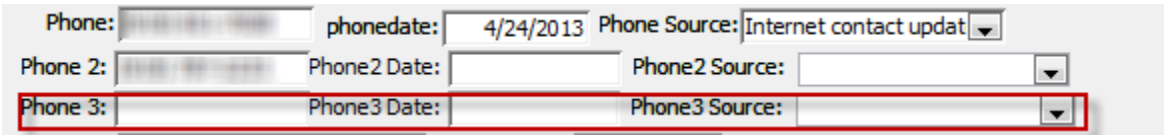
NOTE: When numbers are deleted in the REG database per the below instructions, they should be replaced one-for-one. For example, if all three numbers are known to be "bad", but only one new, current number is obtained, only one number will be selected to be replaced using the instructions below. The other two "bad" numbers will REMAIN recorded in their respective rows. Please see a CRA, LSI, or the Call Center Coordinator if you have questions.

1. Verify the "new" phone number is not already listed. If it IS listed, update the date and **Phone # Source** fields.



2. OTHERWISE, use the following procedures:

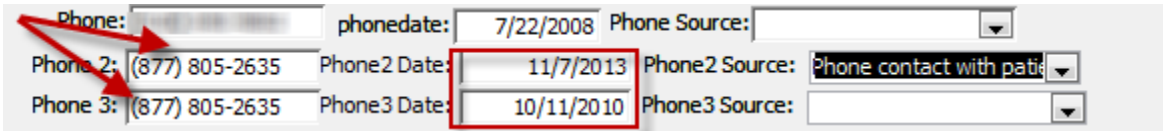
a. If we do not have the phone number in the database, and ***there is an AVAILABLE (EMPTY) PHONE ROW***:



i. Enter the new phone number in first *empty* phone row.

ii. Record the date and **Phone Source**.

b. If we do not have the new phone number in the database and ***there is no available (empty) phone row*** but ***a DUPLICATE number is listed***:



i. Keep the row with the MOST RECENT date and make sure the **Phone # Source** is indicated (if known). (If no date or source is given for either number, keep either one.)

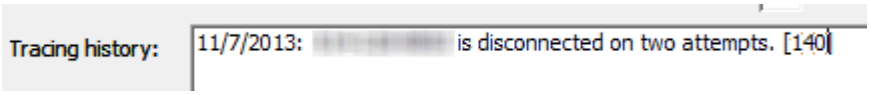
ii. In the **Tracing history** field, document your action. (EXAMPLE: *10/10/2013: Cleared Phone 3, 877-805-2635 which duplicated Phone 2, to make room for new number 877-555-1111. [jb]*)

iii. Clear the values (**Phone #**, **Phone # Date**, and **Phone # Source**) for the number not being kept. (See step i.).

iv. Put the NEW phone number in the row you cleared (in this example, Phone 3). Indicate **Phone # Date** and **Phone # Source**.

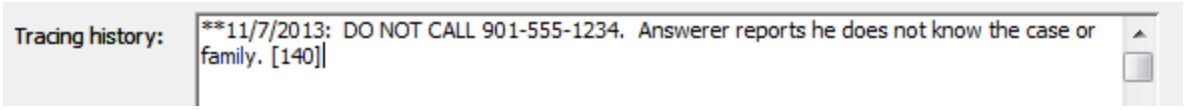
c. If we do not have the new phone number in the database, and ***there is no available (empty) phone row and no duplicate phone numbers***, but there is ***a number known to be DISCONNECTED***:

NOTE: A number may be documented to be disconnected in the MS Word **Phone Contact Log**, documented to be disconnected in the **Tracing history** field, and/or ranked 9-Disconnected in an ancillary study database. See the MS Word **Phone Contact Log** for hints on ancillary studies in which the case may participate. Check each applicable study's database for possible phone rankings. If you do not have access to the database in question, see a CRA, LSI, or the Coordinator.



i. In the **Tracing history** field, document your action. (EXAMPLE: *10/10/2013: Cleared Phone 3, 877-805-2635 which was confirmed today to be disconnected, to make room for new number 877-555-1111, confirmed today to be valid. [jb]*)
ii. Clear the values (**Phone #**, **phonedate**, **Phone # Source**) for that phone number.
iii. Enter the new number in the row you cleared. Indicate **phonedate** and **Phone # Source**.

d. If we do not have the new phone number in the database, and ***there is no available (empty) phone row, no duplicate phone numbers, no numbers known to be disconnected***, but there is ***a number known to be a DO NOT CALL number***:
NOTE: A number may be documented to be a "Do Not Call" number in the MS Word **Phone Contact Log**, documented to be a "Do Not Call" number in the **Tracing history** field, and/or ranked 37-Do Not Call in an ancillary study database. See the MS Word **Phone Contact Log** for hints on ancillary studies in which the case may participate. Check each applicable study's database for possible phone rankings. If you do not have access to the database in question, see a CRA, LSI or the Coordinator.



i. It is VERY IMPORTANT to retain the phone number and the fact that it was ranked Do Not Call.
ii. Therefore, in the **Tracing history** field, CLEARLY document your action. (EXAMPLE: *2/14/13: DO NOT CALL ###-###-####; previously documented as Do Not Call. Cleared from Phone 1 to make room for new number, 901-555-1234. [89])*
iii. Clear the values (**phone, Phone Date**, **Phone Source)** for that phone number.
iv. Enter the new number in the row you cleared. Indicate **Phone # Date** and **Phone # Source**.

REG database – Siblings

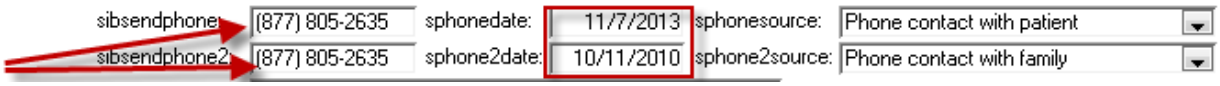
NOTE: When numbers are deleted in the REG database per the below instructions, they should be replaced one-for-one. For example, if both numbers are known to be "bad", but only one new, current number is obtained, only one number will be selected to be replaced using the instructions below. The other "bad" number will REMAIN recorded in its respective row. Please see a CRA, LSI, or the Call Center Coordinator if you have questions.

1. Verify the "new" phone number is not already listed. If it IS listed, update the **sphonedate** and **sphonesource** fields.

2. OTHERWISE, use the following procedures:
   a. If we do not have the phone number in the database, and ***there is an AVAILABLE (EMPTY) PHONE ROW***:

      i. Enter the new phone number in first *empty* phone row.
      ii. Record the **sphonedate**, and **sphonesource**.

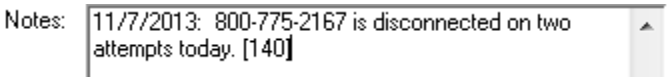
   b. If we do not have the new phone number in the database and ***there is no available (empty) phone row*** but ***a DUPLICATE number is listed***:



      i. Keep the row with the MOST RECENT date and make sure the **sphonesource** is indicated (if known). (If no date or source is given for either number, keep either one.)
      ii. In the **Notes** field, document your action. (EXAMPLE: *10/10/2013: Cleared Phone 2, 877-805-2635 which duplicated Phone 1, to make room for new number 877-555-2121. [jb]*)
      iii. Clear the values (**sibsendphone**, **sphonedate**, and **sphonesource**) for the number not being kept. (See step i.)
      iv. Put the NEW phone number in the row you cleared (in this example, Phone 2). Indicate **sphonedate** and **sphonesource**.

   c. If we do not have the new phone number in the database, and ***there is no available (empty) phone row and no duplicate phone numbers***, but there is ***a number known to be DISCONNECTED***:

      NOTE: A number may be documented to be disconnected in the MS Word **Phone Contact Log**, documented to be disconnected in the **Notes** field, and/or ranked 9-Disconnected in an ancillary study database. See the MS Word **Phone Contact Log** for hints on ancillary studies in which the sibling may participate. Check each applicable study's database for possible phone rankings. If you do not have access to the database in question, see a CRA, LSI, or the Coordinator.

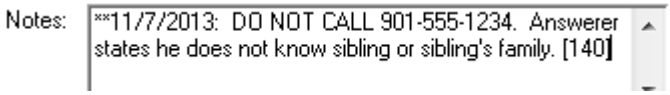


      i. In the **Notes** field, document your action. (EXAMPLE: *10/10/2013: Cleared Phone 1, 800-775-2167 which was confirmed today to be disconnected, to make room for new number 877-555-1111, confirmed today to be valid. [jb]*)
      ii. Clear the values (**sibsendphone**, **sphonedate**, **sphonesource**) for that phone number.
      iii. Enter the new number in the row you cleared. Indicate **sphonedate** and **sphonesource**.

   d. If we do not have the new phone number in the database, and ***there is no available (empty) phone row, no duplicate phone numbers, no numbers known to be disconnected***, but there is ***a number known to be a DO NOT CALL number***:

      NOTE: A number may be documented to be a Do Not call number in the MS Word **Phone Contact Log**, documented to be a Do Not Call number in the **Notes** field, and/or ranked 37-Do

Not Call in an ancillary study database. See the MS Word **Phone Contact Log** for hints on ancillary studies in which the sibling may participate. Check each applicable study's database for possible phone rankings. If you do not have access to the database in question, see a CRA, LSI, or the Coordinator.



i. It is VERY IMPORTANT to retain the phone number and the fact that it was ranked Do Not Call.
ii. Therefore, in the **Notes** field, CLEARLY document your action. (EXAMPLE: *2/14/13: DO NOT CALL ###-###-####; previously documented as Do Not Call. Cleared from Phone 1 to make room for new number, 901-555-1234. [89]*)
iii. Clear the values (**sibsendphone**, **sphonedate**, **sphonesource**) for that phone number.
iv. Enter the new number in the row you cleared. Indicate **sphonedate** and **sphonesource.**

Revision Record Printed 9/20/2016 9:16 AM

Current Filename:		Handling Additional Phone Numbers ver2_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	4/12/12	J.Bates	Initial Development
1.1	4/25/12	J.Bates	Add Recruitment screen shots
1.2	5/10/12	J.Bates	Saving record in recruitment
1.3	10/10/13	R. Massey	Updated audience in Background, added siblings section.
2.0	11/7/2013	R. Massey	Add REG database procedures
2.1	9/2/2016	A. Cobble	Content Revision

Handling Baseline Thank You Incentive Batches

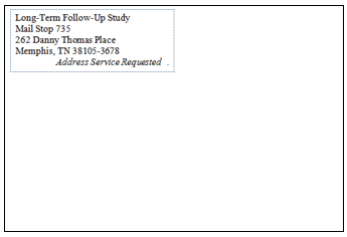
Background

In order to mail the baseline survey Thank You note together with the incentive gift card each week, the CRA2 identifies new cases that have returned the baseline survey. The CRA2 mailmerges a new Word document containing mailing labels that also display the gift card number assigned to the person on the label. As volume warrants, the CRA2 assigns the thank you note assembly batches to the production team, distributes the list, and prepares the assigned gift cards for each team member's batch.

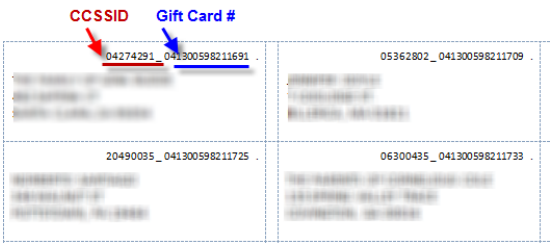
Procedures

1. **NOTE about Spanish Surveys**: The CRA2 handles the thank you note/incentive process for surveys obtained in Spanish by one of the survey interviewers. The CRA2 will manually delete Spanish thank you note cases from the Thank You Incentive batches before the lists are distributed to the production team (or otherwise indicate the cases using strikethrough font).

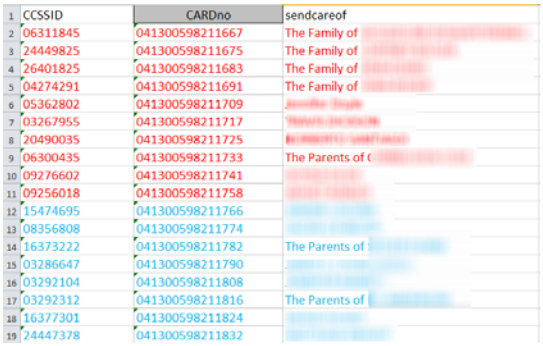
2. A supply of pre-stuffed unsealed thank you notes, with an *Address Service Requested* return address label, will be available in the storage room. If the supply is depleted, notify the CRA2.



3. The CRA2 sends the Thank You production job to the production team by email. This email includes
   a. A formatted, ready-to-print mailing label document (with CCSSID, card number, and complete mailing address).



   b. An assignment list in excel showing CCSSID, CARDno, and the name (sendcareof) identified to receive that specific gift card.



	CCSSID	CARDno	sendcareof
2	06311845	041300598211667	The Family of
3	24449825	041300598211675	The Family of
4	26401825	041300598211683	The Family of
5	04274291	041300598211691	The Family of
6	05362802	041300598211709	
7	03267955	041300598211717	
8	20490035	041300598211725	
9	06300435	041300598211733	The Parents of
10	09276602	041300598211741	
11	09256018	041300598211758	
12	15474695	041300598211766	
13	08356808	041300598211774	
14	16373222	041300598211782	The Parents of
15	03286647	041300598211790	
16	03292104	041300598211808	
17	03292312	041300598211816	The Parents of
18	16377301	041300598211824	
19	24447378	041300598211832	

4. Based on the cases assigned, the ***assigned production team member*** will

    a. In the label file, locate the rows that go with the assigned cases. (You can delete the rows that you do not need.) Print only those labels that belong to YOUR batch. Print them directly onto the clear mailing label stock (30 labels per sheet).
    b. Attach the mailing label on an unsealed pre-assembled thank you note having the Address Service Requested return address label from the storage room
    c. In person, request the gift cards for the assigned batch from the CRA2
    d. For each gift card, locate the labeled thank you note having that specific card's number on it.
    e. Insert the gift card *inside* the folded thank you note with the matching mailing label. DO NOT SEAL the envelope.
    f. Personally give the stack of unsealed thank yous (after you insert the gift cards) to the person assigned to QA that batch.

5. When the batch is handed off to the designated QA person, the ***QA person*** will

    a. Make sure each thank you note contains one and **only one** gift card
    b. Make sure the number on the gift card that is inside the thank you note matches the number on the envelope's mailing label
        i. IN CASE OF ANY MISMATCHES, flag the envelope so you can investigate after checking the rest of the batch
    c. Do NOT seal the thank you note until the ENTIRE BATCH has been QA'd perfectly.
    d. If there were any errors in the batch, check first with the person assigned to the batch. If necessary, check back with the CRA2.
    e. Once the entire batch is perfect, securely seal the envelopes from the batch
    f. Double-check to be sure the envelope is tightly sealed (so the flap won't come open or the card will be able to slip out). If necessary, use tape.
    g. Give the sealed envelopes to the CRA2

6. When all batches are QA'd and received, ***the CRA2*** will
    a. Set all the thank you cards out for mail pick up
    b. Update the thank you note date sent in the database. Spanish thank you's require an additional notation.
    c. Post the incentive distribution transactions in the incentive tracking database.

Revision Record Printed 12/13/2012 2:05 PM

Current Filename:		Handling Baseline Thank You Incentive Batches ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/13/12	J.Bates	Initial Development

Handling Call Center Voice Messages

Background

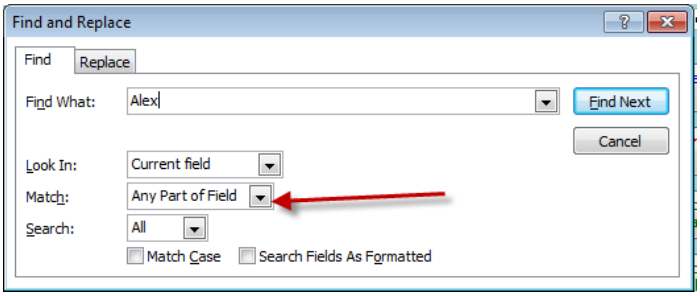
Unanswered incoming calls for the LTFU Study Call Center will be directed to the group voice mailbox. All LTFU Survey Interviewers (SIs) will receive an emailed audio copy of these voice messages in their primary MS Outlook Inboxes and are responsible for checking all incoming voice messages. To ensure we do not have duplicate efforts or neglect to follow through with these voice messages, all SIs will be responsible for the following procedures.

Procedures

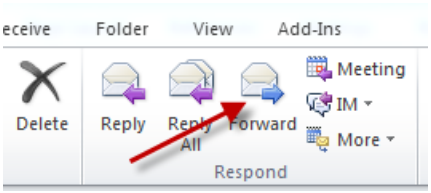
I. Check voice messages:
   A. To manually check voice messages, check the mailbox for both the Recruitment and the LTFU Study lines:
      1. From any telephone, dial 3899. Press the # button. Following the audio prompts, enter Recruitment mailbox 6680 and the current Recruitment password. To locate the current password, open the document **Voicemail Passwords mmddyy**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools*.
      2. From any telephone, dial 3899. Press the # button. Following the audio prompts, enter the mailbox number 6316 and the current LTFU Study password. To locate the current password, open the document **Voicemail Passwords mmddyy**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools*.
      NOTE: If checking this mailbox *from the study line*, you will not need to press the # button or enter the mailbox number.
   B. To listen to a voice message delivered via email, click on the email attachment. If assistance is needed with this process, please see a member of the LSI team or the Call Center Coordinator.

II. Handle the messages:
   A. Messages addressed to a specific LTFU Survey Interviewer, referenced by name, can be deleted by all SIs except the specified LTFU Survey Interviewer. The specified LTFU SI is responsible for handling the incoming message.
   B. For all other messages, the SI should first check the remaining unread emails in his/her Inbox to confirm whether or not the message in question has already been handled by another SI. If there is no indication the message has been addressed, the SI will consider the issue unresolved and handle it as follows:
      1. Messages addressed to a specific St. Jude employee who is *not* a LTFU SI should be forwarded to the specified recipient using the St. Jude Address Book in MS Outlook, copying the email list "CCSS Interviewers" on the email so that the rest of the LTFU Study Interviewer team will know that this particular message has been handled.

2. For messages that do not specify a recipient, Survey Interviewers will use any available information in the message to identify the correct recipient.
   a. Search all parent databases (REG, Recruitment, and Expansion Tracking) and the SJLife Tracking Read Only database using identifying information provided in the message. Ensure the **Match** field in the Find and Replace window is set to "Any Part of Field".



   b. Once the caller is located in a database, check all documentation (MS Word *Phone Contact Log*, database call log, database trace log, Call Log Report, etc.) to determine who placed the original call to him or her.
   c. Forward the message to the appropriate recipient and cc the email list "CCSS Interviewers" to alert the team that the issue has been resolved. If the LTFU Study Survey Interviewer determines that he or she is the appropriate recipient, he or she will:
      i. Click the forward button to forward the original email to the email list "CCSS Interviewers".
      ii. Delete the attachment.
      iii. Indicate in the body of the email that the issue is being handled.
      iv. Send the email.



   d. For messages where the caller cannot be identified, the LTFU Study Survey Interviewer will forward a copy of the message to the St. Jude Life team, cc'ing the email list "CCSS Interviewers", and asking if anyone on that team recognizes the caller.

Revision Record
Printed 2/7/2014 3:05 PM

Current Filename:		Handling Call Center Voice Messages ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	1/31/2014	D. Rinehart, R. Massey	Initial Development

Handling LTFU Consent Discrepancies

Background

Standard procedures define in-processing baseline surveys with unsigned or undated LTFU consent documents. (See ***Processing LTFU Expansion Cohort Baseline Questionnaires***.) That procedure does *not* delineate how to handle two additional situations: (1) the parents of an adult survivor complete the survey and/or sign the consent and LTFU HIPAA; and (2) the minor survivor completes the survey and/or signs the consent and LTFU HIPAA. As we attempt to obtain signatures of the appropriate party, the fact that the survey has been received needs to be recorded in the tracking database. The remainder of the in-processing will wait until the signature situation is resolved.

SITUATION 1	**Adult survey received, completed & consent signed by adult patient's parents.** In such situations, the survivor may have been recruited as minor, with parent signature on Inst HIPAA. Parents *may* be guardian/LAR, but did not indicate on the forms. If parents are the LAR, no discrepancy exists.
SITUATION 2	**Minor survey received, completed and forms signed by minor.**

Procedure

1. Date stamp front of survey. Add initials after date stamp. Do NOT enter initials/date in box at bottom of survey.
2. In the tracking database,
    a. Update the address/phone/email and additional contact information, with date survey received and survey as source.
    b. Do NOT post information on the Baseline or Script tabs.
3. **Give survey to CRA2** (Attach post-it note indicating situation: e.g., parents of adult completed/signed consent, or minor patient completed/signed consent.

The rest of the procedure is handled by the CRA2:

1. Prepare letter to parent with signature forms and return envelope (samples available Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\!LETTERS-templates). Open the template, save the template in the in the SENT subfolder in the templates folder using Save As, and appending the CCSSID at the front of the file name. (Do NOT overwrite the original template!)
    a. Letters for different situations
        i. Situation 1: letter to parent asking for adult child consent:
        (Requesting Participant Signature Parent signed SEND TO PARENT)
        ii. Situation 2: minor signed; letter to parent asking for parent consent/signature:
        (Requesting Parent signature-Minor Signed-Sent to Parent)
    b. Signature Forms: COPY the "no watermark" version of the PDF file from the Participant Copies folder. Rename the copy by appending the CCSSID at the front of the file name. Save the form in the SENT Open the file Adobe add the CCSSID in the footer (so it appears on each page), and use the typewriter tool to type the name and DOB on the LTFU Authorization page.

2. Assemble and mail
    a. For cases from U of Minnesota (01), mail the letter with the forms.
    b. For other cases, may opt to DELAY MAILING:
        i. Assemble the letter, forms, and return envelope in LTFU white mailer with address label. Do not seal envelope.
        ii. Set the packet aside for next scheduled thankyou/incentive mailing (at which time a thank you with incentive gift card will be added to packet and then mailed).

3. Enter <u>date survey returned</u> on baseline tab; ***leave consent/MR fields blank***.

4. Enter dated comment on Baseline tab
    a. Situation 1: m/d/yy: prepared parent ltr {w/ incentive TY} asking for adult child consent [init]
    b. Situation 2: m/d/yy: minor signed; prepared parent ltr {w/ incentive TY} asking for consent/signature [init]

5. Alert LeadSI about letter and pending call, requesting they email us to report any call they receive regarding the case. E.g.

    a. **CCSSID: Survey received mm/dd/yy <u>completed by parent(s) for adult survivor</u> with consent signed by parent(s). Letter and new forms sent to parent for adult survivor signature or LAR status; please advise when/if call received.**

    b. **CCSSID: Survey received mm/dd/yy <u>completed by minor survivor</u> with consent signed by minor. Letter and new forms sent to parent for signature; please advise when/if call received.**

6. <u>HOLD survey w/ copy of letter</u>
    a. HOLD survey with copy of letter in box of Baseline Surveys pending IRREGULAR CONSENTS.
    b. Set 30-day reminder with CCSSID in Outlook to check on status of case.
    c. In 30 days, check database for status. If no action, refer the case to the SI team to call to obtain materials and/or verbal consent.

7. *<u>At receipt of appropriate signature or acquisition of verbal consent</u>*, CRA2:
    a. Signed documents: Date-stamp and initial
    b. Retrieve booklet from HOLD; remove and shred copy of original letter
    c. Restamp and initial front of survey, beneath initial date stamp
    d. In Tracking database
        i. If the newly obtained consent is from a now-adult participant, check the status of ReconsentNeeded (AgeOfMajority tab). If Reconsent Needed is YES, this means you will need to consider the consent newly obtained from the participant as REconsent and subsequently post ReconsentOutcome as 1-Consented, with Reconsent date the date signed, and reconsent outcome date. Document fully in AOMReconsentComments. If reconsent was obtained by SI/verbally, post the IntID in Verbal Consent Int Id.

        ii. For signed consent (and MR if obtained)
            1. Record <u>date consent signed, MR signature, status (Complete)</u> on Baseline tab using dates on the new documents
            2. *Update* <u>Date survey returned with the date we received the consent</u>
            3. Enter dated note on baseline tab (m/d/yy: received consent/MR signed by {adult participant|parent}; upated survey return date [init])
            4. For MR: if signed, enter date signed and status as Complete. If not signed, leave MR date blank and enter status as 6
            5. Paperclip new signed documents inside survey booklet.

        iii. For verbal consent
            1. Record <u>date consent obtained verbally, status</u> (Verbal) on Baseline tab using date obtained.
            2. *Update* <u>Date survey returned with the date we obtained the consent</u>
            3. Enter dated note on baseline tab (m/d/yy: SI ## obtained verbal consent from {adult participant|parent}; upated survey return date [init])

    e. Return survey (with inserted signed documents) to in-processing queue. Signed inserts will be scanned as attachments.

8. If parent of adult survivor notifies us of LAR status: retrieve booklet, annotate in database, and return booklet to processing queue. Use consent and MR dates from materials initially received.
9. NOTE: When scanning the survey, scan any inserted documents as attachments.

Revision Record Printed 2/12/2013 2:21 PM

(57) Current Filename:		Handling Consent Discrepancies ver 1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	11/22/11	J.Bates	Initial Development
1.1	2/12/13	J.Bates	Modifications due to incentive; reconsent needed impact

Health eHeart Study Calls

Background

Because survivors of childhood cancer may have an increased risk of heart disease, the Long-Term Follow-Up (LTFU) Study partnered with the University of California at San Francisco (UCSF) on an existing study called the Health eHeart Study in 2015. The study goals are to improve our understanding of and find new ways to prevent cardiovascular disease. Participation involves completing semi-annual surveys about the participant's life and health.

A set of 500 adult LTFU participants who indicated on the Follow-Up 5 (FU5) survey that they use the internet will be invited to join the Health eHeart (HeH) Study. Enrollment for these participants will use a web address with a special LTFU landing page and will require a personal verification code. Participants must have a personal email address and internet access to join.

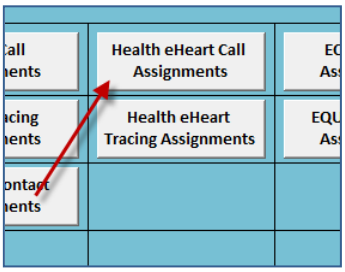
Introductory packets will be mailed by the LTFU Coordinating Center to the 500 selected participants. Two weeks later, a reminder email will be sent by the LTFU Coordinating Center to non-responders. One week following the email, Survey Interviewers (SIs) will make outgoing reminder calls to the remaining non-responders. SIs will also handle incoming calls to address participant questions and concerns about the study, referring the participant to the HeH team, when necessary.

Tools

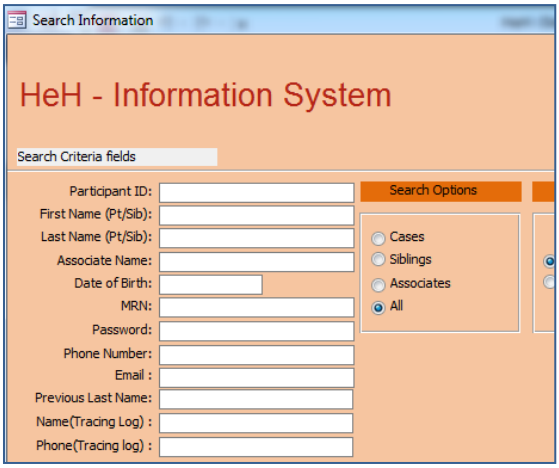
1. **Health eHeart Study Calls** SOP (located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
2. CCSS SI Assignments database (located at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
3. Health eHeart database (located at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
4. CCSS LTFU Participants database (located at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
5. **Pre-Post Call Checklist - Health eHeart** (located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
6. **LTFU Participant Database Data Entry** SOP (located in the SOP library at https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx)
7. **Phone Message Guidance_Rev 5-30-2014** (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools*)
8. **Health eHeart Study Calls Script** (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Health eHeart Study\Scripts*)
9. **Health eHeart Email Template** (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Health eHeart Study*)

Procedures

Before the Call – Create a Profile

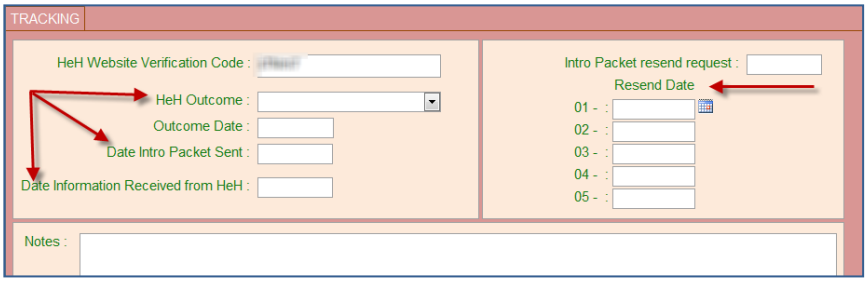


1. Open the CCSS SI Assignments database. Click the **Health eHeart Call Assignments** button, enter the SI ID at the prompt, and click **OK**. Note the first participant in the list. If s/he is in multiple studies, as indicated in the "# of Studies" column, prepare to address the HeH study and the other studies in the same call. Coordination with another SI may be needed.



2. Open both the CCSS LTFU Participants and the Health eHeart databases, and locate the participant's record in each database. See the SOP titled **LTFU Participant Database Data Entry** for instructions on using the Search Information screen in both databases.

3. Review the following data in the participant's record:
   A. LTFU Participant database –Review all fields indicated in the **Pre-Post Call Checklist - Health eHeart** to create a pre-call profile.
   B. Health eHeart database
      i. **HeH Outcome** field – If this field is populated, do not call the participant. S/He has already consented, refused, been determined to be deceased, or been replaced.
      ii. **Notes**
      iii. **Date Intro Packet Sent** and **Resend Dates**



During the Call

Use the documents **Health eHeart Study Calls Script** and **Phone Message Guidance_Rev 5-30-2014** to make calls to the assigned participants.

1. If the participant **received the packet**:
   A. Ask if the participant has reviewed the materials. If not, introduce the study.
   B. Answer the participant's questions about the study.
   C. Ask if s/he is willing to participate in the HeH study.
      i. If yes:

a. Advise the participant to access the website (www.Health-eHeartStudy.org/LTFU) and use his/her verification code to enroll.
   1. Advise the participant that verification codes are case sensitive.
   2. Offer to email the link.
b. Although SIs should not proactively offer to complete the survey via telephone, if the participant requests to complete the enrollment survey via telephone, proceed with the consent and survey. Read the consent, every question, and all possible responses exactly as written.

ii. If no:
a. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
b. If it is unclear if the participant is refusing just the HeH Study or all further participation in the LTFU Study, clarify.

D. Confirm all contact information.
E. Thank the participant for his/her involvement in the LTFU Study.

2. If the participant **did not receive the packet**:
A. Verify the participant's contact information.
B. Introduce the study.
C. Answer the participant's questions about the study.
D. Ask if s/he is willing to participate in the HeH study.
i. If yes:
a. Advise the participant how to enroll online by accessing the website (www.Health-eHeartStudy.org/LTFU) and using his/her personal verification code.
   1. Advise the participant that verification codes are case sensitive.
   2. Offer to email the link.
b. Although SIs should not proactively offer to complete the survey via telephone, if the participant requests to complete the enrollment survey via telephone, proceed with the consent and survey. Read the consent, every question, and all possible responses exactly as written.

ii. If no:
a. Try to capture a reason for the refusal. If there are concerns that can be addressed, do so. If a hold is more appropriate, offer this.
b. If it is unclear if the participant is refusing just the HeH Study or all further participation in the LTFU Study, clarify.

E. Thank the participant for his/her involvement in the LTFU Study.

3. If the participant reports that s/he is **already a HeH Study participant**, ask when s/he enrolled in the study and thank them for their participation.

4. If the participant reports that s/he **does not have a personal email address**:

A. Use the "no personal email address" portion of the **Health eHeart Study Calls Script** to advise the participant that s/he is not eligible for the HeH Study.
B. Confirm the participant's contact information, including additional contact(s).
C. Thank the participant for his/her involvement in the LTFU Study.

5. If the participant **reports any trouble with the HeH website** (e.g. logging in, signing in after registering, etc.):
   A. Advise the participant that you will send an email to the HeH Coordinator on his/her behalf. Let the participant know that s/he will be copied on the email.
   B. Ask the participant for the best contact method and weekday/time for the HeH Coordinator to contact him/her to assist with the issue.

6. If the participant **requires or prefers a Spanish-speaking SI**:
   A. And a Spanish-speaking SI is available, tell the participant, "Un momento, por favor," and transfer the call to the Spanish-speaking SI.
   B. And a Spanish-speaking SI is not available but the participant can understand, ask the best time for a Spanish-speaking SI to call back.

7. If it is determined that the **participant has expired**, offer condolences and, if possible, complete the **Expired Participant Information Sheet**. Do not pursue participation.

After the Call

1. **Send the enrollment email**, if requested by the participant.
   A. Open the **Health eHeart Email Template**.
   B. Create a new email in Outlook.
      i. Copy the body of the template, and paste it into the body of the new email using the "Keep Source Formatting" paste option.
      ii. Replace any automatic Outlook signature in the body of the email with the signature in the template.
      iii. *Do NOT copy and paste the subject line* from the template to the body of the email.
      iv. Copy the subject line from the template (NOT the words "Subject Line:"), and paste it into the **Subject:** bar of the new email.
      v. Without saving changes to the template, close the template.
   C. Personalize the new email.
      i. Update the greeting in the email with the correct salutation and name.
      ii. Replace "[from the Health eHeart database]" in the body of the email with the correct password. Copy the value from the participant's HeH record and paste it using the "Match Destination Formatting" paste option.
      iii. In the signature of the email, replace "[Survey Interviewer's Name]" with the first and last name of the SI sending the email.

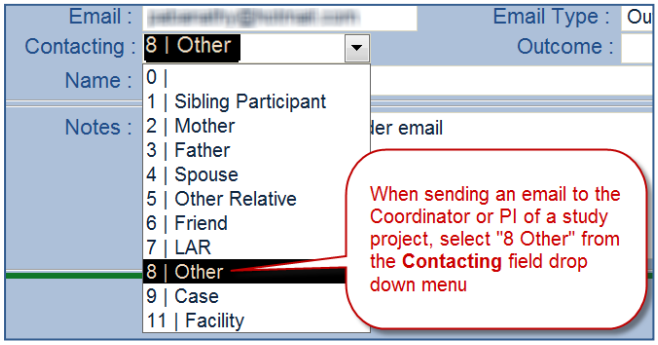
D. Copy the participant's email address from the LTFU Participant database, and paste it into the **To:** bar of the email.
E. Proofread the email to ensure there are no mistakes.
F. Click the **Send** button to send the email.
G. Document the email in the LTFU Participant database's contact log. See the "Update the LTFU Participant database" instructions, below, for details.
H. Health eHeart database, **Notes** field – Log a dated note with your SI ID documenting that the enrollment link was sent.

2. **Email the HeH Coordinator** to report any participant difficulty with the HeH website:
   A. Create a new email message:
      i. **To:** bar – Enter the HeH Coordinator's email address: Coordinator@health-eheartstudy.org
      ii. **CC:** bar – Copy the participant's email address from the LTFU Participant database and paste it into this field of the new email. Also copy the Call Center Coordinator and LSI team in this field.
      iii. **Subject:** bar
         a. If the email will contain PHI, type "[Encrypt]" *without the quotation marks* at the beginning of this field.
         b. Type "LTFU Study Participant – HeH Website Issue" *without the quotations marks* into this field (after the "[Encrypt]" prepend, if used).
      iv. Email body
         a. Include a clear, concise, and complete summary of the website issue.
         b. Include the best contact method and weekday/time for the HeH Coordinator to contact the participant.
   B. Proofread the email to ensure there are no mistakes.
   C. Click the **Send** button to send the email message to the HeH Coordinator, participant, Call Center Coordinator, and LSI team.
   D. Document the email in the LTFU Participant database's contact log. See the "Update the LTFU Participant database" instructions, below, for details.
   E. Health eHeart database, **Notes** field – Log a dated note with your SI ID documenting that the email was sent.
   F. Create an Outlook calendar reminder to contact the participant in one week to follow up. If the HeH Coordinator has not contacted the participant and resolved the issue at that time, notify the Coordinator via email and copy the LSI team.

3. **Update the LTFU Participant database**:
   A. Contact/Trace Log – Create a new contact or trace log record for each communication (call, email, etc.). See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
      i. **Project** – Use the drop-down menu to choose 13-Health eHeart.

ii. **Contact Reason** – Populate with 1-Project Recruitment.

iii. **Contacting** – If sending an email to the HeH Coordinator, choose 8-Other.



B. Update the LTFU Participant database with all confirmed contact information for the participant and his/her associates. See the SOP titled **LTFU Participant Database Data Entry** for detailed instructions.

C. Hold – Update the **CCSS Hold** and **Hold Date** fields if the participant requested or agreed to a hold. See the SOP titled **LTFU Participant Database Data Entry** for full instructions. Holds are documented in the LTFU Participant database only.

D. Needs Tracing – Update the **Tracing Code** and **Tracing Date** fields on the Participant tab. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.

4. **Refusals** – If the participant refused participation in the HeH Study or refused all further participation in the LTFU Study:

A. LTFU Participant database

i. **Outcome** field of the contact or trace log – Populate with 7-Refused.

ii. Refused HeH Study *ONLY* – Do NOT update the **CCSS Study Outcome** or **CCSS Outcome Date** fields.

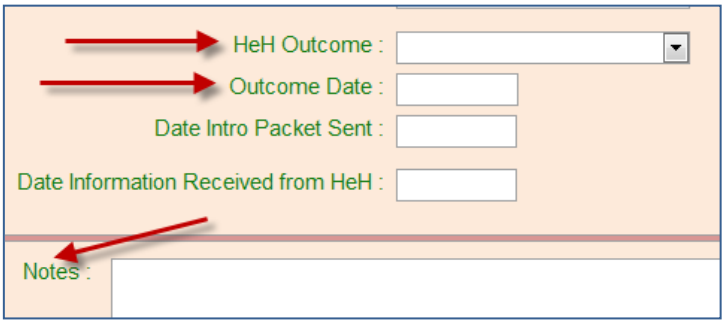
iii. Refused All Else (i.e. the case refused all further participation in the LTFU Study) – Update the **CCSS Study Outcome** or **CCSS Outcome Date** fields in the header. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.

B. Health eHeart database:

i. **HeH Outcome** – Populate with the appropriate outcome.

a. 2-Refused – Use this code if the participant refused the HeH study ONLY.

b. 3-Refused all else – Use this code if the participant refused all further participation in the LTFU Study.



ii. **Outcome Date** – Populate with the current date.

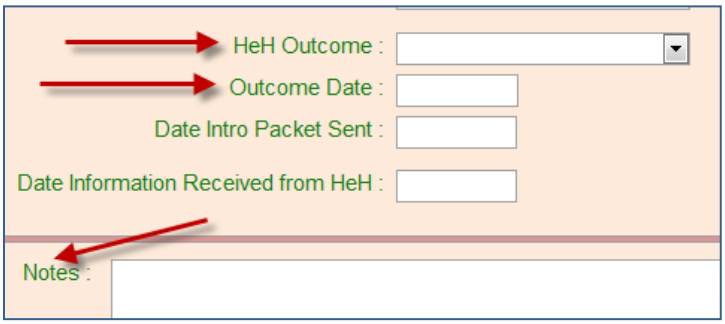
iii. **Notes** – Enter a dated note with SI ID documenting the refusal and the changes to the outcome fields. Indicate if the participant refused the HeH study only or refused all else.

5. **Ineligible** – If the participant is suspected to be ineligible, including ineligibility due to lack of access to technology (e.g. no personal email address):

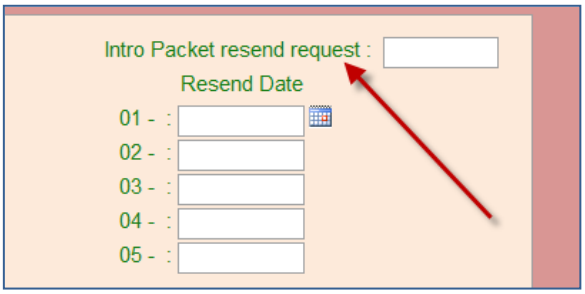
A. LTFU Participant database – In the contact log:
   i. **Outcome** – Populate with 10-Other.
   ii. **Notes** – Document the circumstances of the suspected ineligibility.
   iii. **DB Change** – Populate with 4-Ineligible.

B. HeH database
   i. **Notes** field – Enter a dated note with your SI ID explaining the suspected ineligibility.
   ii. No other fields are updated in the HeH database. The LSI team will follow up.

6. **Deceased** – If it was discovered that the participant is now deceased:
   A. LTFU Participant database – The deceased outcome should be documented in the **DB Change** field of the contact or trace log. See the SOP titled **LTFU Participant Database Data Entry** for full instructions.
   B. **Expired Participant Information Sheet** – Submit the completed form in the "Refusals and Deceased" folder in file cabinet A.
   C. Health eHeart database:
      i. **HeH Outcome** – Populate with 4-Deceased.
      ii. **Outcome Date** – Populate with the current date.
      iii. **Notes** – Enter a dated note with SI ID documenting the newly discovered deceased status and the changes to the outcome fields.



7. **Resend Requests** – If the participant requested a resend of the paper introductory packet, in the Health eHeart database:
   A. **Intro Packet resend request** – Populate with the current date.
   B. **Notes** – Enter a dated note with SI ID documenting the resend requested.



8. If it was discovered during telephone call that the **participant was already a HeH participant**, email the Call Center Coordinator. In the email, include the CCSSID and enrollment date provided by the participant.

[285] Current Filename:		Health eHeart Study Calls ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	1/23/15	R. Massey, D. Rinehart	Initial Development
1.1	5/7/2015	R. Massey, D. Rinehart, A. Oyuela	Content Revision

HIPAA only Packet Production for Recruitment

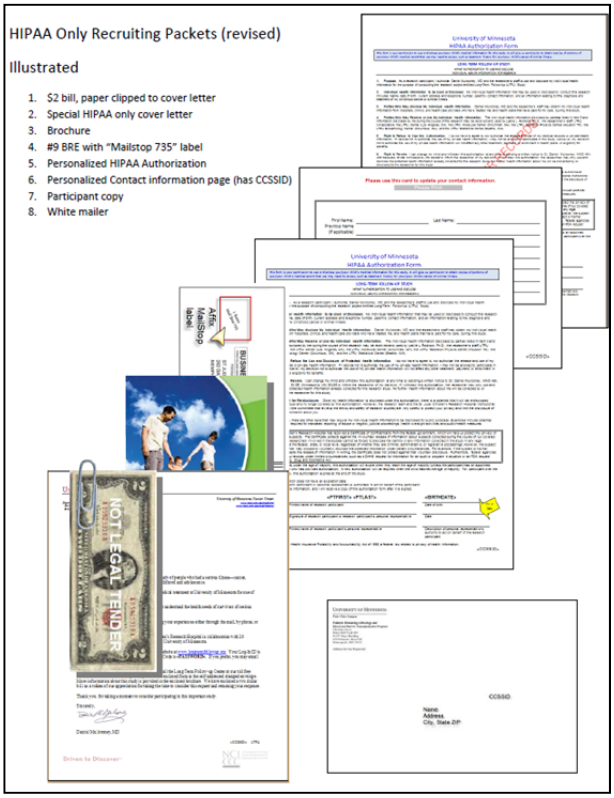
Background

Producing the "Institutional HIPAA-only" recruiting packets involves a cover letter, personalized HIPAA, and a participant copy. We do NOT print a survey for these packets. U.S. addressed materials are mailed with a #9 BRE (instead of the blue BREs used for the questionnaires). Canadian addressed materials need a white #9 self-addresssed, stamped (1 Canadian stamp) envelope (NOT a business-reply envelope). For cases needing Spanish packet, include the Spanish materials. (See *Spanish Packets Recruitment Materials* for more information.)

Procedure

Production involves **mail merging** (1) a cover letter, (2) a personalized institutional HIPAA, and (3) a mailing label. **Assembly** is outlined below. After assembly, carefully QA the packets.

Summary of packet assembly:



1. $2 paper clipped to front of letter (only if indicated)
2. Cover letter
3. Brochure
4. #9 self-addressed Return envelope: MailStop 735 label. *Tuck envelope flap around documents they will return to us (i.e., mailmerged HIPAA with contact information sheet)*
   a. US: use BRE
   b. Canadian: use white, add 1 Canadian stamp
   c. See !LABELS-5667 JBates Mailstop735.doc in Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting
5. Personalized HIPAA (print front/back if indicated) (See Printing HIPAA front/back)
6. Personalized contact information sheet (has CCSSID)
7. NOTE: staple #5 and #6 together.
8. Participant copy of institution-specific HIPAA (pre-printed)
9. Institutional white mailing envelope
10. Mailing label with CCSSID
11. Check with the CRA2 to see whether to include a **PEN**.
12. Spanish packet, for indicated cases: Cover letter, mail merged HIPAA, participant copy in envelope with Spanish label

CRA

Data files and Document production

1. Three data files will be produced for an institution: adults, minors, and deceased. We also produce a label data file with all records to facilitate bulk label production.
2. Use the data file for 3 separate merges:
   a. Cover letter-HIPAA ver (file name designates "**HIPAAonly**"): different for adults, deceased, and minors
   b. Personalized institutional HIPAA –different for living (adults OR minors) and deceased. (Adds name, CCSSID, and date of birth; in some institutions, also includes MRN). Look for filename with HIPAAonly.
   c. Mailing label (If you use the label data file, be sure to select YOUR assigned cases.)
3. Mail merging the **institutional HIPAA**
   a. Locate the merge file in the **InstHIPAA** folder for the institution.
   b. NOTE we use SAME merge file for both adults and minors. (Deceased have separate merge file.)
   c. Use the data files distributed for the mailing.
   d. You can PROBABLY merge with the data straight to the printer.
      i. Print IN COLOR.
      ii. The final page is the information update page.
      iii. Refer to Printing HIPAA Front/Back (below) to determine whether you print one-sided or two-sided.
      iv. After printing, staple the contact information page to the HIPAA page(s).

Participant copies

- The HIPAA-only participant copies contain ONLY the institutional HIPAA. (The LTFU consent form and the LTFU HIPAA are NOT part of these participant copies.)
- A preprinted supply of participant copies will be available.
- BE CAREFUL you pick the CORRECT participant copy version (deceased or living). "GTLT18" in footer indicates living version; "‡" in footer indicates deceased version.

Printing HIPAA Front/Back

- Print all institutions **one-sided *EXCEPT*** Pittsburgh (03), Sloan (09), CHLA (22), UCLA (23), and Riley (24) which print two-sided. (Michigan (26) participant copies also print 2-sided, but we do NOT currently mail HIPAA-only documents to Michigan prospects.)

Revision Record Printed 7/6/2012 8:10 AM

Current Filename:		HIPAA only Packet Production ver 1_7.docx	
Revision No.	Date	Responsible Author	Change Description
1	11/3/10	J.Bates	Initial Development
1.1	2/7/11	J.Bates	#9 BREs
1.2	2/14/11	J.Bates	Canadian
1.3	3/10/11	J.Bates	HIPAAonly
1.4	3/14/11	J.Bates	Remove pilot references
1.5	4/26/11	J.Bates	Clarify print front/back; Spanish packet
1.6	6/28/11	J.Bates	Stapling
1.7	2/22/12	J.Bates	Update list of 2-sided printing institutions; label data file

How to Send a Treatment Summary to a Participant

Background

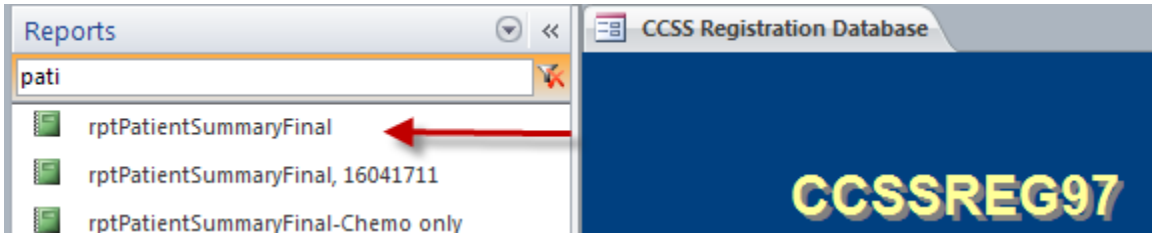
On occasion, a participant will request a copy of childhood medical records. The LTFU Study has only an abstracted research record, and thus, we always first advise the participant to contact the original treating institution for the complete medical records.

If the participant still wants the information we have, we can send the information, preferably via email. If the participant agrees to an emailed copy, the party should advise him or her that the document will be encrypted to secure the personal data and that the password will be the participant's DOB in mm/dd/yyyy format. If the participant requests a hard copy, the party should confirm the address.

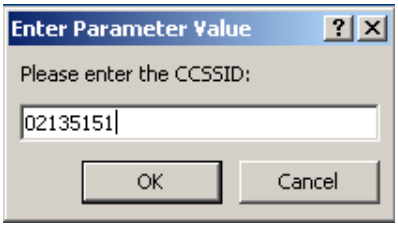
Procedure

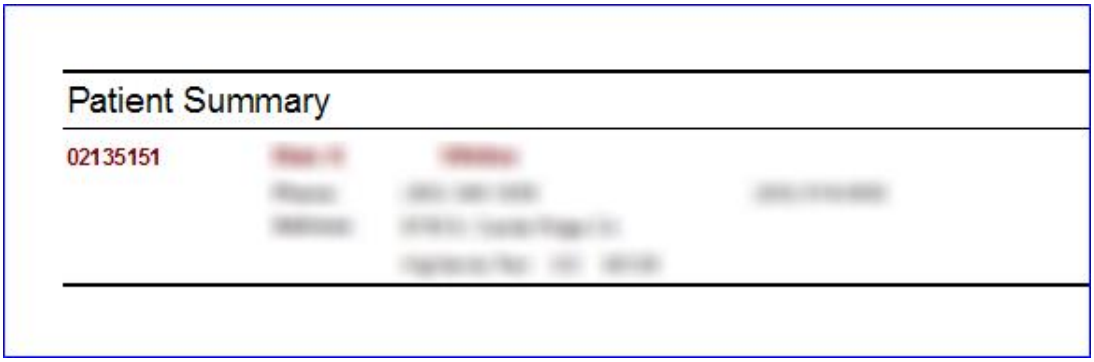
For the Original Cohort survivors:

1. Open the REG database.
2. In the Navigation bar, select "Reports" from the category drop-down menu.
3. In the Search bar, type "Patient." A series of reports will appear below.
4. Double-click on the report **rptPatientSummaryFinal**.

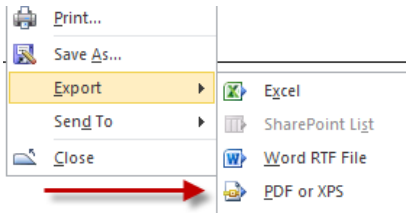


5. Enter the CCSSID number in the Enter Parameter Value dialog box, and then click **OK**. The **Patient Summary** will appear.

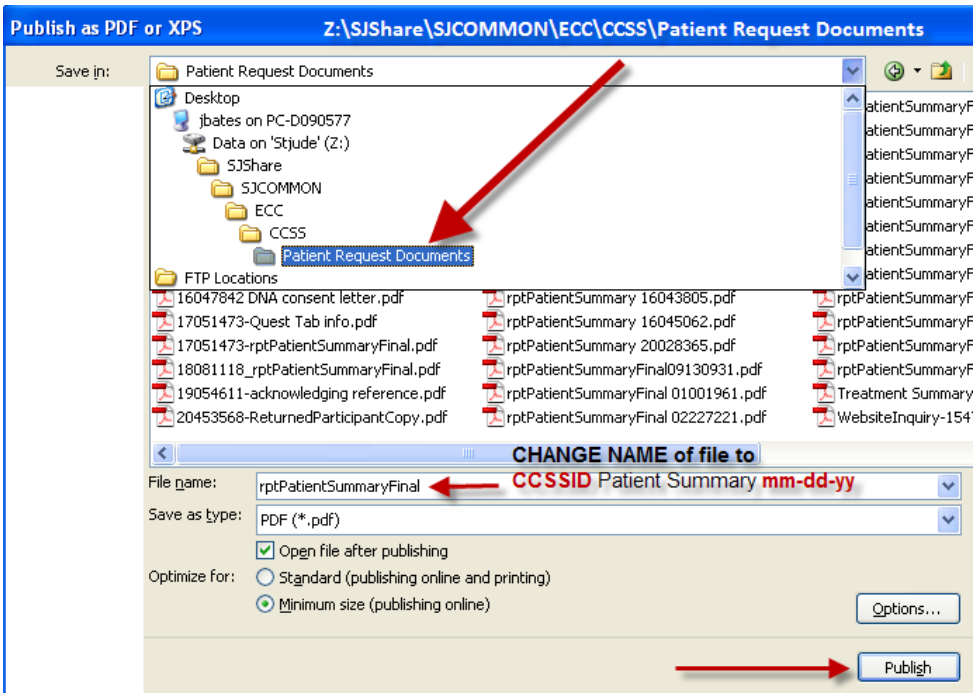




6. Right-click the report. From the popup menu, select **Export.** Then select **PDF or XPS**.

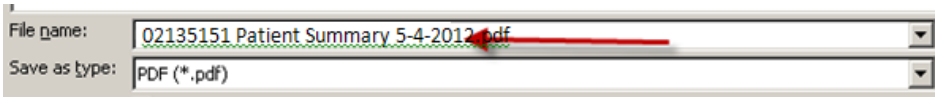


7. The **Publish as PDF or XPS** dialog box opens:



8. In the **Save in** field, drill down to *Z:\SJShare\SJCOMMON\ECC\CCSS\Patient Request Documents*.

9. Change the **File name** field from "rptPatientSummaryFinal" to "(CCSSID) Patient Summary (mm-dd-yyyy)". (i.e., Type the case's CCSSID in place of "rpt"; type the current date in the format mm-dd-yyyy in place of "Final").



10. Click the **Publish** button.

11. Close the Export – PDF screen (Do NOT check the **Save export steps** checkbox.), and close the rptPatientSummaryFinal form.

12. If sending a hard copy of the summary, print a copy of the report for mailing.

13. Close the PDF document.

14. If sending via hardcopy:
    A. Open the cover letter template titled **Cover Letter Template - Sending Patient Treatment Summary** and located at *Z:\SJShare\SJCOMMON\ECC\Interviewers \LSI\Admin\Participant Requests*. Personalize it as follows:

i. Remove the line, "Sample cover letter to participants who request a copy of their summary of treatment." From the top of the template.
ii. Type the participant's name in the salutation.
iii. Type the institution name in the two appropriate locations.
iv. Type the institution's medical records request telephone number in the appropriate place.
v. Type your closing signature and credentials.
vi. Print the personalized letter on St. Jude stationery
vii. Close the cover letter template *WITHOUT SAVING YOUR CHANGES*.
viii. Sign or initial the hard copy letter.

B. Open the envelope template titled **Envelope** and located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies*. Personalize it as follows:
i. Replace "CCSSID" in the format with the participant's CCSSID.
ii. Replace the name and address placeholder with the participant's name and address.
iii. Print the personalized envelope to a St. Jude stationery envelope.
iv. Close the envelope template *WITHOUT SAVING YOUR CHANGES*.

C. Mail the report to the participant:
i. Stack the cover letter on top of the summary.
ii. Hold the 2 documents together, and then fold in thirds. In the second fold, the top of the letter should face outwards.

iii. Insert the documents into the envelope with the letterhead facing up and facing the back of the envelope. Seal.
iv. Put the envelope in the outgoing mail to send the copy to the participant.

15. If sending via email:
A. Secure the document.
i. Open the PDF document in question from *Z:\SJShare\SJCOMMON\ECC\CCSS\Patient Request Documents*.
ii. In Adobe Acrobat (*not* Adobe Reader), go to the Advanced menu, then choose Security, then Encrypt with Password.
iii. At the "Are you sure want to change the security on this document?" question, click the **Yes** button.
iv. At the Password Security – Settings window, check the **Require a password to open the document** checkbox.
v. At the **Document Open Password** field, type the participant's DOB in mm/dd/yyyy format, then click **OK**. Retype the password at the next **Document**

Open Password field, and then click **OK**.

vi. Save the document.

B. Assemble the email.
   i. Open a new email in outlook.
   ii. From the database, copy the participant's email address, and then paste the email address into the **To:** field of the new email message.
   iii. Attach the password-protected patient summary from *Z:\SJShare\SJCOMMON\ECC\CCSS\Patient Request Documents* to the new email message.
   iv. In the **Subject:** bar of the new email message, use the following verbiage: *Requested Records From the Long-Term Follow-Up Study*
   v. Copy the email template below, and paste it into the body of the new email message. Update relevant fields (shown in red).
   vi. Check the spelling.
   vii. Click the **Send** button to send the email to participant.

C. Remove the document password.
   i. Open the PDF document in question from *Z:\SJShare\SJCOMMON\ECC\CCSS\Patient Request Documents*, entering the DOB password.
   ii. In Adobe Acrobat (*not* Adobe Reader), go to the Advanced menu, then choose Security, then Remove Security.
   iii. At the "Are you sure want to remove security from this document?" question, click the **OK** button.
   iv. Save the document.

[EMAIL/COVER TEMPLATE]

Subject line of the email: **Requested records from the Long-Term Follow-Up Study**

Dear (Mr./Ms. [Participant's name]):

Thank you for your recent contact with us. Attached is the copy of the summary records you requested.

As mentioned, we have only limited data, and your original treating institution would be your best source for detailed information.

Please let us know if you have any questions and thank you again for your participation in the Long-Term Follow-Up Study.

Best Regards,

(Your name)

16. Open the Excel file **_Participant Correspondence Log**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Patient Request Documents*:
    A. Enter the relevant information as seen in previous entries.
    B. Save and close the log.

Expanded Cohort

We do not have a comparable patient summary report for the Expanded Cohort. Requests from expanded cohort participants can be sent to Aaron McDonald.

Revision Record

Printed 8/19/2014 1:07 PM

Current Filename:		How to Send a Treatment Summary to a Participant ver1_2.docx	
Revision No.	Date	Responsible Author	Change Description
1	5/4/2012	D. Rinehart	Initial Development
1.1	5/17/12	Procedure Team	Content and format editing
1.2	8/12/2014	R. Massey, D. Rinehart, A. Oyuela, A. McDonald	Content revision, add detailed instructions for mailing

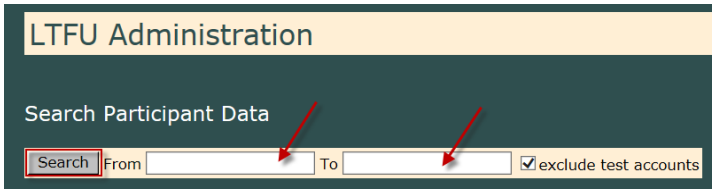
Importing Online (www.longtermfollowup.org) Recruits to the Recruitment Database

Background

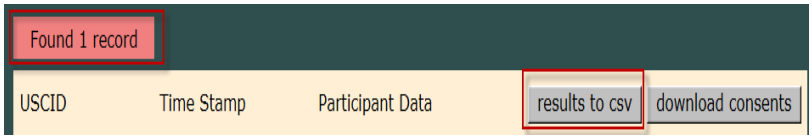
Individuals invited to participate in the LTFU study have the option of completing the recruiting process online. (They also have the option of completing the survey online). Records of online recruiting activity are downloaded from the online recruitment database once a day. The following procedure outlines the steps needed to update the Recruitment database with the results of this online recruitment activity.

Procedure

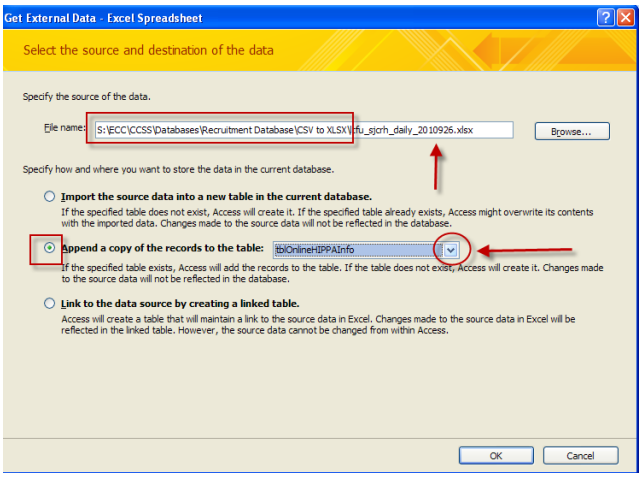
1. Go to http://sjm3vwdltfu01.stjude.sjcrh.local/
2. Enter the date range of interest and click Search.



3. If there are *no results*, then you can stop here.
4. If *there are results*, then click the *results to csv* button



5. Save as *ltfu_sjcrh_daily_(YearMonthDay)* as a XLSX file here: \\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Databases\Recruitment Database\CSV to XLSX
6. If there WERE any **REFUSALS** (enrollment_code = 2) in the spreadsheet,
    a. Save the file a second time (again as an XLSX file and in the same location), but add "REFUSALS" at the end of the file name
        i. (e.g. *ltfu_sjcrh_daily_(YearMonthDay)-REFUSALS.xlsx*)
    b. In this REFUSALS Excel file, delete all *except* the refusal record. Resave and close.
    c. Then re-open the original xlsx file, and delete the refusal record. Resave and close. *It is critical that the refusal record be deleted from the file you will import BEFORE importing records into the Recruitment database!*
7. Open the Recruitment Database
8. Import the spreadsheet (i.e., External Data tab)
    a. On the Source and Destination screen, select the file that you want to import.
    b. Click the button for option that says "Append a copy of the records to the table" and then

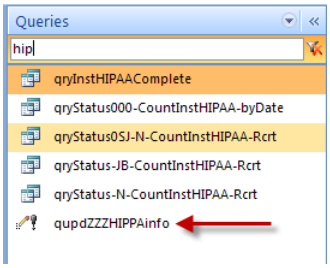


select "**tblOnlineHIPPAInfo**" from the drop down menu.

c. Click OK, and complete the import wizard.

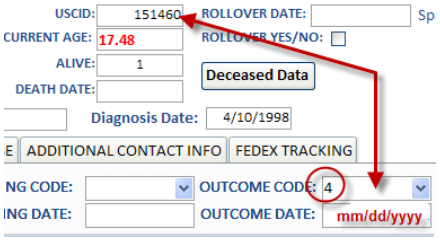
d. Note – when you have more than one file to import, you import them one at a time

9. If there were any **records submitted online IN ERROR**, you must MANUALLY delete the record from **tblOnlineHIPAAInfo**, preferably *before* running the **qupdZZZHIPPAinfo** query. If you do not delete the record from the table, then the update query will post the outcome code (recruited) the next time it is run.



10. Run the update query called **qupdZZZHIPPAinfo**

11. If there were any **REFUSALS** in the morning spreadsheet, search for the records by the USCID (id in the spreadsheet). Code the OUTCOME CODE with '4' (refused) and enter the OUTCOME DATE. Document in RECRUIT NOTES (e.g., m/d/y: refusal submitted online [inits]).



12. Next, continue with ***Processing Updated Online Recruitment Name and Contact Information*** (q.v.) BEFORE you run the rollover macro. This ensures that updated information will be rolled over with the recruited record.

Revision Record — Printed 5/16/2018 2:36 PM

[120] Current Filename:		Importing Online Recruits ver 2_4.doc	
Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development
1.1	12/14/10	J.Bates	Add server path
1.2	7/20/11	J.Bates	Check adrs/codes
2.0	7/27/12	J.Bates	Checking for REFUSALS in daily website spreadsheet
2.1	10/2/12	J.Bates	Purging records submitted online IN ERROR
2.2	7/8/14	L.Harrison	Removed ref. to \\sjmemdwp\LTFUEXPORT\Daily
2.3	8/10/16	J. Ford	Added new online retrieval process
2.4	5/16/18	J. Ford	Added new server path to procedure

Incoming Call Triage and Documentation

Background

Because the Call Center serves the needs of the entire department, callers routed to the Call Center may or may not be in the Long-Term Follow-Up (LTFU) Study. Asking a series of questions helps to determine why the caller is telephoning and how to assist them. The Survey Interviewer (SI) should use the **Incoming Call Reference List** located at, *Z:\Departments\ECC\common\Interviewers\Calling Tools,* to route the call, if appropriate. For callers who are participants in the LTFU Study, incoming calls regarding their participation should be properly documented in the appropriate database call log.

Suggested Questions

Use a combination of the following questions to determine why a caller is contacting the Call Center and to determine how best to assist the caller. The order in which the questions are asked and number of questions asked will be determined by the information obtained from the caller.

- **Are you returning a call? Do you remember the name of the person who called you?**
  - This information can assist in routing the call to the appropriate party, if he or she is available.
  - With SIs assigned to different types of calls, this information can help determine the type of call based on who left the message.
- **Do you know the day and time of the call you received?**
  This information may assist in routing the call. The answerer would determine who was working at the time the call was made.
- **Are you a pediatric cancer survivor or the sibling of a pediatric cancer survivor? Was anyone in your family treated for a childhood illness?**
  This can help determine if the caller is a survivor versus a sibling or if the caller may have been called during tracing efforts.
- **What is the correct spelling of your first and last name? Could your record be under any other name?**
  - This facilitates a successful search of the databases for the correct person.
  - Asking about other names may assist in locating the correct record and helps capture name changes to keep study records accurate.
  - This may help the SI or Tracer who worked the case identify the message if the answerer is unable to identify the caller.
- **What is your birth date?**
  - This allows the SI to search the databases for the caller.
  - For participants, the DOB will serve to confirm identity to assist the SI in protecting protected health information (PHI).
- **Where was your pediatric cancer diagnosed and treated? (*if the caller is a cancer survivor*)**
  If the caller was diagnosed or treated at St. Jude Children's Research Hospital (institution 15), he or she could be calling for St. Jude Life or for the LTFU Study.
- **Are you calling about information you received in the mail? Do you have a letter or questionnaire you can reference to help me better assist you?**
  If the caller references one of the following, then they are likely calling regarding St. Jude Life.
  - Home Survey
  - Health Habits Survey
  - Psychosocial Survey
  - Post-visit Survey
  - Heart and lung testing
  - MIND study
- **Are you calling regarding the Long-Term Follow-Up Study?**
  - If the answer is no and they are a cancer survivor, they may be calling for St. Jude Life or a non-study issue.
  - If they reference an institution where their childhood cancer was treated, they may be calling regarding LTFU study recruitment. Check to see if the institution is one of the LTFU participating centers.
  - Keep in mind that not all callers are clear regarding the difference between "LTFU Study" and "St. Jude Life." That is, the caller may answer "yes" when they are actually in SJL (or both). It is up to the Survey Interviewer to determine this.
- **Are you calling regarding the St. Jude Life Study?**
  - If the answer is no and they are a cancer survivor, they may be calling for the LTFU Study or a non-study issue.
  - Keep in mind that not all callers are clear regarding the difference between "LTFU Study" and "St. Jude Life." That is, the caller may answer "yes" when they are actually in the LTFU Study (or both). It is up to the SI to determine this.

- **Is this the first time you will have completed a survey for the Long-Term Follow-Up Study?**
  This will help determine if the participant is calling about an expansion baseline survey or a follow-up or ancillary survey. This will be useful if you've determined the person is not calling for St. Jude Life.

- **What was your diagnosis date? (*if a cancer survivor*)**
  This assists in determining which cohort the participant is in. For diagnosis dates prior to 1987, participants would be in the original cohort (survivor or sibling). From diagnosis dates in 1987 and later, participants would be in the expansion cohort. This will be useful if you've determined the person is not calling for St. Jude Life.

Searching Databases

Based on the responses to the questions, the Survey Interviewer should search one of the below databases to locate the participant's record:

- **CCSS Recruitment Database** – for LTFU Study expansion cohort survivors who have not yet started the LTFU Study enrollment process
- **CCSS Expansion Tracking** – for:
  - LTFU expansion cohort survivors who have completed the institutional HIPAA but have not completed the baseline survey (or who completed the baseline survey too recently to have "rolled over" to the LTFU Participant database)
  - LTFU expansion cohort siblings who have not completed the baseline survey (or who completed the baseline survey too recently to have "rolled over" to the LTFU Participant database)
- **CCSS LTFU Participant Database** – for LTFU original and expansion cohort survivors and siblings who have completed at least the baseline survey
- **SJLife Tracking Read Only (Not for Data Entry)** – for St. Jude Life participants (See the LSI team for assistance on searching in the St. Jude Life database and reviewing the Communication Report for a log of calls made.)

Routing and Documenting Incoming Calls

Participant Record Located

Once the participant's record has been located, the Survey Interviewer should review the call or trace log (for LTFU Study participants) or the Communication Report (for St. Jude Life participants) to determine what party placed the most recent outgoing call, if any.

1. If the incoming call is a return call and the party who placed the most recent outgoing call is available, the SI should transfer the incoming call to that person using the **Incoming Call Reference List** located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*, and the answerer's task is complete.
2. If the incoming call is a return call and the party who placed the most recent outgoing call is not available:
   A. For LTFU Study incoming calls:
      i. If the call is regarding an issue on which the answering SI has training, the SI should:
         1. Take ownership of the call and proceed according to the SOP for the project in question, providing assistance to the caller.
         2. Confirm all contact information.
         3. Document the incoming call in the appropriate call log.
         4. Update the appropriate database with all confirmed contact information.
         5. Email the party who placed the most recent outgoing call to advise them of movement on their assigned participant.
      ii. If the call is regarding an issue on which the answering SI is *not* trained (e.g. a specialized ancillary study), the SI should:
         1. Advise the caller when the party who placed the most recent outgoing call will next be available.
         2. Take a detailed message including when the caller can be reached and the number at which they prefer to be called.
         3. Confirm all contact information.
         4. Document the incoming call in the appropriate call log.
         5. Update the appropriate database with all confirmed contact information.
         6. Email the party who placed the most recent outgoing call to advise them that the participant called.
   B. For St. Jude Life incoming calls, the SI should:
      i. Take a message with the name of the caller, the phone number at which he or she can be reached, the best day and time to return the call, the name of the participant (if different than the caller), and the participant's Medical Records Number (MRN) or date of birth.
      ii. Email the message to the St. Jude Life CRA and Survey Interviewer team.

3. If the incoming call is *not* a return call (e.g. a LTFU Study participant calls to inquire about a recently diagnosed medical condition or a St. Jude Life participant calls to ask if there are new studies that will bring him or her back to campus):
    A. For LTFU Study participants:
        i. Take ownership of the call. Record as much information about the caller's inquiry as possible including the best number at which he or she can be reached and the best day and time to call.
        ii. Confirm all contact information.
        iii. Document the incoming call in the appropriate call log.
        iv. Update the appropriate database with all confirmed contact information.
        v. Consult with the LSI team and/or Coordinator for assistance in handling any unusual questions or requests.
    B. For St. Jude Life participants:
        i. Record as much information about the caller's inquiry as possible including the name of the caller, the phone number at which he or she can be reached, the best day and time to return the call, the name of the participant (if different than the caller), the participant's Medical Records Number (MRN) or date of birth, and the reason for the call.
        ii. Email the message to the St. Jude Life CRA and Survey Interviewer team.

Note: *<u>Always</u> include the CCSSID AND MRN in the Subject line and email body, whenever sending internal emails regarding former St. Jude patients.*

Sample Email:

Subject bar: CCSS Pt 15234567, MRN 1234, requests to speak to LTFU Study physician

Email body:

Dr. Stalactite:

CCSS Pt 15234567, MRN 1234, would like to speak to LTFU Study physician regarding health concerns related to treatment.

Please advise.

Thank you.

Kimberly Witherspoon
Survey Interviewer

<u>Participant Record NOT Located</u>

For return calls where the Survey Interviewer is unable to locate the caller in any database, email all information obtained during the question process to the Survey Interviewer team and copy the LSI team, Call Center Coordinator, St. Jude Life CRA, and the St. Jude Life Survey Interviewer team, asking if anyone recognizes the call.

If a Survey Interviewer recognizes the caller, they should always send a "Reply To All" email response.

When in doubt, always consult with a member of the LSI team, Coordinator or Research Scientist for guidance.

Revision Record Printed 8/10/2016 2:13 PM

[200] Current Filename:		Incoming Call Triage and Documentation ver 2_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/16/09	B. Benavides/D. Rinehart	Initial Development
1.2	4/27/12	Procedure Team	Format and content revisions
1.3	4/27/12	D. Rinehart	Updated reference documents in Background
1.4	5/30/13	D. Rinehart	Content revision; name spelling
1.5	8/15/2013	R. Massey	Content Revision; Minor Formatting Revision
2.0	8/5/2014	R. Massey, D. Rinehart	Title update, content revision to include database search and call documentation guidelines
2.1	8/9/2016	D. Rinehart, A. Cobble, R. Daniels	Content revision; Directive for sending internal emails regarding St. Jude Life participants

Initial Review of Reported Subsequent Neoplasms

Background

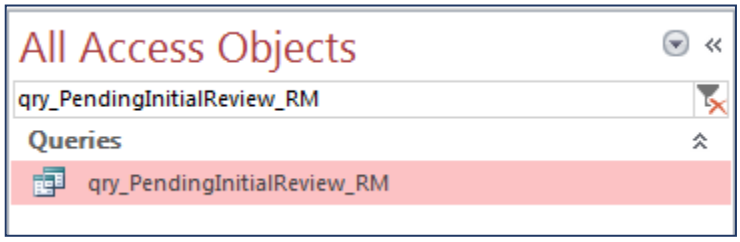
The subsequent neoplasm (SN) project seeks to track SNs with which Long-Term Follow-Up (LTFU) Study participants are diagnosed. When a participant or his/her proxy reports one or more subsequent cancers, leukemias, tumors, or similar illnesses during their participation, study staff members review these reports to screen out conditions that are not likely to be true SNs. If the report appears to be or possibly could be a true SN, the study team will pursue a pathology report from the diagnosing entity to verify the condition.

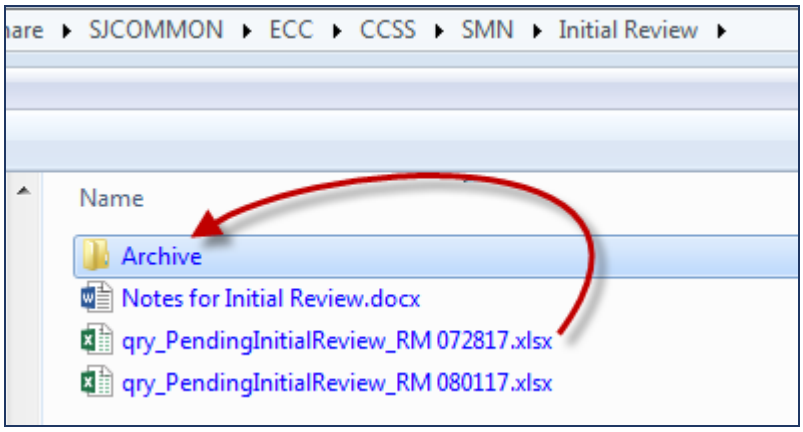
This procedure outlines the process for the initial, screening review of reported SNs. For information about pursuing pathology reports, which follows this procedure, see the SOP titled **Pursuing Subsequent Neoplasm Pathology Records**.

Procedures

Generate a list of reported SNs awaiting an initial pursue decision:

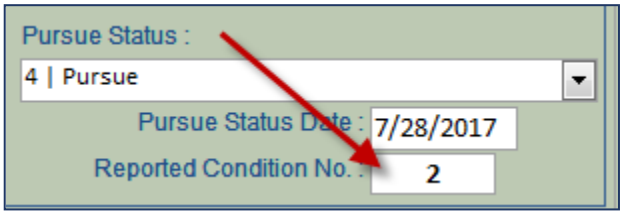
1. Open the SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Minimize the Search form, and open the Navigation Pane.
3. **Run qry_PendingInitialReview_RM**. **Export the results** as an Excel workbook.
   A. Save the file at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Initial Review*.
   B. Add the date to the file name: **qry_PendingInitialReview_RM mmddyy**.
4. In *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Initial Review*, **archive the previous run**'s results.



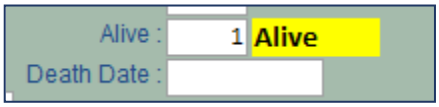


Perform the initial review for each participant in the query results:

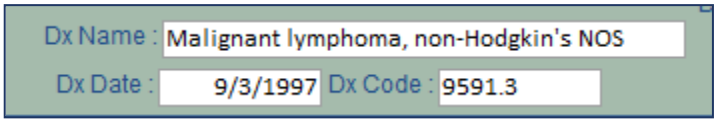
1. Restore the Search form, and locate the first participant's record using the search features.
2. **Navigate to the condition** in question. The ConditionID column in the query results displays the value from the **Reported Condition No.** field in the database.



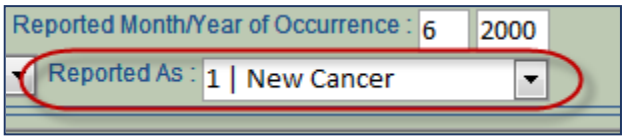
3. **Create a profile** of the participant by reviewing the following:
   A. Study Outcome – Review the StudyOutcome column in the query results and/or the **CCSS Study Outcome** field in the header to determine if the participant has a study outcome that should be taken into consideration (e.g. refusal, ineligible, etc.). NOTE: Refusal does not automatically rule out pursuit of an SN. These are decided on a case-by-case basis.
   B. Vital Status – Review the Alive column (1 = Alive, 2 = Deceased) of the query results and/or the **Alive** field in the header to determine if the participant is alive or deceased.



   C. Original Diagnosis (cases only) – Review the participant's original childhood neoplasm, documented in the **Dx Name** field of the header.
   D. Original Diagnosis Date (cases only) – Review the date the participant's original childhood neoplasm was diagnosed, documented in the **Dx Date** field of the header.



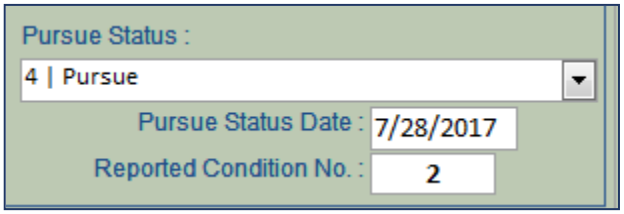
   E. All conditions previously recorded for the participant and the **Pursue Status** value of each.
   F. Reported Condition – Review the newly reported condition as displayed in the ReportedCondition column of the query results and the **Reported Condition** field of the condition record.
   G. Event Type – Review the **Reported As** field in the condition record to determine if the participant reported this as a new cancer, a recurrence, or s/he was not sure.



4. **Make a decision** on whether the condition will be pursued. Consider whether the condition was previously reported and the outcome of the previous report, is related to the original diagnosis, etc.
   A. For recurrences of the primary cancer:
      i. If the recurrence is less than 20 years from the original diagnosis date, reject the SN at the initial screening.
      ii. If the recurrence is 20 years or more from the original diagnosis date, seek guidance from the Research Scientist or Principal Investigator on whether it should be pursued.
   B. For metastases:
      i. If the primary SN WAS previously confirmed, do not pursue the metastasis report.
      ii. If the primary SN WAS NOT previously confirmed, pursue the primary SN.

C. For reported SNs that are similar to a previous SN but have a different diagnosis date, generally pursue these. See the Senior Coordinator and/or Research Scientist for guidance.
D. For non-neoplastic conditions (e.g. hypertension, diabetes), do not pursue.
E. For reported neoplastic conditions that are clearly benign (e.g. lipoma, adenoma), do not pursue. EXCEPTION: Although meningiomas are benign tumors, we pursue all new meningioma reports.
F. Pursue any neoplastic process that is clearly a new report and is not clearly benign. NOTE: Although meningiomas are benign tumors, we pursue all new meningioma reports.
G. If in doubt, it is better to pursue the condition and have a benign, non-neoplastic, or metastatic condition later rejected during the MD reviews than to reject a potential SN and inadvertently exclude it from the research analysis.
H. For further guidance on pursue decisions, see **Notes for Initial Review** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Initial Review*. Also seek guidance from the Senior Coordinator and/or Research Scientist.

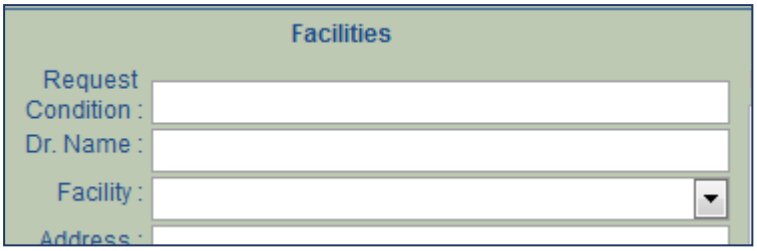
5. On the appropriate SN condition record:
   A. **Record the review decision**:
      i. If the newly reported condition WILL be pursued and there IS an LTFU HIPAA on file:
         a. **Pursue Status** – Use the drop-down menu to populate the field with 4-Pursue.
         b. **Pursue Status Date** – Populate with the current date.



      ii. If the newly reported condition WILL be pursued but there IS NOT an LTFU HIPAA on file:
         a. **Pursue Status** – Use the drop-down menu to populate the field with 7-Pursue, Pending First MR.
         b. **Pursue Status Date** – Populate with the current date.
      iii. If the newly reported condition WILL NOT be pursued:
         a. **Pursue Status** – Use the drop-down menu to populate the field with 1-Rejected at Initial Screening.
         b. **Pursue Status Date** – Populate with the current date.
      iv. If there is not enough information to make an initial review decision:
         a. **Pursue Status** – Populate with 6-Pursue, Need Info from Pt.
         b. **Pursue Status Date** – Populate with the current date.
         c. **Condition Notes** – Enter a dated note with initials explicitly explaining to the SIs what information is needed from the pt. *Example: 10/9/2017: SI – Please contact the pt, acknowledge their reported SN, advise no dx date was provided, obtain the approximate dx date, and ask if they are reporting their original childhood cancer. [RM]*

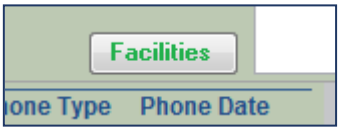
   B. **Date 1st Review** – Populate with the current date.
   C. **Condition Notes** – Record any relevant notes related to the initial pursue decision with a dated comment and the author's initials. Always include a note explaining rejections. *Example: 10/9/2017: Rejected at initial screening; self-reported condition is a recurrence of the original diagnosis within 20 years of original dx date. [RM]*
6. **Populate the Facilities group for those conditions that will be pursued**. If more than one facility is indicated, create more than one facility record.
   A. **Request Condition** – Based on the reported condition, type the diagnosis as it will appear on our request to the facility. Ensure the diagnosis is broad enough to cover most of what the

true diagnosis may be (e.g. type "skin cancer" for reported "melanoma" in case the true diagnosis was "basal cell carcinoma", type "brain tumor" for reported "tumor behind my eye" to cover all malignant and non-malignant brain tumors, type "cervical lesion" for report of "pre-cervical cancer" in case the lesion was actually cancer, etc.).



B. **Dr. Name** – If known, type the correct name of the doctor. Using the participant's self-report, this can usually be found using online resources.

C. **Facility** – Click the **Facilities** button and use the Access search feature to find the facility in question.



i. Facility IS Located - Use the **Move to Tracking** button to move the facility's contact information to the condition's form.

ii. Facility IS NOT Located –

a. Use online resources to locate the facility using the **Reported Facility**, **Reported Address**, **Reported CSZ**, and **Reported Dr** data provided by the participant. Contact the facility to confirm the mailing address, phone number, and fax number to be used *for medical record requests*. NOTE: Some facilities outsource their medical record processing or process medical records at a centralized location, so the facility's normal address and numbers may not be appropriate for requesting medical records.

b. Double-check that the confirmed contact information is not already in the database. For example, review all entries for the city in question.

c. If still not found, add the new facility to the database.

d. Use the **Move to Tracking** button to move the new facility's contact information to the condition's form.

iii. Participant Did Not Provide Sufficient Facility Information

a. **Pursue Status** is currently set to 4-Pursue – (1) Update **Pursue Status** from 4-Pursue to 6-Pursue, Need Info from pt. (2) Enter a dated note in **Condition Notes** explicitly indicating to the SI team what information is needed. *Example: 10/9/2017: SI – Please contact the pt to obtain information about the facility that originally dx'ed this condition. [RM]*

b. **Pursue Status** is currently set to 7-Pursue, Pending First MR – (1) Update **Pursue Status** from 7-Pursue, Pending First MR to 8-Pursue, Need 1st MR & Info from Pt. (2) Enter a dated note in **Condition Notes** explicitly indicating to the SI team what information is needed. *Example: 10/9/2017: SI – Please contact the pt to obtain information about the facility that originally dx'ed this condition. Please alert pt that we are also seeking a signed MR. [RM]*

7. **Repeat the procedure on each participant** until all are completed.

Revision Record Printed 8/1/2017 10:26 AM

Current Filename:		Initial Review of Reported Subsequent Neoplasms ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	8/1/2017	R. Massey	Initial Development

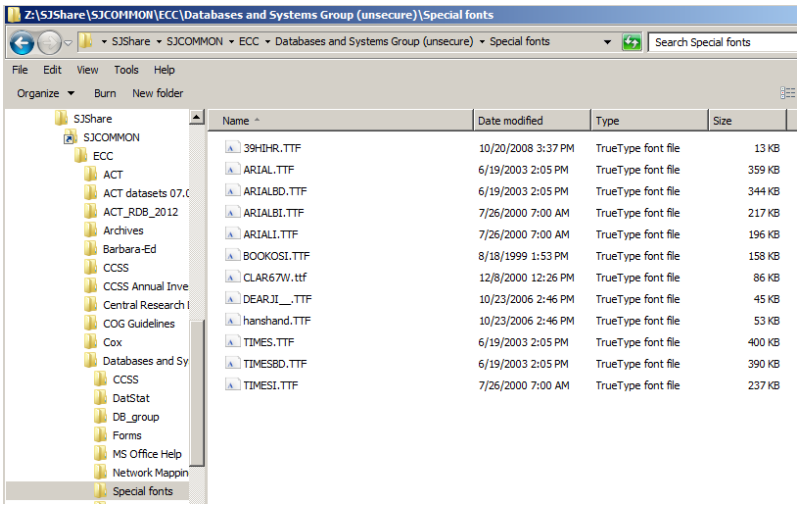
Installing Special Fonts Needed to Print Surveys

Background

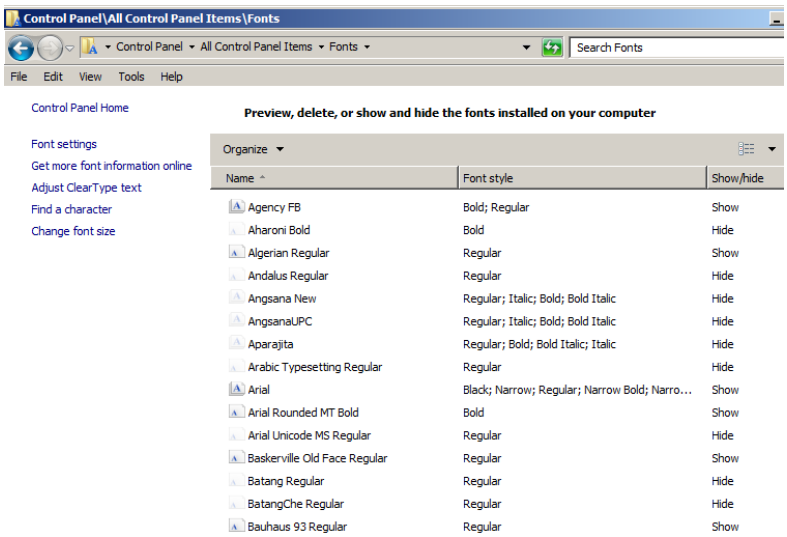
A computer needs to have certain "special" fonts in order to print surveys correctly. A master set of these special fonts is available on the server. These need to be installed on your computer.

Procedure

1. Open the **Special Fonts folder on the server** (go to **Z:\SJShare\SJCOMMON\ECC\ Databases and Systems Group (unsecure)\Special fonts**
   a. Select and COPY all the fonts



2. Open the Fonts folder **on YOUR computer**:
   a. From the Start button, go to Control Panel
   b. In Control Panel, open the Fonts folder



3. INSTALL the copied fonts. To install, just PASTE the fonts you copied into your computer's Control Panel/Fonts location
   a. If prompted that a font already exists, go ahead and replace it.

4. Close both your Fonts and the server's Special Fonts folders.

Revision Record — Printed 11/15/2012 8:38 AM

Current Filename:		Installing Special Fonts for Surveys ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	11/15/12	J.Bates	Initial Development

Institutional HIPAA Correspondence with Participant

Background

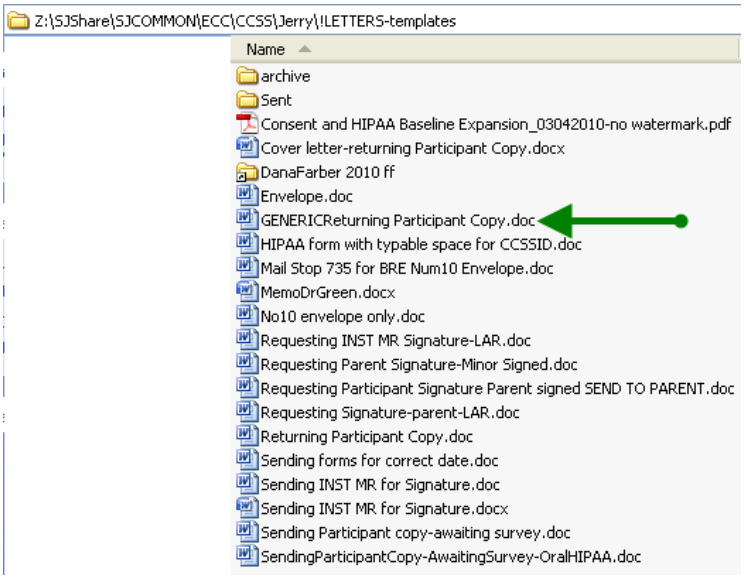
Occasionally, correspondence with participants will be needed regarding Institutional HIPAAs. Correspondence generally falls into two categories:

- The participant returned the "Participant Copy" with the survey booklet or signed HIPAA document. The participant copy will need to be mailed back with a cover letter; or
- The participant returned the HIPAA with either an incorrect or incomplete signature OR improperly dated the HIPAA. The participant will need a new individualized HIPAA (to sign and return) with a cover letter. We keep the incorrect HIPAA.

Procedures

Returning the "Participant Copy" copy

1. Go to the following location on the server: **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\!LETTERS-templates**
2. Find the template: **GENERICReturning Participant Copy**
3. Before making any changes, use the **SAVE AS** function to save the file in the **SENT** folder, *renaming with the participant CCSSID in the lead*.
4. Add the appropriate individualized information to the renamed document on both the envelope and the letter.
5. Resave the document
6. Load a St. Jude envelope into the printer and print the envelope (select "current page" for Print What).
7. Use St. Jude letterhead to print a copy for the participant (select current page for printing)
8. Before mailing, PROOFREAD to be sure you have the correct name, address, and CCSSID.



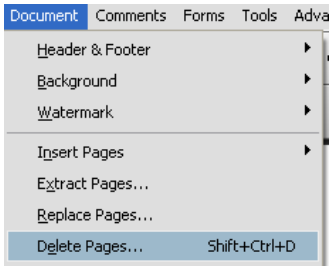
9. Mail the "participant only" copy along with the letter to the participant's address.
10. In the Recruitment database, on the Tracking tab, in Recruit Notes, document that you returned the participant copy.

Returning an Individualized Institutional HIPAA (for further action) with cover letter

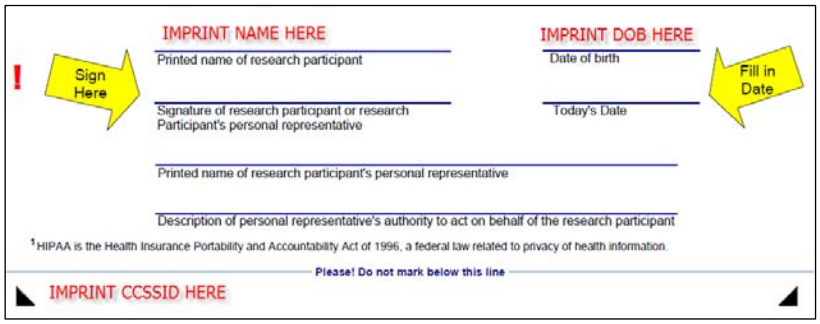
1. Go to the following location on the server: Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\!LETTERS-templates
2. Find the cover letter template that is most applicable to your request (new signature, new date, etc.)
3. *Before editing the letter*, use the **SAVE AS** function to both rename the document with the CCSSID in the lead of the file name, and put the saved document in the **SENT** folder.
4. Add the appropriate individualized information to the renamed document on both the envelope and the letter. Modify the generic content if needed.
5. Once the changes have been made, resave the file in the SENT folder, making sure the participant CCSSID is in the lead of the filename.
6. Load a St. Jude envelope into the printer and print page only.
7. Use St. Jude letterhead to print the letter for the participant (select "current page" for printing).
8. Sign the letter
9. Print a *copy* of the letter on regular paper, to be filed with the originally signed HIPAA.

*Next you will need to generate an individualized **institutional** HIPAA to send to the participant*

10. On the server, go the appropriate institutional folder in the following location
    Z:\SJShare\SJCOMMON\ECC\CCSS\ExpansionRecruiting
11. Open the pdf version of the authorization-no watermark (either deceased or adult/Living) (You need the full version of Adobe Acrobat to complete the remaining steps.)
12. *Before changing the document*, use **SAVE AS** to save it to the Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\!LETTERS-templates\SENT folder, renaming with the CCSSID in the name
13. NOTE: this version of the authorization also contains the LTFU consent and the LTFU HIPAA. You only need the institutional HIPAA pages. Delete the unnecessary pages using the **Document**, **Delete Pages…** function in Adobe.



14. Using Adobe Acrobat **Tools**, **typewriter**, add the *name*, *DOB* and *CCSSID* (and MRN, for selected institutions) in the appropriate places.



15. Re-save the document (in the Sent folder, with the CCSSID at the start of the filename).

16. Print the document in color.
    a. If institutional HIPAA is more than one page:
        i. print two-sided
        ii. staple pages together
        iii. Flag the signature line with an additional "SIGN HERE" post-it flag.

17. Before mailing, PROOFREAD to be sure you have the correct name, address, CCSSID, DOB in the letter/envelope/HIPAA.

18. Assemble the mailing: the signed cover letter, #9 self-addressed return envelope with MailStop 735 label, and the individualized HIPAA. Mail to participant.

19. Document in the Recruitment database, on the **Tracking** tab
    a. In Recruit Notes, document that you mailed another copy of the Inst HIPAA.
    b. Enter the date in the next available **RESEND x** field
    c. Enter "7" as the **RESEND x MODE**

20. Staple the copy of the letter to the original returned HIPAA and file by CCSSID in the "Hold for HIPAA" cabinet.

Revision Record Printed 7/10/2012 12:02 PM

Current Filename:		Institutional HIPAA Correspondence w Participant ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/23/2011	L.Harrison	Initial Development

Institutional HIPAA fact sheet

Background

When a potential participant in the LTFU study is recruited, he/she provides the parent institution with HIPAA authorization. That HIPAA is referred to as the "Institutional (inst) HIPAA". The institutional HIPAA authorization gives the parent institution permission to release Protected Health Information (PHI) to the LTFU study team. This PHI includes name, address/phone numbers, some demographics, and records related to the diagnosis and treatment of the original childhood illness.

Institutional HIPAA

Historically, the institutional HIPAA has been presented to prospective participants in several ways:

(a) as a stand-alone document ("HIPAA-only") mailed to the individual either by USC or the Recruitment Center at St. Jude;

(b) as part of a "full recruitment booklet" that also includes the study consent, LTFU study HIPAA authorization, and baseline survey;

(c) as part of an online registration process; and,

(d) through a scripted telephone interview (for institutions permitting "verbal HIPAA").

Many institutions use virtually the same institutional HIPAA authorization form. The forms are differentiated only by the institution's name in the title and the principal investigator's name in the authorizing sentence. We refer to these as the "generic institutional (inst.) HIPAA."

Some institutions, on the other hand, have their own individualized HIPAA form. We refer to these as the "individualized institutional (inst) HIPAA."

- A completed *parent institution's HIPAA authorization* establishes the individual as "recruited" to the study. It allows the parent institution to release PHI to the LTFU coordinating center. *It does not mean, however, that the person is enrolled in the study. Enrollment occurs only when the study consent form and baseline questionnaire are completed.* Study participation CANNOT proceed without the institutional HIPAA. **The institutional HIPAA may be obtained online, with a signature, or verbally—depending on the related institution's IRB approval.**

LTFU Study HIPAA

When an individual is recruited and consents to the study, it may be necessary to obtain medical records regarding diagnosis and treatment after their childhood illness. Release of these documents is NOT covered by the institutional HIPAA. For this purpose, we use a second HIPAA authorization form. This second HIPAA is referred to as the "LTFU Study HIPAA". The LTFU Study HIPAA authorization document is incorporated into the expansion baseline survey.

- A completed *LTFU Study HIPAA authorization* allows the LTFU study team to request subsequent medical records for recruited individuals. Study participation CAN proceed without a LTFU Study HIPAA. **LTFU study HIPAA is obtained ONLY in signed hard copy form, necessary to request current medical records.**

Both types of signed HIPAA authorizations are signed by the participant (or the participant's legally authorized representative). HIPAAs signed by a minor are not admissible; instead, a parent/guardian signature must be obtained.

CRA

Institution Chart. This chart indicates whether the institution's institutional HIPAA is the generic version or an individualized version. It indicates whether the LTFU Study HIPAA serves as the Institutional HIPAA. It also indicates whether a full recruitment booklet was initially (or is *currently*) used for the institution. Finally, it indicates which institutions do NOT have verbal HIPAA authorization.

Institution	Recruiter	Generic Inst. HIPAA	Individual-ized Inst. HIPAA	Use LTFU Study HIPAA *as* Inst. HIPAA	Full Recruitment booklet	Verbal HIPAA authorized
01 Univ Of Minnesota	SJ		YES		YES (initially)	
02 Denver Childrens	SJ	YES			YES (initially)	
03 Pittsburgh Childrens	USC & SJ	YES				
04 Stanford	SJ	YES			YES (initially)	
05 Dana Farber	USC & DF*			YES		NO
06 Emory	USC & SJ	YES				
03 Washington DC	SJ	YES			YES (initially)	
08 MD Anderson	SJ	YES			YES (initially)	
09 Sloan Kettering	SJ		YES		YES (initially)	
11 UC SanFrancisco	USC & SJ	YES				
12 Childrens Seattle	SJ	YES			YES (initially)	
13 Toronto	SJ		YES **			NO
15 StJude	USC & SJ	YES		YES	YES (initially) ***	
16 Columbus Childrens	SJ	YES			YES (initially)	
17 Roswell Park	USC & SJ	YES				
19 Minneapolis Childrens	USC & SJ	YES				
20 Childrens Philadelphia	SJ	YES			YES (initially)	
21 StLouis Childrens	SJ	YES			YES (initially)	
22 Childrens LosAngeles	SJ		YES		YES (initially)	
23 UCLA	SJ		YES		YES (initially)	
24 Riley U of Indiana	USC & SJ	YES				
25 UAB	SJ	YES			YES (initially)	
26 Mott Univ Michigan	SJ		YES		YES (*currently*)	
27 UT Southwestern	USC & SJ	YES				
28 Texas Childrens	SJ	YES			YES (initially)	
29 City of Hope	SJ	YES			YES (initially)	

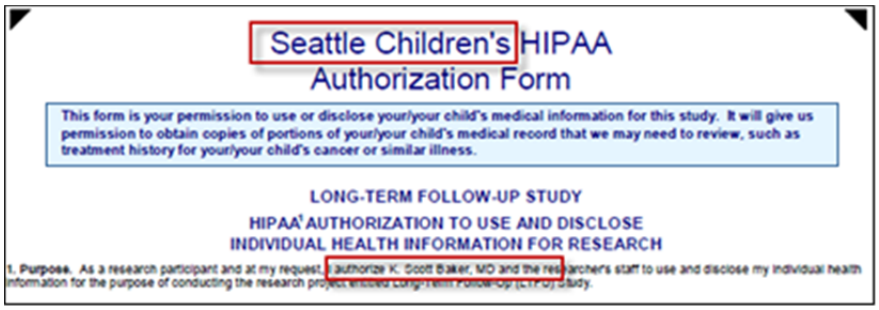
* Dana Farber recruits its own eligible participants by obtaining permission to provide contact information to the coordinating center (but not medical records). Thus, the LTFU Study HIPAA must be provided to Dana Farber as documentation authorizing medical record release. For this reason, we will pursue a signed LTFU Study HIPAA for Dana Farber cases, regardless of reported second malignancy.

** Toronto (Canadian) laws differ from US laws regarding HIPAA and consent. We use a special expansion baseline survey booklet which includes the required Canadian authorization documents.

*** St. Jude. The LTFU Study HIPAA is identical to what would have been the generic institutional HIPAA for St. Jude cases. For this reason, the full recruitment booklet for St. Jude only included the LTFU Study HIPAA.

Sample of Institutional generic HIPAA. The institution's name appears in the title, and the name of the institution's principal investigator appears in the "I authorize ____" statement.

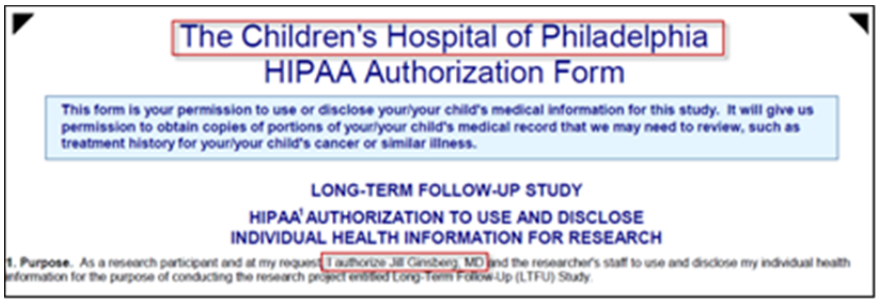
The Institutional HIPAA form appears in the HIPAA only document, in the online registration form, and (when available) as part of the full recruitment booklet. When it appears in the full recruitment booklet, it appears BEFORE the LTFU consent form and the LTFU HIPAA form. The Institutional HIPAA form does NOT appear in the survey booklet used for Expansion Baseline.


Seattle Children's HIPAA
Authorization Form

This form is your permission to use or disclose your/your child's medical information for this study. It will give us permission to obtain copies of portions of your/your child's medical record that we may need to review, such as treatment history for your/your child's cancer or similar illness.

LONG-TERM FOLLOW-UP STUDY
HIPAA AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH

1. Purpose. As a research participant and at my request, I authorize K. Scott Baker, MD and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled Long-Term Follow-Up (LTFU) Study.

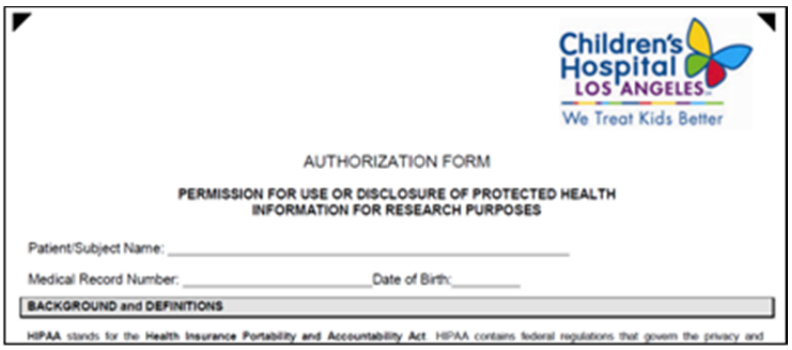

The Children's Hospital of Philadelphia
HIPAA Authorization Form

This form is your permission to use or disclose your/your child's medical information for this study. It will give us permission to obtain copies of portions of your/your child's medical record that we may need to review, such as treatment history for your/your child's cancer or similar illness.

LONG-TERM FOLLOW-UP STUDY
HIPAA AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH

1. Purpose. As a research participant and at my request, I authorize Jill Ginsberg, MD and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled Long-Term Follow-Up (LTFU) Study.

Samples of various **Individualized Institutional HIPAAs**. Like the generic Institutional HIPAA form, these forms clearly identify the institution in the title area. Likewise, the institution's principal investigator is identified within the document. The individualized institutional HIPAA appears in the HIPAA only document, in the online registration form, and (when available) as part of the full recruitment booklet. Like the generic institutional HIPAA form, when an individualized HIPAA appears in the recruitment booklet, it appears BEFORE the LTFU consent form and the LTFU HIPAA form. This form is NOT included in the standard Baseline Questionnaire.


Children's Hospital LOS ANGELES
We Treat Kids Better

AUTHORIZATION FORM

PERMISSION FOR USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

Patient/Subject Name: _____

Medical Record Number: _____ Date of Birth: _____

BACKGROUND and DEFINITIONS

HIPAA stands for the Health Insurance Portability and Accountability Act. HIPAA contains federal regulations that govern the privacy and

CRA

Study No.: HUM00004109 Consent Approved On: 5/25/2010 Project Approval Expires On: 5/24/2011
IRB: IRBMED

University of Michigan
Consent To Be Part Of A Research Study

NAME OF STUDY AND RESEARCHERS

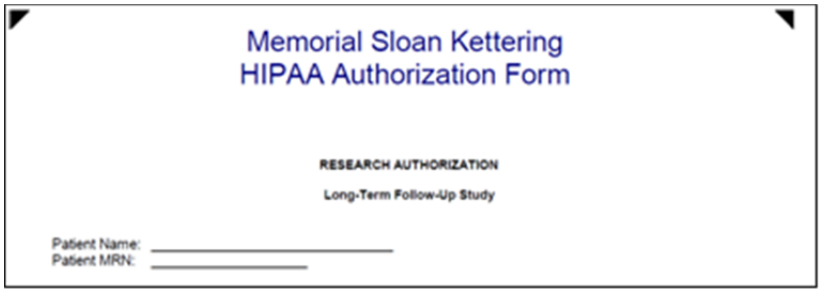
Title of Project: Long-Term Follow-Up (LTFU) Study

Principal Investigator: Raymond J. Hutchinson, MD

Co-Investigator: Rajen J. Mody, MD

GENERAL INFORMATION

We are conducting research about childhood cancer or a similar illness to find out what long-term health and social effects the illness may have on patients and their families.



Memorial Sloan Kettering
HIPAA Authorization Form

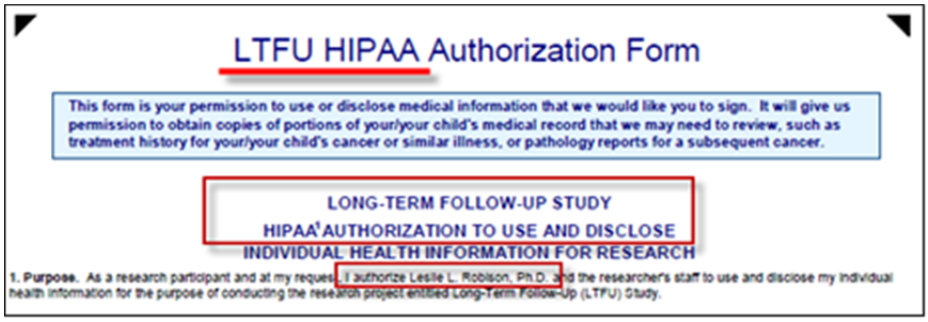
RESEARCH AUTHORIZATION

Long-Term Follow-Up Study

Patient Name: _____
Patient MRN: _____

Sample of **LTFU HIPAA**. The LTFU HIPAA does not name any institution in its title, since it is the Long-Term Follow-Up Study HIPAA authorization. The name of principal investigator for the study, Leslie L. Robison, Ph.D., appears in the "I authorize ____" statement.

The LTFU HIPAA form appears in EVERY expansion baseline survey booklet. It appears immediately after the LTFU consent form. The "full recruitment booklet" also contains the LTFU HIPAA, where it also appears immediately after the LTFU consent form.



LTFU HIPAA Authorization Form

This form is your permission to use or disclose medical information that we would like you to sign. It will give us permission to obtain copies of portions of your/your child's medical record that we may need to review, such as treatment history for your/your child's cancer or similar illness, or pathology reports for a subsequent cancer.

LONG-TERM FOLLOW-UP STUDY
HIPAA AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH

1. **Purpose.** As a research participant and at my request, I authorize Leslie L. Robison, Ph.D. and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled Long-Term Follow-Up (LTFU) Study.

Revision Record Printed 7/9/2012 9:58 AM

Current Filename:		Institutional HIPAA fact sheet v2_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	8/2/10	J.Bates	Initial Development
2	7/18/11	J.Bates	Update re recruitment booklets; table
2.1	5/30/12	J.Bates	Formatting; update verbal HIPAA authorization

International Addresses

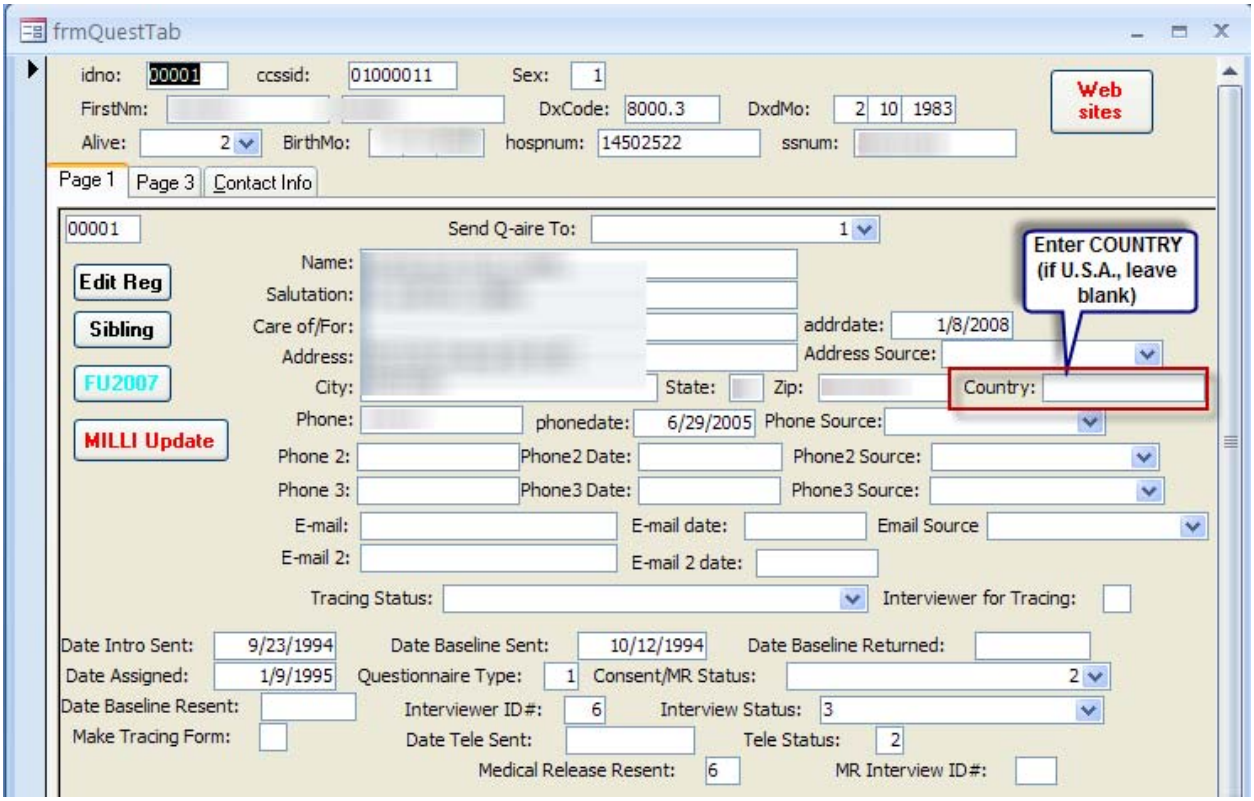
Background

Each of the LTFU database address records now contains a "Country" field.

1. For addresses in the U.S.A., LEAVE THE COUNTRY field blank. For non-US addresses, it will be necessary to enter the country name.

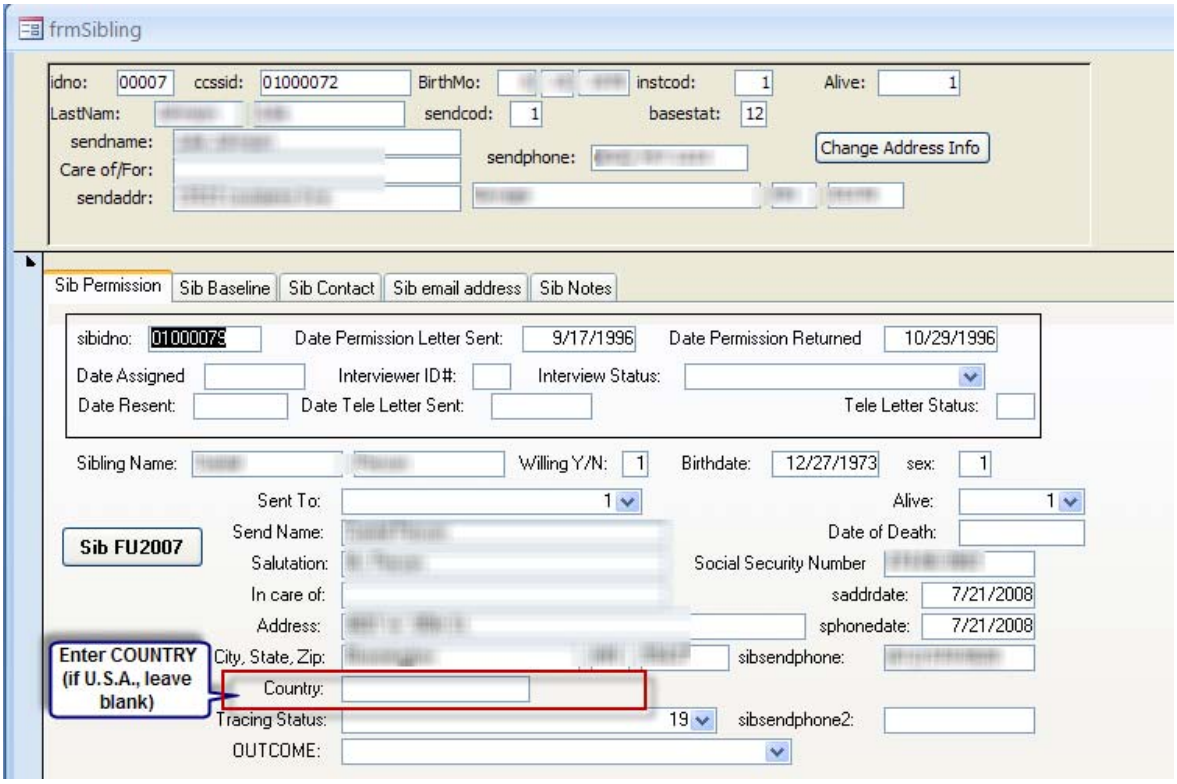
2. Currently, international addresses may have a non-standard ZIP code, or the state differs from the 50 states. Use your investigation skills to identify the country. (Googling for the City/State might be helpful.)

QUEST (Original Cases)

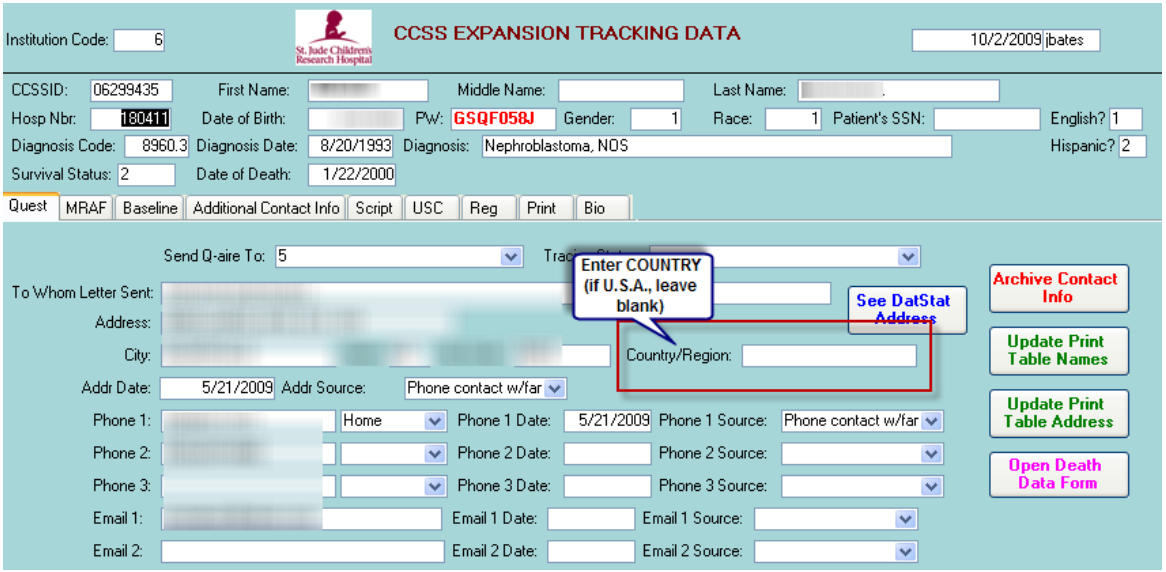


Everyone

Siblings (Original)



Expansion



Revision Record

Printed 7/9/2012 2:18 PM

Current Filename:		International Addresses ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/2/09	J. Bates	Initial Development

Interviewer Follow-Up for Blood and Tissue - Tissue Collection
Pre- and Post- Tissue Request Calls

Background

If a CCSS/ LTFU participant has confirmed subsequent neoplasms (other than non-melanoma skin cancer), then they become eligible for the blood and tissue study. Those who have a confirmed benign condition are excluded, except for a diagnosis of meningioma.

General Eligibility Criteria:

- Confirmed subsequent cancer/ tumor, meningioma, etc. (Non-melanoma skin cancer not included)
- 18 years or older
- Has not refused further participation in the study

Part of this study involves the collection of tissue specimen from a previous biopsy, or surgery. The Call Center will gather information regarding the location of samples we wish to collect and confirm contact information for the Data Manager (DM) to request the tissue specimen by making **Pre-Tissue Request** calls. Once the Data Manager has requested the tissue, the Call Center will follow-up to make sure the samples are sent to us, by making **Post-Tissue Request** calls. Dr. Michael Arnold, at the CCSS Biopathology lab in Columbus OH, stores the tissue samples, usually in the form of slides, scrolls or paraffin blocks.

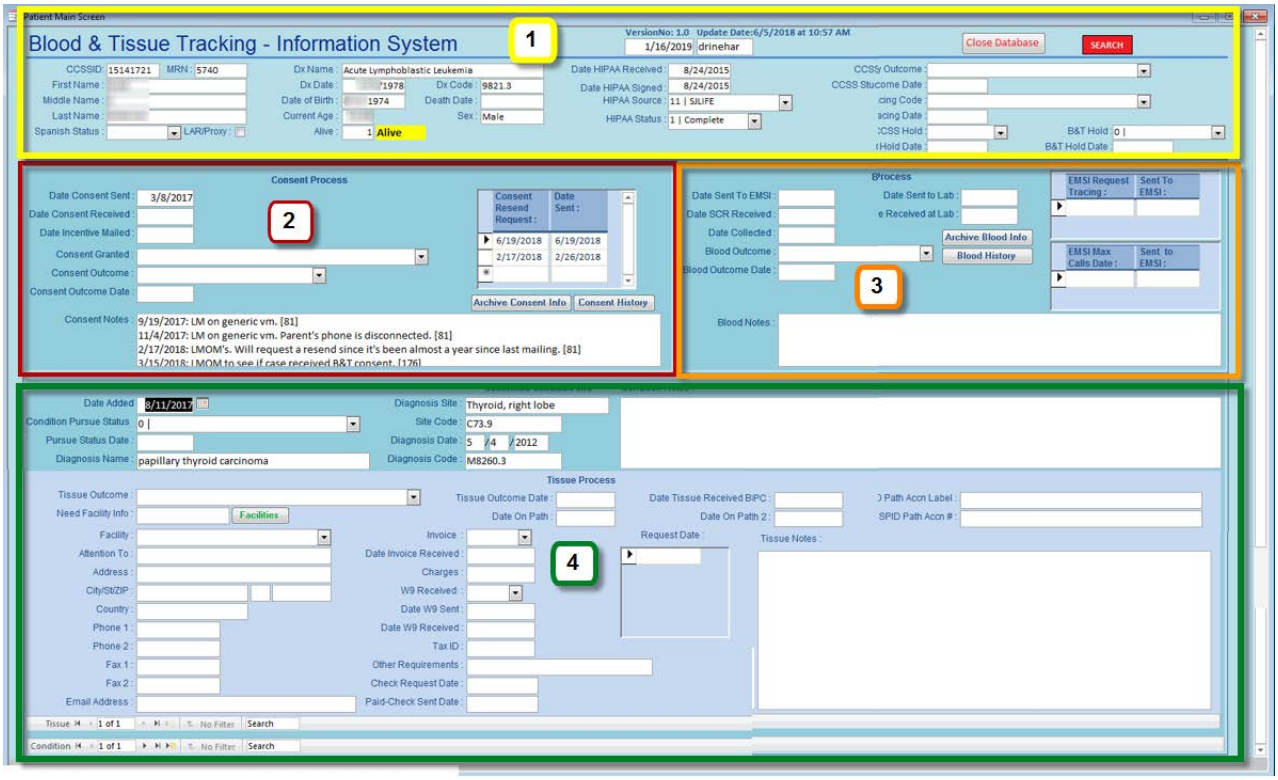
Tools needed for both Pre- & Post-Tissue Request calls:

- LTFU database
- Blood & Tissue database
- SI Assignments database
- LTFU Participant Database Data Entry SOP
- Copies of the faxed requests sent to the facility, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Faxes\Tissue sample request PDF*
- Access to an online search function, such as Google
- Tissue Sample request SCRIPT, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Blood and Tissue\Interviewer scripts*

The Blood & Tissue Tracking Database is arranged as follows:

1 – Participant information
2 – The Consent Process tracking fields
3 – The Blood Process tracking fields
4 – The Tissue Process tracking fields, including the Confirmed Condition Info

(Pre- and Post-Tissue Request Calls, only use sections 1 and 4)

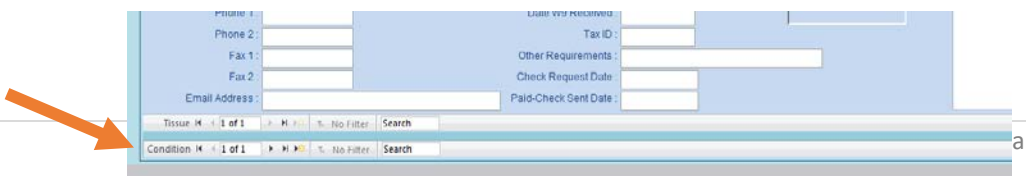


Before the Pre-Tissue Request call:

1. ***Check the SI Assignments Database:***
    a. *For Pre-Tissue Request calls* - open the list titled: B-T Facility Pre-Tissue Request. This is the list of participants who have eligible tissue, but we have not confirmed where it is stored, or we don't have the contact information necessary to send the request.
    b. Select a case to call by the Date Last B-T Facility Call, or the time zone of the Facility.

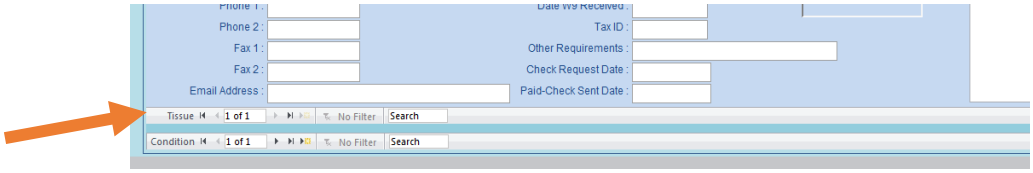
2. ***Open the LTFU Participants Database - participant record:***
    a. Searching by the Participant name or ID number, pull up the Participant record.

3. ***Open the Blood and Tissue Database:***
    a. Searching by Participant name or ID number, pull up the Participant record in the Blood and Tissue database.
    b. Review the information in the Confirmed Condition Info box (top of section **4**).
        i. Does the Participant have more than one condition (Diagnosis) we are pursuing? If yes, use the **Condition scroll bar** at the very bottom of the screen.



ii. What is the condition or Diagnosis Name?
iii. What is the Diagnosis Date?

c. Review the information in the Tissue Process box (lower portion of the window).
   i. What is the Tissue Outcome? This field should be blank (the location of the tissue has not yet been confirmed), or 5 – Facility Response Pending, or 14 – Participant Response Pending. No call is needed if there are any other outcomes.
   ii. Is there a date in Need Facility Info? If yes, the SPID/ Accession number is needed from the facility, or possibly a path report. Check the Tissue Notes.
   iii. What is the Facility name? (This field may be blank. If so, check the Tissue Notes box for instructions from the DM.)
   iv. Is there more than one Facility that may have tissue on this Diagnosis? If yes, use the **Tissue scroll bar** at the bottom of the Tissue Process box.



   v. Do we have contact information, especially a phone number? If not, make an online search to locate a phone number for the doctor's office or medical facility where a biopsy or surgery may have been performed.
   vi. Do we have an Accession number in the SPID Path Accn # box?
   vii. What notes has the DM left in the Tissue Notes box? What notes have been left from previous calls?

Make the Pre-Tissue Request call:

1. Using the Tissue Sample request SCRIPT, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Blood and Tissue\Interviewer scripts,* Call the facility, or potential facility.
2. Be prepared to call multiple numbers, if the facility has no verified contact information.
3. If the facility claims to have no records on our patient, ask questions: maybe the patient's name changed due to marriage, or divorce, maybe the patient goes by a middle name, etc.
4. If the facility does NOT have the tissue we want, they may suggest a facility that does have it. (ie: Dr. Jones at Hospital A treated the patient, but the lab work was done at ABC Laboratory.)

After the Pre-Tissue Request call is made:

1. Record the call in the **LTFU database**.

a. Record the **call**, following the LTFU Participant database SOP, record all information provided in the Pt. Contact log Notes. Populate the other fields as follows:
    i. **Contact Mode**: 1 - Phone
    ii. **Contacting:** 11 – Facility
    iii. **Name:** Name of the Facility as listed in the B&T database.
    iv. **Project**: 10 – Blood & Tissue
    v. **Contact Reason**: 7 – Specimen
    vi. **Outcome**: 2 – No answer, 3 – No answer/ left message, 6 – Disconnect or 10 – Other.
    vii. **Notes**: Make a concise, detailed note of the information gathered.

2. Record the call in the **Blood & Tissue database**.
    a. **For ALL calls:** In the Tissue Notes: box, make a dated note of the call. (ie: 12/6/2018: Called main ph: (212) 263-5800. Transferred to surgical pathology, direct ph: (212) 263-5470. Ms. Jill confirmed they have tissue; fax request to: (212) 263-5477. [81])
    b. When the **SI obtains a new or direct phone or fax#** for a known facility, not currently listed in the Facility contact information:
        i. Locate the appropriate facility record (if we are pursuing tissue for more than one condition.)
        ii. Confirm the phone or fax#, if it is not already listed in the record.
        iii. Under the Facility contact information fields:
            1. Enter the best phone/ fax number in the Phone 1/ Fax 1 box.
            2. If there is a secondary phone/ fax number, enter it in the Phone 2/ Fax 2 box.
            3. If both phone or fax fields are already populated, but a better number is found, make a dated note of any changes made, including phone/ fax numbers that are replaced, then update the record to show the best two numbers.
    c. When the **Facility indicates they have the desired tissue**:
        i. If this is a NEW facility and the Facility information fields are blank, include a note to the DM to add this as a new facility.
        ii. If this is an EXISTING facility, update or add any newly confirmed phone and fax numbers.
        iii. Update the Tissue Outcome field to 12 – Sample Available, Send Request and Tissue Outcome Date to the current date.
        iv. If there was a previous Outcome and Date, note this and the change that was made in the Tissue Notes field.
    d. When the **Facility indicates they had the desired tissue, but it was destroyed.**
        i. Update the Tissue Outcome to 9 – Sample Destroyed and Tissue Outcome Date to the current date.
        ii. If there was a previous Outcome and Date, note this and the change that was made in the Tissue Notes field.
    e. When the **Facility indicates they don't have the tissue, but another facility might**.

i. Gather as much information as possible about the new facility, doctor or lab where the tissue may be stored – especially phone numbers. Note this in the Tissue Notes field.
ii. Update the Tissue Outcome to 10 – No Sample Available and Tissue Outcome Date to the current date.
iii. Using provided phone numbers or by doing an online search, contact the new facility. Each call will have to be logged into the LTFU database Contact log, but there is no need to create a new Tissue facility record.
iv. Once it is confirmed that a facility HAS the desired tissue; email the DM of the new facility name and contact information. The DM will add a new Tissue facility record and the SI or the DM can make the necessary updates.

f. When the **Facility indicates they don't have the desired tissue** or have no record of treating our participant.
   i. Update the Tissue Outcome to 10 – No Sample Available and Tissue Outcome Date to the current date.

g. When the **Facility has additional requirements before they can release the tissue** or there is any other issue that the DM needs to address (ie: there is a fee for tissue slides/ blocks or processing – or the facility only accepts emailed requests – etc.):
   i. Update the Tissue Outcome to 13 – Data Manager Action Required and Tissue Outcome Date to the current date.
   ii. Clearly identify what the issue is, or what the DM needs to address in the Tissue Notes field.

Before the Post-Tissue Request call:

1. *Check the SI Assignments Database:*
   a. *For Post-Tissue Request calls* - open the list titled: B-T Facility Post-Tissue Request. This is the list of participants who have eligible tissue and the Data Manager has sent a request to the facility that is storing the tissue.
   b. Select a case to call considering the Date Last Fax and Date Last B-T Facility Call, or the time zone of the Facility.

2. *Open the LTFU Participants Database - participant record:*
   a. Searching by the Participant name or ID number, pull up the Participant record.

3. *Open the Blood and Tissue Database:*
   a. Searching by Participant name or ID number, pull up the Participant record in the Blood and Tissue database.
   b. Review the information in the Confirmed Condition Info box (center portion of window).
      i. Does the Participant have more than one condition (Diagnosis) we are pursuing? If yes, use the Condition scroll bar at the very bottom of the screen. (See picture on pg. 2)

ii. What is the condition or Diagnosis Name?
iii. What is the Diagnosis Date?

c. Review the information in the Tissue Process box (lower portion of the window).
i. What is the Facility name?
ii. Is there more than one Facility that may have tissue on this Diagnosis? If yes, use the Tissue scroll bar at the bottom of the Tissue Process box. The Tissue Outcome should be 5 – Facility Response Pending. (See picture on pg. 2)
iii. When was the request sent (or most recently sent) to the facility – in the Request Date: field.
iv. What notes has the DM left in the Tissue Notes box?

Make the Post-Tissue Request call:

1. Using the Tissue Sample request SCRIPT, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Blood and Tissue\Interviewer scripts,* Call the facility.

After the Post-Tissue Request call is made:

1. Record the call in the **LTFU database**.
   a. Record the **call**, following the LTFU Participant database SOP, record all information provided in the Pt. Contact log Notes. Populate the other fields as follows:
      i. **Contact Mode**: 1 - Phone
      ii. **Contacting:** 11 – Facility
      iii. **Name:** Name of the Facility as listed in the B&T database.
      iv. **Project**: 10 – Blood & Tissue
      v. **Contact Reason**: 7 – Specimen
      vi. **Outcome**: 2 – No answer, 3 – No answer/ left message, 5 – Resend, 6 – Disconnect or 10 – Other.
      vii. **Notes**: Make a concise, detailed note of the information gathered.

2. Record the call in the **Blood & Tissue database**.
   a. **For ALL calls:** In the Tissue Notes: box, make a dated note of the call. (ie: 12/6/2018: Called surgical pathology, direct ph: (212) 263-5470. Ms. Jill said they did not receive our request, the fax number has changed, please refax it to the new number. [81])
   b. When the **Facility received our request and tissue has already been sent out**:
      i. Locate the appropriate facility record (if we are pursuing tissue for more than one condition.) and simply note the outcome of the call.
   c. When the **Facility did not receive our request**:
      i. Verify the Facility contact information and update any new info provided.
      ii. If the request was **FAXED** to the facility, the SI will locate a copy of the Tissue request, by searching with the Pt.'s CCSS ID # in the *Tissue sample request PDF*

folder located in *Interviewers > SMN and Blood and Tissue > Faxes.* Once found, the SI will:

1. Create a new copy of the existing fax by using "Save as" and changing the File name: by adding the current date to the name.
2. Refax the request to the facility as directed. For data entry, refer to ***Refax the Tissue Request*** and ***After the Tissue Request has been refaxed*** below.

iii. If the request was initially sent – **other than by FAX** – the SI will update:

1. The Tissue Outcome to 13 – Data Manager Action Required and
2. The Tissue Outcome Date to the current date and
3. Include a dated note of these changes and what needs to be done.

d. When the **Facility indicates there are other requirements to meet before they can release the tissue:**

i. Gather as much information as possible about these other requirements.
ii. Make a dated note in the Tissue Notes: field.
iii. If there is something the DM needs to handle (ie: fees, additional release forms, etc.), update the Tissue Outcome to 13 – Data Manager Action Required and Tissue Outcome Date to the current date.
iv. Be sure to outline these other requirements in the Tissue Notes: field.

Refax the Tissue Request:

1. Create a new copy of the existing fax by using "Save as" and changing the File name: by adding the current date to the name.
2. Update the dates on the fax to the current date, if the fax needs to be sent to a different fax number, make that change or if it needs to be sent to the attention of a specific person, add that information, etc. Using the directions in step "c." above resend the Fax.

After the Fax is sent:

1. Record the fax in the **LTFU database**.
   a. Make a contact log in the participants record as follows:
      i. **Contact Mode**: 4 - Fax
      ii. **Contacting:** 11 – Facility
      iii. **Name:** Name of the Facility as listed in the B&T database.
      iv. **Project**: 10 – Blood & Tissue
      v. **Contact Reason**: 7 – Specimen
      vi. **Outcome**: 9 – Will return by mail/online or 10 – Other.
      vii. **Notes**: Indicate that the fax was sent and for what purpose.

2. Record the fax in the **Blood & Tissue database**.
   a. Make a dated note in the Tissue Notes: field.
   b. Add the current date to the Request Date: field.

Revision Record

Current Filename:		Interviewer Follow-Up for Blood and Tissue - Tissue Collection	
Revision No.	Date	Responsible Author	Change Description
1	5/8/19	B. Lewis, D. Rinehart, A. Cobble	Initial Development

Interviewer Follow-up with Blood and Tissue Participants

Background

If a CCSS participant has a confirmed subsequent neoplasm, then the blood and tissue sample collection process may be pursued. There are two situations in which a Survey Interviewer may need to call the participant to obtain information:
(1) The respondent has not recently returned a signed informed consent form for the study.
(2) Examination Management Services, Inc. (EMSI) is unable to reach the participant to schedule a blood draw appointment.

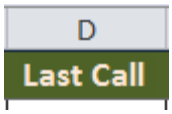
While participants from both the Original and Expanded Cohort are involved in the Blood and Tissue Study, original cohort Blood and Tissue participants are not being pursued at the present time.

Procedures

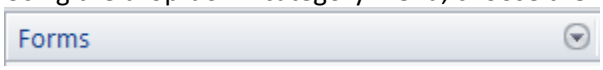
Procedure for Informed Consent Only Calls:

BEFORE THE CALL -

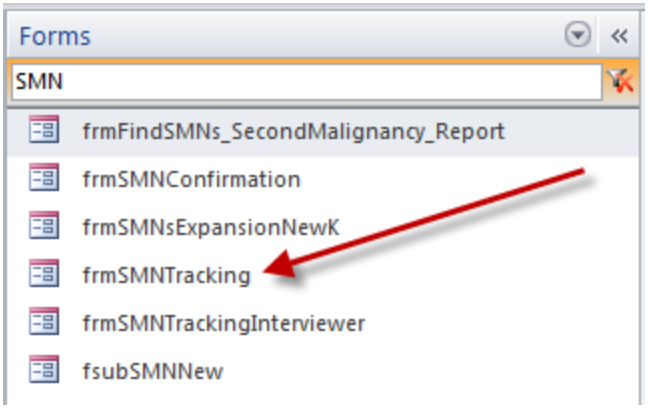
1. Open the spreadsheet containing study participants and begin building the pre-call participant profile:
    a. Use the spreadsheet titled **the Expanded Cohort Blood and Tissue Workbook mm-dd-yyyy** (located in *Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue\Expanded Cohort*) for the Expanded Cohort.
    b. Locate the first participant to be called.
    c. Note the date in the Last Call column.



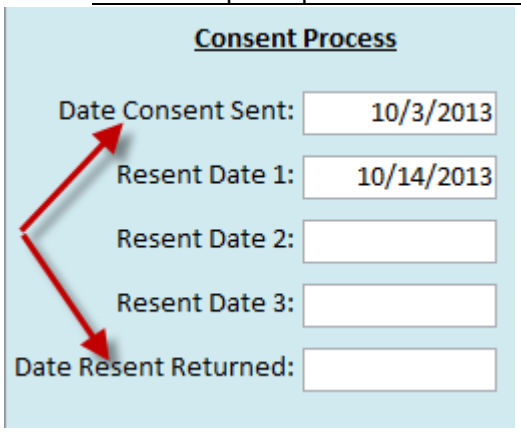
2. Open the CCSS Expansion Tracking database and continue building the pre-call participant profile:
    a. Open the CCSS Expansion Tracking database from the Sharepoint page.
    b. Open the Navigation Pane by clicking the double arrows at the top left-hand corner of the screen, just under the Access ribbon. 
    c. Using the drop-down category menu, choose the “Forms” option.



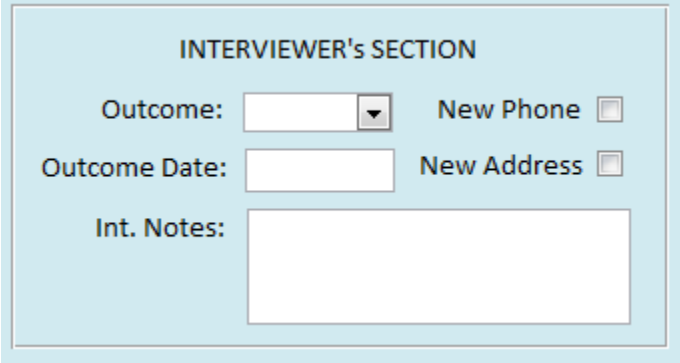
    d. Type “SMN” into the search bar to locate the form named frmSMNTracking. Open this form by clicking on it, then review applicable documentation.



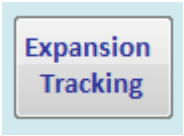
i. Note the **Date Consent Sent** and, if applicable, the **Date Resent Returned** fields.
NOTE: If it the consent has been returned, no call is necessary.
NOTE: Do not call participants until 2 weeks after the consent form was sent.



ii. Review the Interviewer's Section for notes from previous calls.



e. In the upper right-hand portion of the screen, cick the **Expansion Tracking** button to open the main data entry screen for the participant and continue building the pre-call participant profile.



i. On the Quest tab, note the case's **Date of Birth**, **Survival Status**, **Spanish Status**, all contact information, and all notes in the **Comments** field.
ii. Review the Additional Contact Info tab.
iii. Review the Reg tab for possible parent and spouse information.
iv. Review the Print or Age of Majority tab to note the case's current age.

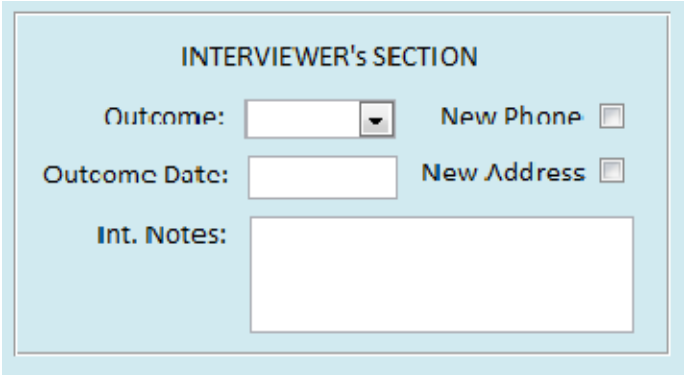
3. Open the MS Word **Phone Contact Log** for the participant and continue building the pre-call participant profile. If no log exists, create one using the SOP titled **Using and Creating Participant Call Logs (Phone Contact Log)**, located in the SOP library.
    a. The logs for the Expanded Cohort are located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Participant call logs*.
    b. Review all call history for the participant.

DURING THE CALL -

1. Use the script titled **INTERVIEWER SCRIPT- SMN - Blood and Tissue_v1**, located in *Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue* to contact the participant.
2. Verify all contact information for the participant.
3. If the interviewer finds that the participant is deceased:
    a. It is not necessary to ask the spouse or surviving family members for consent to obtain the expired participant's tissue.
    b. Complete the **Expired Participant Information Sheet**.
4. If the participant refuses, determine the level of refusal: tissue only, blood only, both blood and tissue, or all else.
   NOTE: If the participant agrees to *either* blood *or* tissue, he or she will still need to complete the informed consent form and indicate which arm of the study they agree to.

AFTER THE CALL -

1. Update the MS Word **Phone Contact Log** with the notes from the call. Begin the **Comments** with the project identifier.
2. Update the spreadsheet with all applicable data including the SI ID, date of call, appropriate outcome, and appropriate color based on the legend.
3. Update the Expansion Tracking database.
    a. In the frmSMNTracking tab, update the **Interviewer's Section**.
        i. Select the appropriate value from the drop-down menu in the **Outcome** field including refusals, deceased, or resends.
        NOTE: Do NOT use code 82-Resend if resending via email as this will alert the lead CRA to send another paper consent form. See also step 4, below.

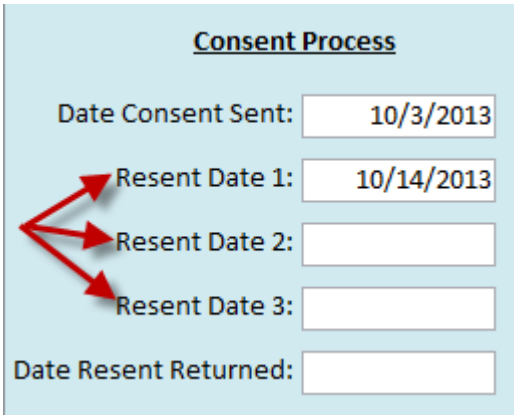


        ii. Enter the current date in the **Outcome Date** field.
        iii. Enter anything unusual (e.g., participant is out of the country, participant has a temporary address, etc.) in the **Int. Notes** field. (Routine matters do not need to be entered into this field.)

iv. The **New Phone** and **New Address** checkboxes are not actively used.

b. Update the main data entry page with any updated contact information obtained during the call. See the SOP titled **Expansion Baseline Survey Calls**, located in the SOP library, for full details.

4. Emailing Informed Consent to the participants:
   a. Use the document titled **LTFU- Blood and Tissue Consent E-mail Request Template** located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue*.
   b. Attach the document titled **NEW CCSS GTand LT18 blood-tissue consent amend 14.0 irb appr 1-4-12nomerge** and located in *Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue*.
   c. Send the email to the participant and cc the lead CRA on the project who will update the database.
   d. Update the **Resent Date #** field in the frmSMNTracking tab with the date of the resend.
5. If the participant was found to be deceased:
   a. File the **Expired Participant Information Sheet** in the "Refusals and Deceased" hanging file.
   b. Add the change in vital status to the **Call Outcomes Log**.



6. Email the lead CRA with the CCSSID of any refusals.
7. Email the CRA leading the project for anything out of the ordinary.

Procedure for EMSI Follow-Up Only Calls:

BEFORE THE CALL -

1. Open the spreadsheet containing study participants and begin building the pre-call participant profile:
   a. Use the spreadsheet titled **Expansion Cohort Follow-Up EMSI Calls** (located in *Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue\Expanded Cohort*) for the Expanded Cohort.
   b. Locate the first participant to be called.
      NOTE: Call the participants based on the "Date Added to the List" column.
      NOTE: You may start phone calls as soon as possible. There is no 2-week time period.
2. Open the CCSS Expansion Tracking database and continue building the pre-call participant profile:
   a. Open the CCSS Expansion Tracking database from the Sharepoint page.
   b. Using the Find feature in Access, locate the participant's record. Continue building the pre-call participant profile:
      i. On the Quest tab, note the case's **Date of Birth**, **Survival Status**, **Spanish Status**, all contact information, and all notes in the **Comments** field.
      ii. Review the Additional Contact Info tab.
      iii. Review the Reg tab for possible parent and spouse information.
      iv. Review the Print or Age of Majority tab to note the case's current age.

3. Open the MS Word **Phone Contact Log** for the participant and continue building the pre-call participant profile. If no log exists, create one using the SOP titled **Using and Creating Participant Call Logs (Phone Contact Log)**, located in the SOP library.
    a. The logs for the Expanded Cohort are located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Participant call logs*.
    b. Review all call history for the participant.

DURING THE CALL -

1. Make the call.
2. If the participant is contacted:
    a. Ask if he or she is still interested in scheduling the EMSI blood draw.
    b. Verify the address and telephone information.
    c. If the participant is still interested, ask for the best time for EMSI to call and schedule an appointment.
    d. If necessary, schedule the appt with the participant.
        i. The appointment should be at least 2 weeks after the day of participant contact.
        ii. The appointment should be Monday – Thursday.
        iii. Update the spreadsheet and email the appointment information to the lead CRA on the project.
    e. If the participant refuses participation in the EMSI blood collection OR refuses all else, thank them for their participation and try to obtain a reason for the refusal.
3. If the interviewer finds that the participant is deceased, complete the **Expired Participant Information Sheet**.

AFTER THE CALL-

1. Update the MS Word **Phone Contact Log** with the notes from the call, including any refusal reasons, if applicable. Begin the **Comments** with the project identifier.
2. Update the spreadsheet with all applicable data.
   NOTE: If the participant was contacted, highlight the participant's row in the spreadsheet in yellow to indicate new information has been obtained for EMSI. The lead CRA on the project will highlight the row in green once the obtained information is forwarded to EMSI.
3. Update the Expansion Tracking database with any new contact information confirmed for the participant. See the SOP titled **Expansion Baseline Survey Calls**, located in the SOP library, for full details.
4. If the participant was found to be deceased:
    a. File the **Expired Participant Information Sheet** in the "Refusals and Deceased" hanging file.
    b. Add the change in vital status to the **Call Outcomes Log**.
    c. Email the lead CRA on the project with the CCSSID.
5. Email the lead CRA with the CCSSID for any refusals, including the reason (if obtained).
6. Email the CRA leading the project for anything out of the ordinary.
7. TRACING: If the interviewer is unable to contact the participant:
    a. Alert the Call Center Coordinator using the **All Others Tracer's Workbook mm-dd-yyyy** spreadsheet located *at Z:\SJShare\SJCOMMON\ECC\Interviewers\Tracing\02. All Others Tracing*.
    b. The Call Center Coordinator will forward the request with any applicable comments to the Tracing division.

c. The Tracing division will trace the case and notify the Survey Interviewers via email (cc'ing the lead CRA on the project) when the case contact information is confirmed.
d. The Survey Interviewers will contact the case and follow-up appropriate.

Revision Record Printed 11/4/2013 1:49 PM

Current Filename:		Interviewer Follow-up with B-T Partcipants v2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	12/3/10	J. Dowdy	Initial Development
2.0	10/28/2013	B. Lewis, L. Harrison, E. Moore, D. Rinehart, R. Massey	Content Revision.

Long Term Follow-Up Study Online Questionnaire Completion Process

Background

Participants within the Long Term Follow-Up Study (LTFU) have the option of completing their questionnaire utilizing a traditional paper-based format, with a phone interviewer, or online via a Web site. The respondents who submit the paper-based questionnaire sign an informed consent form as part of the questionnaire. Online respondents do not sign a consent form, but must actively acknowledge that they consent to participate in the study before they can complete the questionnaire. They are also provided with the opportunity to print a copy of the consent and HIPAA forms for their records. Below is an overview of the online survey completion process:

Procedure

1. Log onto www.stjude.org/expansionbaseline
2. Enter unique individual password and date of birth at log-in screen
3. Review thank you letter, then click the “next” button
4. Review survey staff contact information; click the “next” button
5. Review questionnaire navigation instructions; click the “next” button
6. Review the informed consent authorization form
7. Choose to participate in the study
    a. If a participant clicks “No”, then they are not presented with the questionnaire. The online session concludes here.
    b. If a participant clicks “Yes”, then they are presented with the HIPAA authorization form and the questionnaire
8. Review the HIPAA authorization form
    a. If a participant does not provide HIPAA authorization, then they can still complete the questionnaire as long as they provided informed consent

Revision Record Printed 7/16/2012 9:36 AM

Current Filename:		Online Questionniare Completion v1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	2/2/09	A. McDonald	Initial Development

LTFU Locator Feature

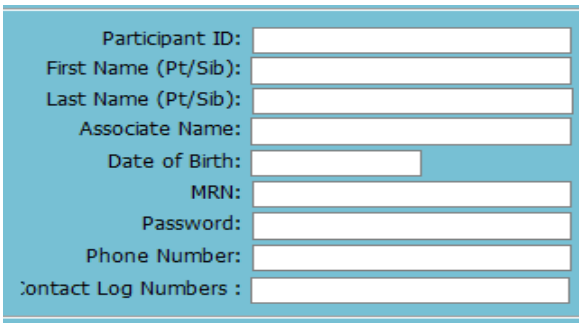
Background

To ensure incoming calls are handled in a way that is prompt and courteous for participants/associates contacting the Call Center, as well as easy and effective for SIs to locate the correct database the individual is located in, a search button has been added to the CCSS Survey Interviewer Assignments Database. Additionally, the SEARCH feature is also available in a standalone LTFU Locator Database accessible through the Databases and Systems intranet site.

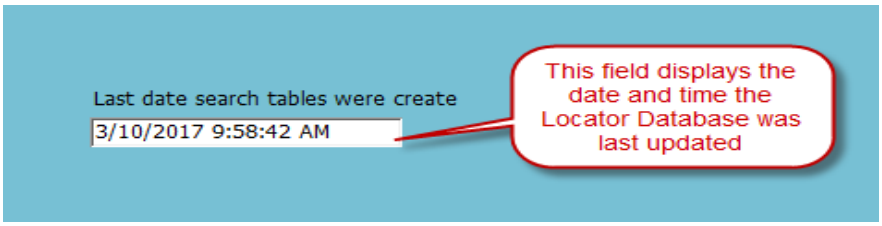
Procedure

1. Click the red "SEARCH" button located at the top of the home screen in the CCSS Survey Interviewer Assignments Database. The search feature is the default screen in the LTFU Locator Database.

   a. This feature will allow you to search all databases (Recruitment, Expansion Tracking, LTFU) in a quick and efficient way.
   b. The first eight search fields will search information that has already been entered into the database (Header, Participant/Quest tab, Associates tab, etc.).
   c. The last search field will search the contact/trace logs and display the SIID of the last SI that contacted the participant/associate, as well as the project and database the participant/associate is located in.



   d. This database will be updated several times throughout the day, and will display the date and time that it was last updated. If you are unable to locate a participant/associate or phone number, then consult with the LSI team or Coordinator to have the search feature updated to real time.



Current Filename:		LTFU Locator Database ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	3/10/17	A. Cobble, D. Rinehart, R. Daniels, J. Ford	Initial Development

LTFU Participant Database Data Entry

Background

The LTFU Participant database contains records for all CCSS participants and their associates. CCSS participants are those cases and sibling participants from both the original and expansion cohorts who have completed at least the baseline survey. Participants in the LTFU Participant database have rolled over from the REG or Expansion Tracking databases.

In general, updates to this database are made upon confirmation of information by the participant or his/her associate by phone, fax, email, or U.S. Mail. In certain situations, updates may also be made based on information located via online resources. For questions, see the Coordinator or a member of the LSI team.

It is critical that information is entered into the database accurately, as the information housed in the database is considered "source documentation" for the study in the event of a study audit.

Procedure

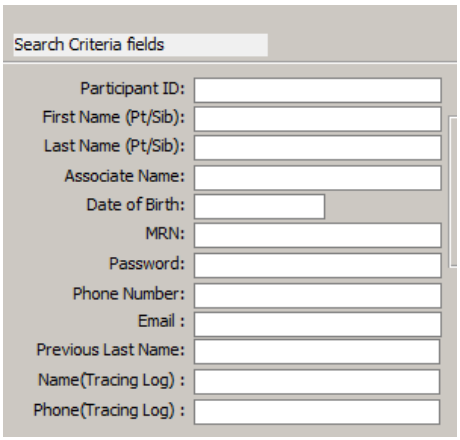
Tools Needed:

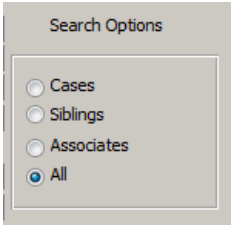
1. CCSS LTFU Participant database (located on the Sharepoint database page at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)
2. **Expired Participant Information Sheet** (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools*)
3. **Requesting "No Proxy Available" Determination** (located in the CCSS SOP Library at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*)

Search Information Screen:

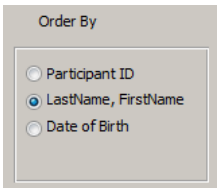
Use the Search Information screen to locate a case or sibling participant's record in the LTFU Participant database:

1. Use the **Clear** button to clear all previously entered search criteria.
2. From a cleared Search Information screen, enter data in the Search Criteria fields:
   A. Enter available information in the presented search fields. Entering more information in the Search Criteria fields will result in narrower search results. (i.e. Enter less information to see more results.) Available fields:
      i. **Participant ID** (CCSSID or SIBID)
      ii. **First Name (Pt/Sib)** (confirm spelling)
      iii. **Last Name (Pt/Sib)** (confirm spelling)
      iv. **Associate Name** (confirm spelling)
      v. **Date of Birth** (use format mm/dd/yyyy)
      vi. **MRN** (medical record number)
      vii. **Password**
      viii. **Phone Number** (without parentheses, dashes, or spaces)
      ix. **Email** (email address)
      x. **Previous Last Name** (e.g. maiden name)
      xi. **Name(Tracing Log)**
      xii. **Phone(Tracing Log)** (without parentheses, dashes, or spaces)





B. Choose from the 4 available **Search Options**. The search function will look for only those records matching the type you specify.
C. Choose the desired **Search Type** for the Search Criteria fields populated above.
D. If searching by **Date of Birth**, choose from the available **Date of Birth Options**.
E. Choose the desired results sort type in the **Order By** options.



3. Click the **Search** button or press the Enter key.
4. Locate and double click on the name of the desired participant in the search results list.

Updating the LTFU Participant Database:

In general, changes to a participant record are automatically saved upon exiting the record. The user should make the appropriate changes to the record, move the cursor to a new field, then exit the record to save the changes. To save changes before leaving the record, move the cursor to a new field and then press the F5 key. To reverse changes *before* leaving the record, press the Esc key one or more times.

1. Special Note Regarding Former St. Jude Patients (Institution 15): If any contact information has changed for a case whose CCSSID begins with "15", send screen shots of the changes to the CRA coordinating the St. Jude Life study.

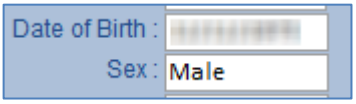
2. **Participant Speaks Spanish** – If an SI encounters a participant who speaks Spanish but for whom this is not indicated in the LTFU Participant database:

A. **Spanish Status** field (header) – Populate with:
   i. "Spanish" if the participant speaks only Spanish
   ii. "Both" if the participant speaks both Spanish and English
   iii. "Spanish Preferred" if the participant speaks both Spanish and English but prefers Spanish
B. **Notes** field (Participant tab) – Document the circumstances and the change to the **Spanish Status** field in a dated comment with SI ID. Click the **Notes** button to access this field.

3. **Participant Unavailable Due to Incarceration** –
   A. For incarceration expected to last 12 months or less, apply a hold appropriate to the expected duration. See the "Request for Hold" section of this document for details.
   B. For incarceration expected to last greater than 12 months:
      i. In the contact log:
         a. **DB Change** – Populate with 7-Other.
         b. **Notes** – Give full details of the information gathered regarding the jail/prison situation.
      ii. A member of the LSI team will consult with the Coordinator and Research Scientist to determine action to be taken.

4. **No Proxy Available** – When a participant is unable to represent himself/herself to participate in study projects, and there is no party available to act as a proxy for the participant, alert the leadership team that a "no proxy available" determination is needed. See the SOP titled **Requesting "No Proxy Available" Determination** for details.

5. **Date of Birth** or **Gender** – If a change is needed in the **Date of Birth** or **Sex** fields in the header of the participant's record:



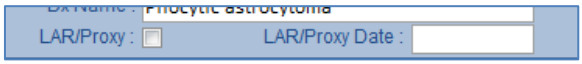
A. **DB Change** and **Notes** fields (contact log or trace log) – Log the

request in both fields. (See instructions in the section of this document titled *Logging a Telephone Call or Email in the LTFU Participant Database*, below.) The Call Center Coordinator, an LSI, or their designee will update the appropriate field(s) in the database.

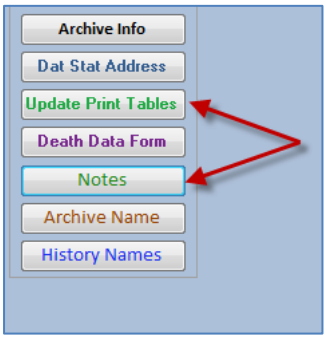
B. **Notes** (Participant tab) – Add a dated comment with your SI ID documenting the change and its source. Click on the **Notes** button to access this field.

6. **Deceased/Vital Status Update** –
   A. **Notes** (Participant tab) – Add a dated comment with your SI ID documenting the change in vital status and its source. Click on the **Notes** button to access this field.
   B. For participants:
      i. **DB Change** and **Notes** fields (contact log or trace log) – Log a request in both fields to update the participant record's **Alive** field. (See instructions in the section of this document titled *Logging a Telephone Call or Email in the LTFU Participant Database*, below.) The Call Center Coordinator, an LSI, or their designee will update the appropriate field(s) in the database.
      ii. File the **Expired Participant Information Sheet**, if applicable, in file cabinet A.
   C. For deceased associates, go to the appropriate Associate record:
      i. **Contact Status** – Update to be "No".
      ii. **Status Date** – Update with the current date.
      iii. **Notes** – Add a dated comment with your SI ID documenting the change in vital status and contact status.
      iv. Only update the Phone Rank to 37-Do Not Call if another associate sharing the same phone number has asked us not to call.

7. **LAR Status** – If it was determined that the participant has a Legally Authorized Representative (LAR) or Proxy (See a member of the LSI team or the Coordinator for assistance determining an authorized proxy for a non-deceased participant. This NOT applicable for minor or deceased participants; these participants would always be represented by a proxy.):

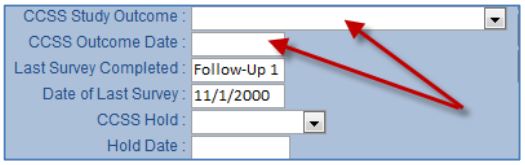


   A. **LAR/Proxy** checkbox (header) – Mark the checkbox.
   B. **LAR/Proxy Date** (header) – Enter the date the LAR status was discovered.
   C. **Care of** (Participant tab) – Populate with "C/O" plus the LAR/proxy's first and last name, move the cursor to a new field, then click the **Update Print Tables** button. NOTE: Keep the format of the name consistent with the rest of the address (e.g. ALL CAPS or Upper-lower case).



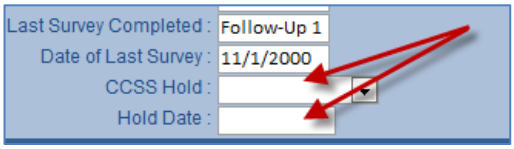
   D. **Notes** (Participant tab) – Add a dated comment with your SI ID clearly documenting the LAR/proxy status and circumstances. Click the **Notes** button to access this field.
   E. Associates tab – Check the Associates tab to determine if the LAR/Proxy is already listed as an associate of the case.
      i. If yes, update the LAR/Proxy's contact information in the appropriate associate record using the **Associate Records** instructions, below.
      ii. If no, add the LAR/Proxy to the Associates tab using the **Associate Records** instructions, below.

8. **Refused all else** –
   A. **Outcome** and **Notes** fields (contact or trace log) – Document the refusal in both fields. (See instructions in the section of this document titled *Logging a Telephone Call or Email in the LTFU Participant Database*, below.)
   B. **Notes** (Participant tab) – Enter a dated comment with your SI ID documenting the refusal. Click on the **Notes** button to access this field.
   C. In the header:



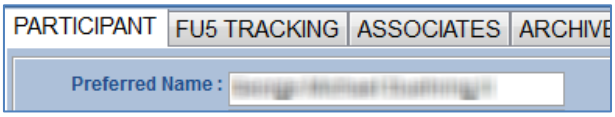
      i. **CCSS Study Outcome** – Populate with 37-Refused all else. If this field is already populated, consult a member of the LSI team prior to modifying the value.
      ii. **CCSS Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.
      iii. NOTE: If the participant has refused only a follow-up survey or ancillary study but agrees to remain in the CCSS, *DO NOT UPDATE THESE HEADER FIELDS*.
   D. If the participant refused all else in response to a particular project (e.g. FU5, EMSI, etc.), see also the project-specific SOP for documenting the project-level refusal.

9. **Request for Hold** –
   A. **CCSS Hold** (header) – Populate with the appropriate value using the drop-down menu.



   NOTE: The "Calls" hold, which puts the participant on indefinite hold for outgoing calls but not for mailings or emailings, is applied on a case-by-case basis. As with all special outcomes, notify the LSI team and Coordinator of the circumstances to determine if a "calls" hold is appropriate.
   B. **Hold Date** (header) – Populate with the current date.
   C. **Notes** (Participant tab) – Enter a dated note with your SI ID documenting the hold field changes and the hold circumstances. Click the **Notes** button to access this field.
   Example – 8/29/2015: Due to spouse's serious illness, case requested a 6-month hold. [174]
   D. Do NOT add an Outlook reminder to follow up with the participant. The LSI team will return hold participants to call rotation when appropriate.

10. **Participant Name** (located on the Participant tab) – If the participant has a name update:
   A. Click the **Archive Name** button.

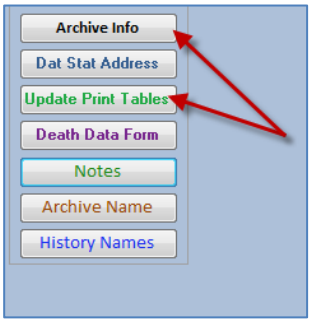


   B. **Preferred Name** – Update to the participant's current preferred first and legal last name, keeping the formatting consistent with the rest of the address (e.g. ALL CAPS or Upper-lower case).
   NOTE: This is the name that will print on our mailings to the participant.

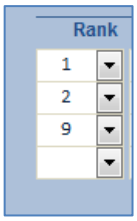
   C. **Notes** – Add a dated note with your SI ID fully explaining the name change (e.g. updated due to marriage/divorce/adoption, updated due to preferred name different than legal name, etc.). Click the **Notes** button to access this field.
   D. Move to the cursor a new field on the record.
   E. Click the **Update Print Tables** button.

F. For changes to the participant's legal name (e.g. due to marriage, divorce, etc.), log a request in the contact or trace log's **DB Change** and **Notes** fields to update the **First Name**, **Middle Name**, and/or **Last Name** fields in the header. (See instructions in the section of this document titled *Logging a Telephone Call or Email in the LTFU Participant Database*, below.) The Call Center Coordinator, an LSI, or their designee will update the appropriate field(s) in the database.

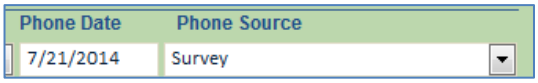
11. **Participant Mailing Address** (located on the Participant tab) –
    A. If the existing address for the participant has been confirmed (i.e. There is NO NEW information to enter.), update the **Address Date/Source** fields with the date the mailing address was confirmed and the source of the confirmation.
    B. If there is new address information for the participant:
        i. Click on the **Archive Info** button.
        ii. Enter the new participant address, date, and source. If the **Preferred Name** field is in ALL CAPS, the address should be typed in ALL CAPS as well to ensure our mailings look professional.
        iii. Move the cursor to a new field, and then click on the **Update Print Tables** button.



12. **Participant Telephone Number(s)** (located on the Participant tab) –
    A. Rank numbers according to your best judgment using the drop-down menu for the appropriate **Rank** field.
        i. Rank of 1 – 5 identifies the preference in dialing with rank "1" being the best number at which to reach the participant, rank "2" being the second-best number at which to reach the participant, etc.
        ii. Rank "9" indicates that the number was found to be disconnected.
        iii. Rank "11" indicates that the number is a wrong number. This rank does NOT indicate that the number should never be called again.
        iv. Rank "37" indicates that the number should not be called again.
            a. IMPORTANT NOTE: *Any time a number is ranked "37", the SI should add an explanatory note to the **Notes** field formatted with a leading double-asterisk, the date, MESSAGE IN ALL CAPS, and SI ID.* Click the **Notes** button to access this field.
            b. *Example:* **10/19/2015: DO NOT CALL 901-555-1234. PT'S FATHER REQUESTED NO FURTHER CALLS TO THE HOME NUMBER. [163]



    B. If an existing participant telephone number has been confirmed:
        i. **Phone Date** – Update with the date the number was confirmed.
        ii. **Phone Source** – Update with the source of the confirmation.
        iii. **Rank** – Update, if necessary.



    C. If there is a new participant telephone number to enter:
        i. NOTE: Phone numbers for associates of the participant should NOT be entered on the Participant tab. See the **Associate Records** instructions, below, outlining procedures for entering associate information.
        ii. Enter the new number in the first empty row, and populate the associated **Rank**, **Phone Class**, **Phone Type**, **Phone Date**, and **Phone Source** fields.

a. If **Phone Type** is populated with "Other Phone", add a dated note with your SI ID in the **Notes** field of the Participant tab describing what the "other phone" type is. Click the **Notes** button to access this field.
b. Note that Canadian telephone numbers should be entered with **Phone Class** = Domestic.

iii. Move the cursor to a new field, and click the **Update Print Tables** button.

13. **Participant Email Address** (located on the Participant tab) –

A. Based on information obtained during telephone calls, rank email addresses according to your best judgment using the drop-down menu for the appropriate **Rank** field.

i. Rank of 1 – 5 identifies the preference in emailing with rank "1" being the best email address at which to reach the participant, rank "2" being the second-best email address at which to reach the participant, etc.

ii. Rank "9" indicates that the email address is no longer an active account.
iii. Rank "11" indicates that the email address is a wrong address.
iv. Rank "37" indicates that the email address should not be used again.
a. IMPORTANT NOTE: *Any time an email address is ranked "37", the SI should add a note to the **Notes** field formatted with a leading double-asterisk, the date, MESSAGE IN ALL CAPS, and SI ID.* Click the **Notes** button to access this field.
b. *Example:* **10/22/2015: DO NOT USE EMAIL ADDRESS MAXSMOM@GMAIL.COM. PER CASE, THIS IS HER MOTHER'S EMAIL ADDRESS. [156]

B. If an existing participant email address has been confirmed:

i. **Email Date** – Update with the date the email address was confirmed.
ii. **Email Source** – Update with the source of the confirmation.
iii. **Rank** – Update, if necessary.

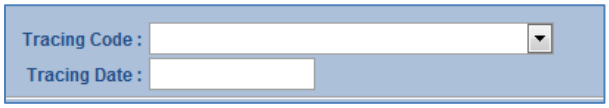
C. If there is a new participant email address to enter:

i. NOTE: Email addresses for associates of the participant should NOT be entered on the Participant tab. See the **Associate Records** instructions, below, outlining procedures for entering associate information.
ii. Enter the new email address in the first empty row, and populate the associated **Rank**, **Email Date**, and **Email Source** fields.

14. **Tracing Status Update** (located on the Participant tab) –

A. If all available numbers in the database are disconnected, wrong, or "Do Not Call":

i. And the **Tracing Code** field is currently <null>, update the field to be 19-Disconnect, and populate the **Tracing Date** field with the current date.



ii. And the **Tracing Code** field is currently populated with 18-Search New Addr or 81-Newsletter returned w/o new addr, update the field to be 13-Needs Tracing, and update the **Tracing Date** field to be the current date.
iii. **Notes** – Add a dated note with your SI ID documenting the changes in the Tracing fields and why the changes were made. Click the **Notes** button to access this field.

B. If calls to all numbers meet the following criteria, the participant may be placed in tracing for bad numbers, as directed above:

i. If the voicemail announcement indicates the participant's or his/her associate's name, and there has been no response after 5 calls and 3 messages
ii. If the voicemail announcement is generic, and there has been no response after 4 calls and 2 messages
iii. If there is no voice mailbox (i.e. we cannot leave a message), and no one has been reached after 3 calls

C. If we are notified that the participant's mailing address is incorrect but an updated address is not provided:
   i. And the **Tracing Code** field is currently <null>, update the field to be 18-Search New Addr, and populate the **Tracing Date** field with the current date.
   ii. And the **Tracing Code** field is currently populated with 19-Disconnect, update the field to be 13-Needs Tracing, and update the **Tracing Date** field to be the current date.
   iii. **Notes** – Add a dated note with your SI ID documenting the changes in the Tracing fields and why the changes were made. Click the **Notes** button to access this field.

D. If the **Tracing Code** is currently set to 13-Needs Tracing and contact information is confirmed:
   i. If a telephone number for the participant is confirmed but not an address:
      a. Update the **Tracing Code** field from 13-Needs Tracing to 18-Search New Addr, and update the **Tracing Date** field to the current date.
      b. **Notes** – Document the changes to the tracing fields in a dated note with your SI ID. Click the **Notes** button to access this field.
      c. Complete all appropriate database updates for a participant telephone number.
   ii. If a mailing address for the participant is confirmed but not a phone number:
      a. Update the **Tracing Code** field from 13-Needs Tracing to 19-Disconnect, and update the **Tracing Date** field to the current date.
      b. **Notes** – Document the changes to the tracing fields in a dated note with your SI ID. Click the **Notes** button to access this field.
      c. Complete all appropriate database updates for a participant mailing address.
   iii. If both a telephone number and a mailing address for the participant are confirmed:
      a. **Tracing Code** and **Tracing Date** – Clear both fields.
      b. **Notes** – Document the changes to the tracing fields in a dated note with your SI ID. Click the **Notes** button to access this field.
      c. Complete all appropriate database updates for a participant telephone number and mailing address.

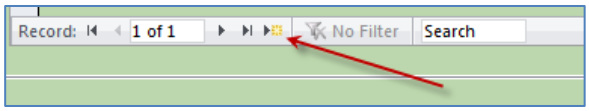
E. If the **Tracing Code** is currently set to 19-Disconnect and a telephone number for the participant is confirmed:
   i. **Tracing Code** and **Tracing Date** – Clear both fields.
   ii. **Notes** – Document the changes to the tracing fields in a dated note with your SI ID. Click the **Notes** button to access this field.
   iii. Complete all appropriate database updates for a participant telephone number.

F. If the **Tracing Code** is currently set to 18-Search New Addr or 81-Newsletter returned w/o new addr and a mailing address for the participant is confirmed:
   i. **Tracing Code** and **Tracing Date** – Clear both fields.
   ii. **Notes** – Document the changes to the tracing fields in a dated note with your SI ID. Click the **Notes** button to access this field.
   iii. Complete all appropriate database updates for a participant mailing address.

G. For other tracing issues, consult with the LSI team and the Coordinator for a directive.

15. **Preferred Contact Time** – If the participant indicated a best weekday/time of day to contact him/her, document this information in the **Preferred Contact info/time** field at the bottom of the Participant tab.

16. **Associate Records** (located on the Associates tab) – Associates are all parties related to or otherwise associated with the participant and may include parents, spouses, other family members, friends, neighbors, additional contacts, and others.
    NOTE: When making updates to associates in a sibling record that will also apply to the case's record (or vice versa), update the same information in the case's record as well, where appropriate.
    A. To add a **new Associate record**:
        i. Before adding a new associate record, review all existing associate records to verify that the associate is not already documented. *THERE SHOULD BE ONLY ONE ASSOCIATE RECORD PER ASSOCIATE.*
        ii. If the new associate is a brother or sister of the participant, check both the case and sibling records in both the LTFU Participant database and the Expansion Tracking database to confirm the associate is not an LTFU Study participant.
            a. If the associate IS also an LTFU Study participant:
                1. **Notes** (Participant tab) – Log a dated comment with your SI ID documenting that the participant has an associated sister or brother that is also an LTFU Study participant. Click the **Notes** button to access this field.
                2. Click the **New (blank) record** button at the bottom of the Associates tab to make a new associate record.

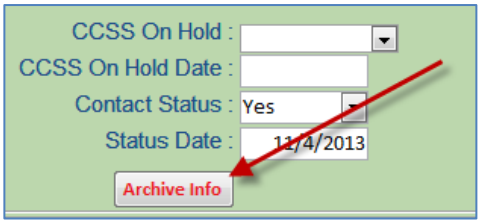


                3. Enter the name of the sister or brother associate who is also a participant using the **Associate Name** instructions below.
                4. **Relationship** – Populate with the appropriate value. NOTE: This field MUST be populated before leaving the new associate record.
                5. Document the additional contact status, if applicable. See the **Associate Contact Status** instructions, below, outlining the procedure.
                6. DO NOT enter the sister or brother associate's contact information in the associate record. Make a dated note in the **Notes** field that this will be documented only in his/her primary study record.
                7. Update the contact information in the sibling's record in the LTFU Participant database. If not yet rolled over to the LTFU Participant database, update the Expansion Tracking database.
            b. If the new associate IS NOT an LTFU Study participant:
                1. Click the **New (blank) record** button at the bottom of the Associates tab.
                2. **Relationship** – Populate with the associate's relationship to the participant. If the relationship is unknown, populate this field with "Other". NOTE: This field MUST be populated before leaving the new associate record.
                3. Enter the associate's name, address, telephone numbers, email addresses, and contact status information, as indicated below.
    B. **Associate Name** - Associate names are recorded in individual records on the Associates tab. Only one party should be recorded in each associate record (e.g. Do NOT list "John and Joan Doe" in the **Name** field.) The name should be formatted as Legalfirst "Preferredname" Legallast in the **Name** field of the record. If our record of an associate's name needs to be changed:

i. **Notes** (Associates tab) – Add a dated note with your SI ID in the appropriate associate record documenting what the name is being changed from, what the name is being changed to, and why the change is being made.

ii. Click the **Archive Info** button on the associate's record.

iii. **Name** – Update with the new name, then move to a new field. Use the format Legalfirst "Preferredname" Legallast (e.g. Katherine "Kat" Jackson).



C. **Associate Address** (located on the Associates tab) –

i. If the existing address for the associate has been confirmed (i.e. There is NO NEW information to enter), and the associate IS NOT also an LTFU Study case or sibling participant:
   a. **Address Date** – Update with the date the mailing address was confirmed.
   b. **Address Source** – Update with the source of the confirmation.

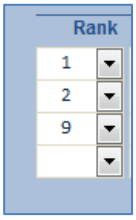
ii. If there is new address information for the associate, and the associate IS NOT an LTFU Study participant:
   a. Click on the **Archive Info** button on the associate's record to archive existing data.
   b. Enter the new associate address, date, and source on the appropriate associate record.

iii. If the recorded address information for the associate is *known* to be incorrect, no new address information is provided, and the associate IS NOT an LTFU Study participant:
   a. Click on the **Archive Info** button on the associate's record to archive existing data.
   b. Remove the incorrect mailing address from the address fields.
   c. **Notes** – Add a dated note with your SI ID documenting the circumstances and the action taken.

iv. If the associate IS also an LTFU Study case or sibling participant:
   a. Update the associate's contact information in his/her primary LTFU record.
   b. Click the **Archive Info** button on the associate's record to archive the address information currently documented.
   c. Clear the address information currently documented in the associate record.
   d. **Notes** – Log a dated comment with your SI ID indicating that the associate's contact information can be found in his/her primary participant record.

D. **Associate Telephone Number** (located in the Associates tab) –

i. Rank numbers according to your best judgment using the drop-down menu for the appropriate **Rank** field.
   a. Rank of 1 – 5 identifies the preference in dialing with rank "1" being the best number at which to reach the associate, rank "2" being the second-best number at which to reach the associate, etc.
   b. Rank "9" indicates that the number was found to be disconnected.
   c. Rank "11" indicates that the number is a wrong number. This rank does NOT indicate that the number should never be called again.
   d. Rank "37" indicates that the number should not be called again.
      1. IMPORTANT NOTE: *Any time a number is ranked "37", the SI should add a note to the **Notes** field formatted with a leading double-asterisk, the date, MESSAGE IN ALL CAPS, and SI ID.*



2. *Example:* **11/17/2015: DO NOT CALL 731-777-1234. PT'S FATHER REQUESTED NO FURTHER CALLS ON HIS CELL PHONE DUE TO LIMITED MINUTES AVAILABLE. PLEASE CALL HOME NUMBER. [168]

ii. If an existing associate telephone number has been confirmed, and the associate IS NOT also an LTFU Study case or sibling participant:
   a. **Phone Date** – Update with the date the number was confirmed.
   b. **Phone Source** – Update with the source of the confirmation.
   c. **Rank** – Update, if necessary.

iii. If there is a new associate telephone number, and the associate IS NOT also an LTFU Study participant, enter the new number in the first empty row, and populate the associated **Rank**, **Phone Class**, **Phone Type**, **Phone Date**, and **Phone Source** fields.
   a. If **Phone Type** is populated with "Other Phone", add a dated note with your SI ID in the **Notes** field describing what the "other phone" type is.
   b. Note that Canadian telephone numbers should be entered with **Phone Class** = Domestic.

iv. If the associate IS also an LTFU Study case or sibling participant:
   a. Update the associate's telephone information in his/her primary LTFU record.
   b. **Notes** – Archive the telephone information currently documented in the associate record by making a dated note with SI ID. Specify that the associate's contact information can be found in his/her participant record.
   c. Clear the telephone information currently documented in the associate record.

E. **Associate Email Address** (located on the Associates tab) –

i. Based on information obtained during telephone calls, rank email addresses according to your best judgment using the drop-down menu for the appropriate **Rank** field.
   a. Rank of 1 – 5 identifies the preference in emailing with rank "1" being the best email address at which to reach the associate, rank "2" being the second-best email address at which to reach the associate, etc.
   b. Rank "9" indicates that the email address is no longer an active account.
   c. Rank "11" indicates that the email address is a wrong email address.
   d. Rank "37" indicates that the email address should not be used again.
      1. IMPORTANT NOTE: *Any time an email address is ranked "37", the SI should add a note to the **Notes** field formatted with a leading double-asterisk, the date, MESSAGE IN ALL CAPS, and SI ID.*
      2. *Example:* **8/14/2015: DO NOT USE EMAIL ADDRESS TSMITH@AAAELECTRIC.COM. PER FATHER, THIS EMAIL ACCOUNT IS FOR HIS FORMER JOB. [121]

ii. If an existing participant email address has been confirmed, and the associate IS NOT also an LTFU Study case or sibling participant:
   a. **Email Date** – Update with the date the email address was confirmed.
   b. **Email Source** – Update with the source of the confirmation.
   c. **Rank** – Update, if necessary.

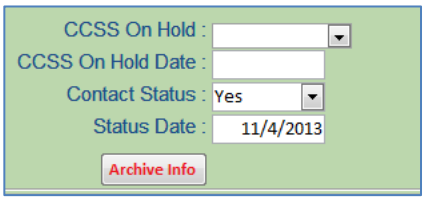
iii. If there is a new participant email address to enter and the associate IS NOT also an LTFU Study participant, enter the new email address in the first empty row, and populate the associated **Rank**, **Email Date**, and **Email Source** fields.

iv. If the associate IS also an LTFU Study case or sibling participant:
   a. Update the associate's email information in his/her primary LTFU record.

b. **Notes** – Archive the email information currently documented in the associate record by making a dated note with SI ID. Specify that the associate's contact information can be found in his/her participant record.
c. Clear the email information currently documented in the associate record.

F. **Associate Contact Status** –

i. Additional contacts are those parties that the *participant* has AUTHORIZED us to contact if we are unable to reach the participant for any reason. If the *participant has authorized* the associate in question to be an additional contact:



a. **Contact Status** – Set to "Yes".
b. **Status Date** – Populate or update with the date of the most recent authorization.
c. **Notes** – Add a dated note with your SI ID documenting the most recent authorization and the updates to the fields.

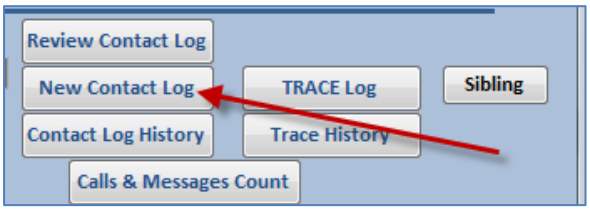
ii. If either the associate has requested not to be contacted OR the participant has requested that we no longer contact the associate:
a. **Contact Status** – Update to be "No".
b. **Status Date** – Update with the date of the status.
c. Change the telephone and email ranks to "37" for the associate's contact information.
d. **Notes** – Add a dated note with your SI ID in the field documenting the circumstances of the "37" ranks. The note should be formatted with a leading double-asterisk, the date, and the note in ALL CAPS.

17. **Suspected Ineligibility** – Document the suspected ineligibility in the contact log's or trace log's **DB Change** and **Notes** fields. (See instructions in the section of this document titled *Logging a Telephone Call or Email in the LTFU Participant Database*, below.) The **Notes** should explain why the participant is believed to be ineligible for the LTFU Study. A member of the LSI team or their designee will address this with the Coordinator and Research Scientist for an eligibility determination.

Logging a Telephone Call or Email in the LTFU Participant Database:

1. If calling a previously confirmed number, documenting an incoming call, documenting a sent or received email, or otherwise **communicating with an external party for non-tracing purposes**:

A. Click on the **New Contact Log** button in the header of the participant's record and populate the fields as follows for each communication event:



i. **Int ID** – Enter your SI ID.
ii. **Date** – Enter the date of the communication.
iii. **Contact Mode** – Select the appropriate option from the drop-down menu.
iv. **Phone** – For telephone calls, enter the telephone number to which the call was placed or from which the call was received. For non-telephone communication, leave this field blank.
v. **Email** – For emails, enter the email address to which the message was sent or from which the message was received. For non-email communication, leave this field blank.
vi. **Contacting** – Use the drop-down menu to select the appropriate option. For outgoing communication, choose the party reached or, when no one is reached, choose the party you

are trying to reach. For incoming communication, choose the party contacting the LTFU Study. If unsure of the exact relationship, use 8-Other.

vii. **Name** – For outgoing communication, type the name of the party reached or, when no one is reached, type the name of the party you are trying to reach. For incoming communication, type the name of the party contacting the LTFU Study. If unsure, type "unknown".

viii. **Time START** – Enter the time the telephone number was dialed (for outgoing calls), the time the call was received (for incoming calls), or the time the email was sent/received (for email communication). Contact logs on the same date for the same SI should not have overlapping times.

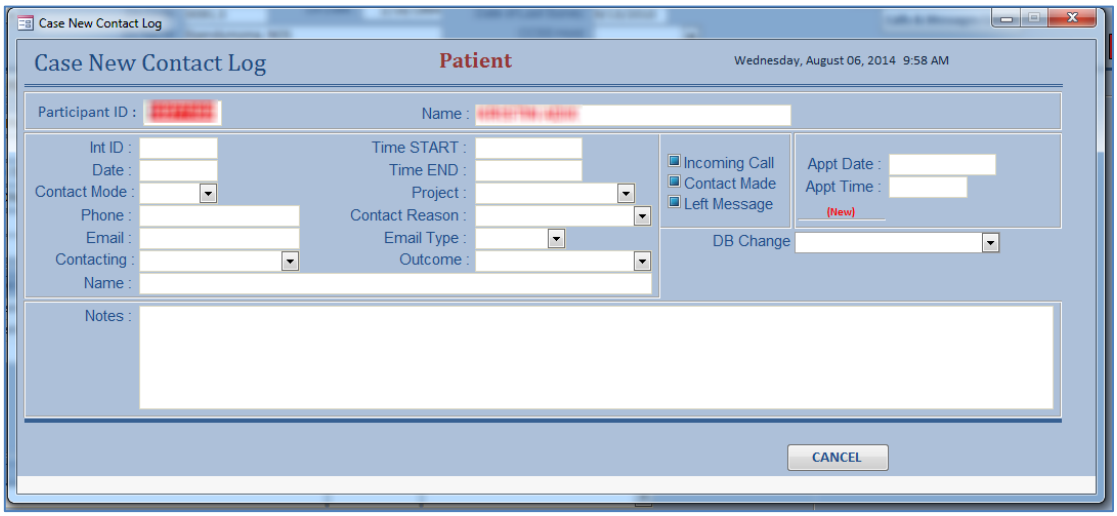
ix. **Time END** – Enter the time the telephone was hung up (for calls) or the time the email was sent/received (for emails). Note that email communication will have the same time in both the **Time START** and **Time END** fields.

x. **Project** – Select the appropriate option from the drop-down menu. NOTE: If the SI addressed two or more distinct projects in a single telephone call, s/he should create a separate contact record for each project.

xi. **Contact Reason** – Select the appropriate option from the drop-down menu.

xii. **Email Type** – For emails sent or received, select the appropriate option from the drop-down menu. For non-email communication, leave this field blank.

xiii. **Outcome** - Select the appropriate option from the drop-down menu to describe the outcome of the communication.



xiv. **Notes** – Enter notes about the communication and its outcome.

a. If calling one party and reaching another, specify. *Example: "Called for pt. Pt's mother answered and…"*

b. If any database change is requested in the **DB Change** field, clearly document the change in this field (e.g. "*change DOB from 1/7/85 to 11/7/85*", "*gender is listed as F, please change to M*", or "*change name from Zahara Adia to Zahara Pitt due to adoption*").

c. For email communication, enter only a summary of what was sent. Do not paste the full body of the email into this field.

xv. **Incoming Call** checkbox – Mark this checkbox if the record is for an incoming telephone call. Leave this checkbox blank for outgoing calls and all other types of communication.

xvi. **Contact Made** checkbox – Mark this box if someone was contacted during an incoming or outgoing telephone call. Leave this box blank for all non-telephone communication.

xvii. **Left Message** checkbox – If a voice message was left on an answering device, check this box. This will update the tallies displayed in the **Calls & Messages Count** report. DO NOT check this box for messages left with a live person or for non-telephone communication.

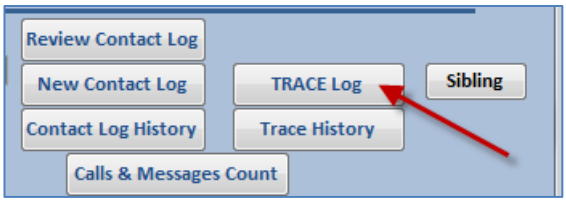
xviii. **Appt Date** – If an appointment was set to complete an LTFU Study event (e.g. survey), enter the date of the appointment.

xix. **Appt Time** – If an appointment was set to complete an LTFU Study event (e.g. survey), enter the time of the appointment in Central Time, regardless of the participant's time zone.

xx. **DB Change** – If an LSI-level change needs to be made to the database (e.g. DOB change, gender change, participant is suspected to be ineligible, legal name change, survival status change, etc.) or if a survey was partially completed or completed in Spanish, flag the change request or survey event using the drop-down menu in this field. *IMPORTANT: Clear notes regarding the change request or event must be documented in the **Notes** field of the same contact record.*

xxi. Save the record(s) by clicking the red X exit button at the top of the window, or cancel all records by clicking the **Cancel** button located below the last contact card.

2. If calling an unconfirmed number or otherwise **communicating with external parties for Tracing purposes**:



A. Click on the **Trace Log** button in the header of the participant's record, then on the **New Record** button.

B. For each communication event, populate the fields as follows:

i. **Interviewer ID** – Enter your SI ID.

ii. **Date** – Enter the date of the communication.

iii. **Contact Mode** – Select the appropriate option from the drop-down menu.

iv. **Phone** – For telephone calls, enter the telephone number to which the call was placed or from which the call was received. For non-telephone communication, leave this field blank.

v. **Contacting** – Use the drop-down menu to select the appropriate option. For outgoing communication, choose the party reached or, when no one is reached, choose the party you are trying to reach. For incoming communication, choose the party contacting the LTFU Study. If unsure of the exact relationship, use 8-Other.

vi. **DB Change** – If an LSI-level change needs to be made to the database (e.g. DOB change, gender change, participant is suspected to be ineligible, legal name change, survival status change, etc.) or if a survey was partially completed or completed in Spanish, flag the change request or survey event using the drop-down menu in this field. *IMPORTANT: Clear notes regarding the change request or event must be documented in the **Notes** field of the same contact record.*

vii. **Name** – For outgoing communication, type the name of the party reached or, when no one is reached, type the name of the party you are trying to reach. For incoming communication, type the name of the party contacting the LTFU Study. If unsure, type "unknown".

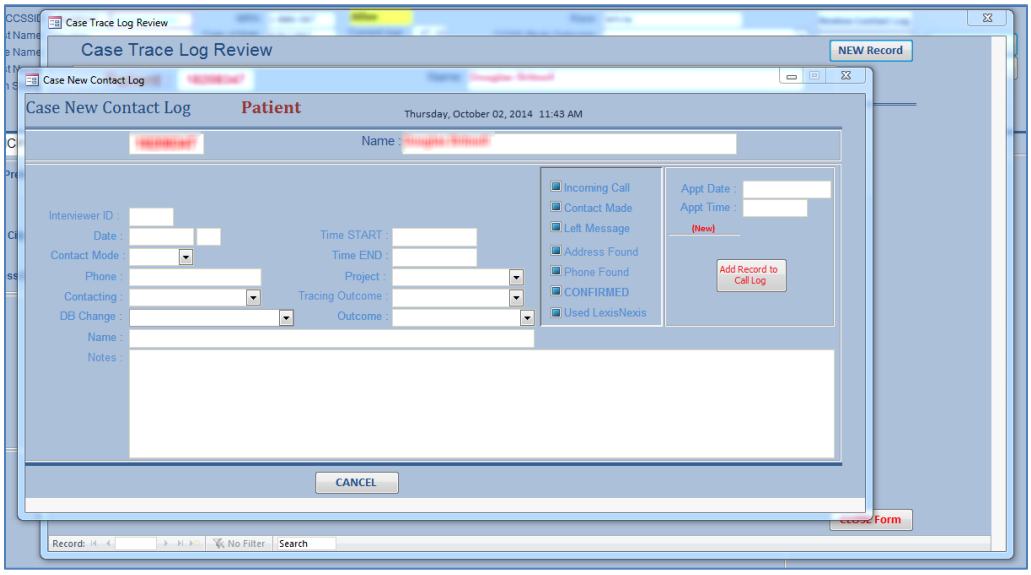
viii. **Time START** – Enter the time the telephone number was dialed (for outgoing calls), the time the call was received (for incoming calls), or the time the email was sent/received (for email communication)**.** Trace logs on the same date for the same SI should not have overlapping times.

ix. **Time END** – Enter the time the telephone was hung up (for calls) or the time the email was sent/received (for emails). Note that email communication will have the same time in both the **Time START** and **Time END** fields.

x. **Project** – Select the appropriate option from the drop-down menu.

xi. **Tracing Outcome** – Choose the appropriate value from the drop-down menu. If no option applies, leave this field blank.

xii. **Outcome** – Select the appropriate option from the drop-down menu to describe the outcome of the communication as it relates to the participant.



xiii. **Notes** – Enter notes about the communication and its outcome.

a. If calling one party and reaching another, specify. *Example: "Called for pt. Pt's mother answered and…"*

b. If any database change was requested in the **DB Change** field, clearly document the change in this field (e.g. "*change DOB from 1/7/85 to 11/7/85*", "*gender is listed as F, please change to M*", or "*change name from Zahara Adia to Zahara Pitt due to adoption*").

c. For email communication, enter only a summary of what was sent. Do not paste the full body of the email into this field.

xiv. **Incoming Call** – Mark this checkbox if the record is for an incoming telephone call. Leave this checkbox blank for outgoing calls and all non-telephone communication.

xv. **Contact Made** checkbox – Mark this checkbox if someone was contacted during an incoming or outgoing telephone call. Leave this box blank for all non-telephone communication.

xvi. **Left Message** checkbox – If a voice message was left on an answering device, check this box. This will update the tallies displayed in the **Calls & Messages Count** report. DO NOT check this box for messages left with a live person or for non-telephone communication.

xvii. **Address Found** checkbox – If the participant's mailing address is located in online resources, mark this checkbox.

xviii. **Phone Found** – If the participant's telephone number is located in online resources, mark this checkbox.

xix. **CONFIRMED** – If the participant's mailing address and telephone number are confirmed with a live person (i.e. the participant is being removed from tracing), mark this checkbox.

xx. **Used LexisNexis** – Tracers should mark this checkbox if LexisNexis is used during a tracing session. Non-tracers should leave this box unchecked.

xxi. **Appt Date** – If an appointment was set to complete an LTFU Study event (e.g. survey), enter the date of the appointment.

xxii. **Appt Time** – If an appointment was set to complete an LTFU Study event (e.g. survey), enter the time of the appointment in Central Time, regardless of the participant's time zone.

xxiii. **Add Record to Call Log** button – If a call to an unconfirmed number becomes a "live" call (i.e. The party reached is either the participant or an associate of the participant.):

a. The individual call should also be logged in the contact log by clicking the **Add Record to Call Log** button after the trace log is populated.

b. If the party reached is an associate of the participant:

1. And is not currently in the Associates tab, add him or her to the Associates tab using the **Associate Records** instructions, above.
2. And is currently in the Associates tab, update his or her contact information using the **Associate Records** instructions, above.

C. Save the record(s) by clicking the red X exit button at the top of the window, or cancel all records by clicking the **Cancel** button located below the last contact card.

Revision Record Printed 4/24/2015 2:29 PM

[259] Current Filename:		LTFU Participant Database Data Entry ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/25/2014	R. Massey, A. Oyuela, D. Rinehart, A. McDonald	Initial Development
1.1	8/7/2014	J. Ford, R. Massey	Updated Contact Log and Trace Log directives for new fields, other content revision
1.2	10/2/2014	R. Massey, D. Rinehart	Content Revision
1.3	4/23/2015	R. Massey, A. Oyuela, D. Rinehart, A. McDonald, J. Ford, L. Harrison	Content Revision

Maintaining Data Manager List

Background

Each LTFU collaborating institution has a data manager who is primary point of contact for the Coordinating Center's Lead CRA correspondence with the institution. The data manager is identified in the study tracking database as well as in a file posted on the St. Jude Share site. While individual data managers can update the share site file, the Lead CRA maintains oversight of the file to ensure that the data manager list is up to date. Data managers typically notify the coordinating center of staffing changes at their respective institutions. The Data Manager list also includes the site PI, IRB contact, and institutional address. A local copy of the list is maintained on the server.

Procedures

Study Tracking Database

In the Expansion Tracking database, **tblDataManager** contains the name, email address, and phone number of one data manager per institution. To update an institution's data manager record, edit the table directly. (The Expansion Tracking database displays data manager information on the MRAF tab.)

St Jude Share Site and Local Copy

1. An Excel spreadsheet **Data Managers_mm-dd-yy** is posted in the CCSS folder on the St. Jude share site (with mm-dd-yy representing the date the file was most recently updated).
2. The Lead CRA maintains the original source file locally on the server (in **Z:\SJShare\SJCOMMON\ECC\CCSS\Addresses & Names**).
3. To update an entry,
    a. Copy the most recent file in the local folder and then rename the copy with the current date in the mm-dd-yy portion of the file name.
    b. Move the previous version into the Archive folder.
    c. Edit the new file and save it.
    d. Upload the updated file to the St. Jude share site.
    e. After uploading the new file to the share site, delete the previous version from the share site.

Revision Record Printed 1/22/2013 7:53 AM

231 Current Filename:		Maintaining Data Manager List ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	1/22/13	J.Bates	Initial Development

Maintaining Saliva Kit Inventory

Background

To keep an accurate count of saliva kit materials and actual kits, we maintain an inventory catalog. This document must be updated as materials are utilized. Do this after a saliva kit mailing as well as after a successful SJL saliva appointment (i.e. participant consented and provided a specimen sample).

Procedure

1. Open the **Saliva Inventory m-d-yy** spreadsheet located here:
   Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Inventory
2. On the **Saliva Inventory Summary** tab
   a. Based on the amount of **Materials** (e.g. Jiffy Lite, Bags) used, reduce the number in **Quantity**
3. On the **Saliva Kit Inventory** tab
   a. Find row of **Box #** where you got the actual kit(s)
   b. Reduce **# of Kits**, based upon number of kits used.

Materials	Quantity*
# of Jiffy Lite Envelopes	950
# of Specimen Bags	5,700
# of Peach 1st Class Envelopes	4,200
# of Peach International Envelopes	0
# of Blank Peach Envelopes	2,000
# of Brown Manilla Folders	0
# of 1st Class Tyvek Envelopes	3,800
# of Bulk Mail Tyvek Envelopes	3,900

*Approximately

Saliva Inventory Summary | Saliva Kit Invent

Box #	# of Kits	Expiration Date	OG-250 Lot #	Purifier Lot #	Ref	Location
35-107	195	March 2012	LI20	LH19	OG-L2P-5	Kit Processing Room
35-106	198	March 2012	LI20	LH19	OG-L2P-5	Kit Processing Room

4. If a box of kits located in the kit processing room (Rm S4011) is depleted, go to the basement cage, locate a box with an "Expiration Date" closest to the *current* date, and transport it to the kit processing room. (The cage is arranged so kits set to expire the soonest are closest to door)
   a. Then on the tab for **Saliva Kit Inventory**, find the Box# of the box(es) you brought up to the 4th floor.
   b. Change the **Location** for this box from *Basement Cage* to *Kit Processing Room*

Box #	# of Kits	Expiration Date	OG-250 Lot #	Purifier Lot #	Ref	Location
35-102	200	March 2012	LI18	LH19	OG-L2P-5	Basement Cage
35-154	100	March 2012	LI23	LI14	OG-L2P-5	Basement Cage
02-345	200	September 2012	MC20	MC01	OG-L2P-5	Basement Cage

5. After updating the appropriate fields in the document, save the document in the same location but add the *current* date at the end of the file name (do not over-write the previous file). Close the file.
6. Move the previous "Saliva Inventory [Date]" document to the Archive folder

Address Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Inventory
Archive
Saliva Inventory 1-24-12
Saliva Inventory 12-9-11

Revision Record
Printed 12/13/2012 7:49 AM

Current Filename:		Maintaining Saliva Kit Inventory ver 1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	1/31/2012	J.Ford	Initial Development
1.1	2/13/12	J.Bates	Formatting

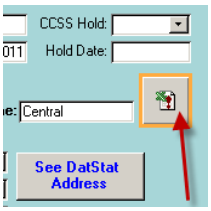
Maintaining the Expansion Baseline Print Tables

Background

In the Expansion Tracking database, it is important that minor participants are **moved** into the adult print table and **removed** from the minor print table once they are 18 years of age. The CRA 2 performs this maintenance as part of the daily morning routine, after all the DatStat and Age of Majority macros have been run. The procedure "graduates" minor cases to adult status. Note that a comparable procedure is NOT needed for expansion siblings.

Procedure

In the Expansion Tracking database, on the Quest tab, use the button icon for this procedure. There is no name on the button, but the system knows it as *CommandrefreshAll*. The button runs the macro **mcrPrintTablesUpdate** which then runs two queries:



- **qryPrintMinor2Adult**: locates records in the Under18 print table where date Diff between now and BirthDate is .=17.962. Appends the record from the Minor print table "as is" to the adult print table, using cstr (birthdate) to feed DOB_ and
- **qryDeleteAdultFrom PrintMinor** (hidden query): deletes all records from the main minor print table where the date diff (between birthdate from main table and now is >= 17.962.

1. After running the macros: **mcrDatStatCompleteDateCommentsUpdate** and **mcrJB_UpdtAOMReconsent** double click the *CommandRefreshAll* button icon.

2. Continue through the process by clicking "Yes" at each prompt.

3. When you have finished, the tables have been updated.

4. Sibling participants are housed in both the minor and adult print tables, so there is no macro button to "move" the minor siblings as there is no need for it.

NOTE: More detailed information concerning the specific queries that run can be found in the query documentation file (in …CCSS\Jerry_QueryDirectory-JB) document: *Researching the Update Print Table Event in Expansion Database*

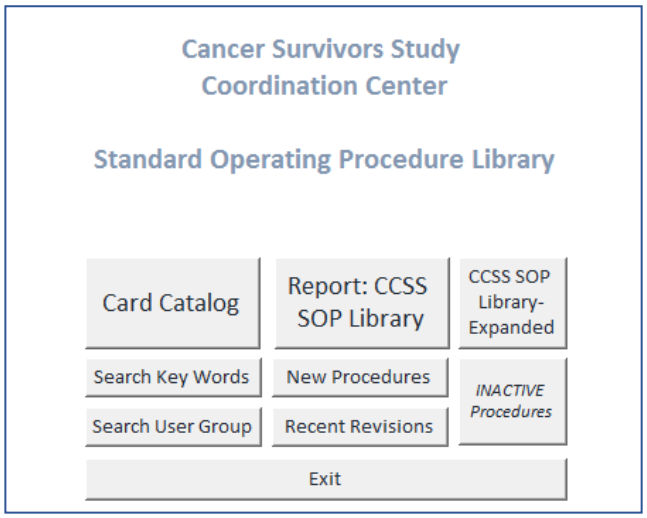
Revision Record Printed 5/24/2013 8:29 AM

[244] Current Filename:		Maintaining the Expansion Baseline Print Tables ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	5/22/13	L. Harrison	Initial Development

Maintaining the SOP Library

Background

The CCSS SOP Library database provides users with online access to all standard operating procedures (SOPs) used by the CCSS team. Persons responsible for the various CCSS processes are also responsible for ensuring the corresponding SOP is kept up-to-date.



The LeadCRA or his/her designee maintains the SOP Library as described in this procedure. Maintenance includes editing and publishing revised and new procedures.

Procedures

Publishing a Revised Procedure

1. Carefully **review** submitted revisions of existing SOPs for logical flow and proper formatting. See the SOPs titled **Creating and Updating Procedure Documents for the SOP Manual** and, where applicable, **Survey Interviewer Guidelines for Creating and Updating SOPs** for guidance. Work with the submitter to resolve any questions or concerns until the revision is ready for publication.
2. When the revision is ready for publication, **save** the revised MS Word document at *Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Procedures*.
3. From the MS Word revision, **export** the procedure to a PDF file, publishing it to *Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Procedures\SOPlibrary*.
4. Open the CCSS SOP Library, located at *https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*, and open the form frmCardCatalog_Librarian. Use the Find function in Access to locate the record for the existing procedure (e.g. using the title or file name field).
5. In the record for the existing procedure:

   A. **Title** – Ensure the title matches the full title printed at the top of the revised SOP document. This field is included when searching the SOP Library by key words.
   B. **Descriptors** – Review this field to ensure it includes appropriate words and phrases that are not included in the **Title** or **Description** fields and that will be useful when searching for this procedure. (This field is included when searching the SOP Library by key words.) Separate the descriptors with semicolons.
   C. **Description** – Review this field to ensure the brief description of the procedure is up-to-date. It may be useful to copy and paste the Background from the MS Word procedure

document, then edit this for clarity and brevity. This field is included when searching the SOP Library by key words.

D. **Filename** – Update to the file name of the revised procedure. NOTE: **Filename** must EXACTLY match name of the PDF file (not the Word document), including the .pdf extension.

E. **Users** – Confirm there is a "Y" in the box for each user type in the SOP's audience. If box **All** is set to "Y", all user boxes should be set to "Y", and vice versa.

F. **CurrentVersion** – Update to the version listed with the revised procedure.

G. **Date** – Update to the current date.

H. **Save** the record.

I. Click the **Build or Refresh Link** button. If the **Build or Refresh Link** button does not work, there is likely a typo in the **Filename** field. Once the needed corrections are made, run the build/refresh process again by clicking the **Build or Refresh Link** button.

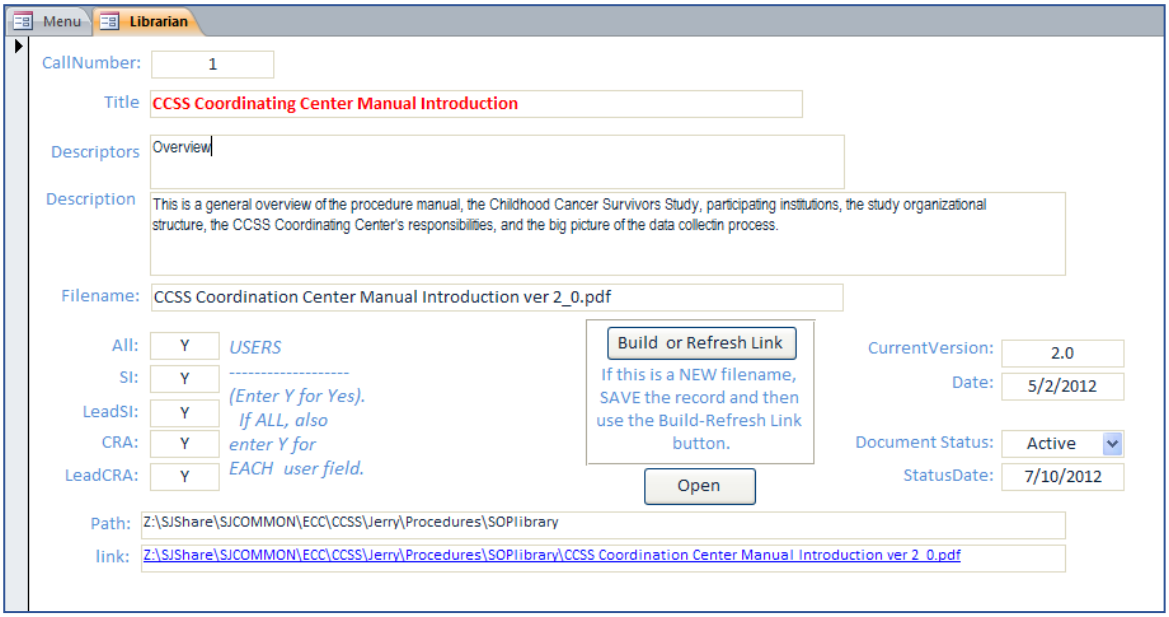
J. Click the **Open** button to **ensure the link to the revised procedure works**. If the **Open** button does not work, there is likely a typo in the **Filename** field. Once the needed corrections are made, run the build/refresh process again by clicking the **Build or Refresh Link** button, then try to open the procedure again.

6. **Notify the submitter** that the procedure has been updated. If any formatting or other changes were made to the document, notify the submitter.

7. **Archive** the previous MS Word document and PDF file.

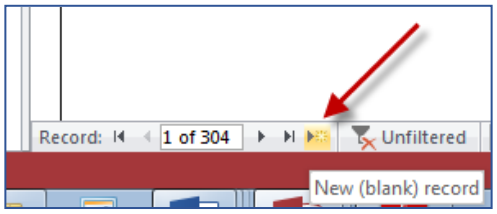
A. Locate the now-outdated MS Word document at *Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Procedures*. Drag it to *Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Procedures\Archive*.

B. Locate the now-outdated PDF file at *Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Procedures\SOPlibrary*. Drag it to *Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Procedures\SOPlibrary\Archive*.



Publishing a New Procedure

1. Carefully review submitted new SOPs for logical flow and proper formatting. See the SOPs titled **Creating and Updating Procedure Documents for the SOP Manual** and, where applicable, **Survey Interviewer Guidelines for Creating and Updating SOPs** for guidance. Work with the submitter to resolve any questions or concerns until the revision is ready for publication.
2. When the new SOP is ready for publication, save the MS Word document at *Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Procedures*.
3. From the MS Word document, export the procedure to a PDF file, publishing it to *Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Procedures\SOPlibrary*.
4. Open the CCSS SOP Library, located at *https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*, and open the form frmCardCatalog_Librarian.
5. Click the **New (blank) record** button at the bottom of the page to create a new card catalog record.



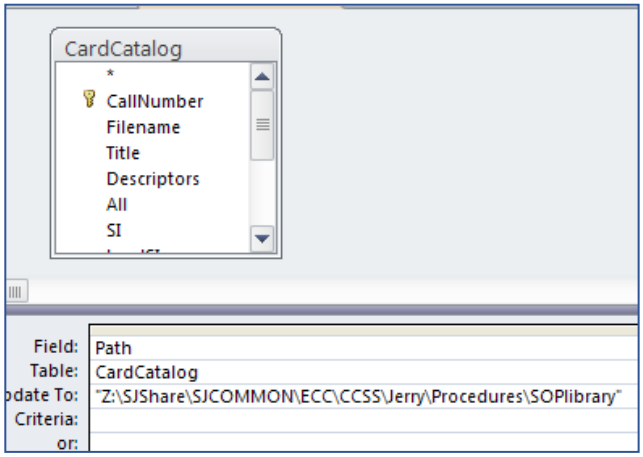
6. In the new record:
   A. **Title** – Enter the full title as printed at the top of the procedure. This field is included when searching the SOP Library by key words.

   B. **Descriptors** – Enter words and phrases that are not included in the **Title** or **Description** fields and that will be useful when searching for this procedure. (This field is included when searching the SOP Library by key words.) Separate the descriptors with semicolons.
   C. **Description** – Enter a brief description of the procedure. It may be useful to copy and paste the Background from the MS Word procedure document, then edit this for clarity and brevity. This field is included when searching the SOP Library by key words.
   D. **Filename** – Populate with the file name of the new procedure. NOTE: **Filename** must EXACTLY match name of the PDF file (not the Word document), including the .pdf extension.
   E. **Users** – Enter "Y" in the box for each user type in the SOP's audience. If box **All** is set to "Y", all user boxes should be set to "Y", and vice versa.
   F. **CurrentVersion** – Populate with the version of the new SOP, usually 1.0.
   G. **Date** – Enter the current date.
   H. **Document Status** – Defaults to "Active".
   I. **StatusDate** – Defaults to the current date.
7. **Save** the record.
8. Click the **Build or Refresh Link** button. If the **Build or Refresh Link** button does not work, there is likely a typo in the **Filename** field. Once the needed corrections are made, run the build/refresh process again by clicking the **Build or Refresh Link** button.

9. Click the **Open** button to **ensure the link to the new procedure works**. If the **Open** button does not work, there is likely a typo in the **Filename** field. Once the needed corrections are made, run the build/refresh process again by clicking the **Build or Refresh Link** button, then try to open the procedure again.
10. Notify the source that the procedure has been published. If any formatting or other changes were made to the document, notify the submitter.

Moving the Library

If the entire library of procedures is moved to a new folder on the network, the database needs to be updated with the new path.



1. **Open the query qry_UpdatePath** in design view, and then key in the criteria.
2. Save and **run the query**. This updates the **Path** field, which specifies the location of the database, on the record for each existing procedure.
3. **Run the query qry_BuildLink** to rebuild the link for each record using the new path and the filename already on record. The **link** field on each procedure record specifies where the procedure is located.
4. Go to the form frmCardCatalog_Librarian, and **spot check** to be sure the procedures open.

Retiring Inactive Procedures

The SOP Library has the ability to flag procedures as "Archived" or "Inactive" using the **Document Status** field. These flags allow the procedure to be kept in the library for archival or historical reference purposes while providing notice to the user that the procedure is no longer in use.

To retire a procedure:

1. Open the CCSS SOP Library, located at *https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*, and open the form frmCardCatalog_Librarian. Use the Find function in Access to locate the record for the existing procedure (e.g. using the title or file name field).
2. Update the procedure record:
   A. **Document Status** – Change to either "Inactive" or "Archive," as appropriate.
   B. **Status Date** – Update to the the current date.
   C. **Description** – Add a note to the end of the description such as, "[Retired Procedure – For Historical Reference Only].
   D. No change needs to be made to the procedure itself.
3. **Save** the record.
4. Notify the source of the request that the procedure has been retired.

Revision Record Printed 10/23/2015 11:03 AM

[226] Current Filename:		Maintaining the SOP Library ver 1_4.doc	
Revision No.	Date	Responsible Author	Change Description
1.1	7/16/12	J. Bates	Initial Development
1.2	12/13/12	J. Bates	Moving previous versions to archive folder
1.3	7/23/13	J. Bates	After move version; run update link query
1.4	10/23/2015	R. Massey, J. Ford	Content Revision: Title change, updated content flow, specified locations

Managing Saliva Study Participant Status

Background

Once we receive notification that a potential saliva participant has refused involvement in the saliva study or CCSS as a whole, is deceased, or has returned a valid sample of saliva, we will remove them from saliva recruitment. The following procedures outline how to update the appropriate databases when these events arise. Procedures for expanded cohort and siblings have yet to be developed.

Procedures

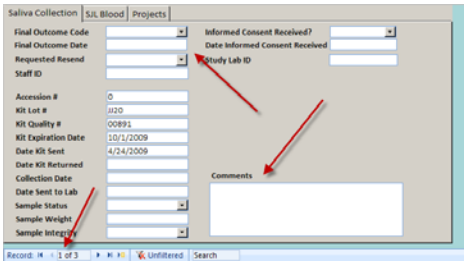
ORIGINAL COHORT:

Identify participants who should be removed from saliva recruitment calls and saliva resends

1. Run **qry_JF_CompareSaliva_RegOutcomes**:

CCSSID	Outcomecod	tblSalivaCalls	outcome	dbo_Quest.o	sa_finaloutrome	sa_finaloutda
			18			
	5	2/6/2012				
	6	5/10/2012				
	6	12/30/2011				

2. If there are any saliva/CCSS refusals or deceased cases in the "Outcomecode" field, update Registration database
   a. For **saliva study refusals** (Outcomecode 1)
      i. Open Reg frmSalivaCollection_New and search for CCSSID
      ii. On the first record, enter "Final Outcome Code" "7"; "Final Outcome Date" as "MaxOfDateLastCall"; "Staff ID" as your initials; document notes from the call in the "Comments" section



   b. For **CCSS refusals** (Outcomecode 2)
      i. Open Reg frmSalivaCollection_New and search for CCSSID
      ii. On the first record, enter "Final Outcome Code" "37"; "Final Outcome Date" as "tblSalivaCalls"; "Staff ID" as your initials; document notes from the call in the "Comments" section
      iii. Open Reg frmQuestTab and search for CCSSID
      iv. Change "Alive" status from "1 alive" to "2 dead"
      v. Document notes from the call in the "Tracing history:" section
      vi. Open "Edit Reg" and "Check In Death Data"
      vii. Enter "Date of Death" (if known)
      viii. If the cause of death is known, enter it in "Parent's reason for Death;" if cause is unknown, enter "Unknown" in "Parent's reason for Death"
      ix. Go back to frmQuestTab
      x. Click on "Page 3" tab; enter "outcome:" "38"; "Outcome Date:" as "tblSalivaCalls"

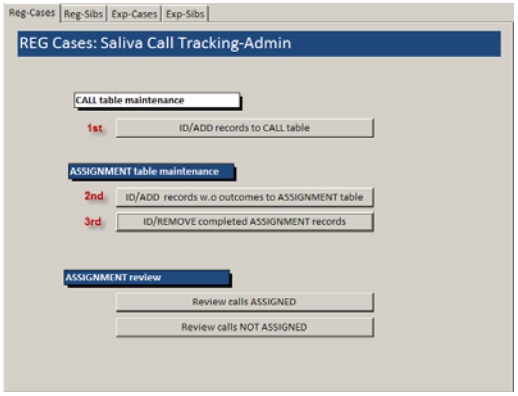
c. For **deceased** cases (Outcomecode 3)
   i. Open Reg frmSalivaCollection_New and search for CCSSID
   ii. On the first record, enter "Final Outcome Code" "38"; "Final Outcome Date" as "MaxOfDateLastCall"; "Requested Resend" "2"; "Staff ID" as your initials; document notes from the call in the "Comments" section
   iii. Open Reg frmQuestTab and search for CCSSID
   iv. Document notes from the call in the "Tracing history:" section
   v. Go to "Page 3" tab; enter "outcome:" "37"; "Outcome Date:" as "MaxOfDateLastCall"

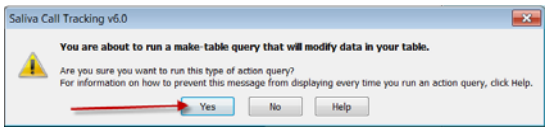
3. If there are any outcome codes in the Registration database that would exclude a participant from the saliva study ("outcome" field; e.g. 37, 38, 40, etc):
   a. Open Reg frmSalivaCollection_New and search for CCSSID
   b. On the last record, enter "Final Outcome Code" as "outcome"; "Final Outcome Date" as "outcomeDate"; "Staff ID" as your initials; document any pertinent notes from the "Tracking history:" frmQuestTab "Page 3" tab in the "Comments" section

ORIGINAL COHORT*:*

Identify saliva participants who should be added to or removed from saliva recruitment calls and saliva resends

1. Open **frmAdmin_V60** and go to the "Reg-Cases" tab
2. Click the following buttons in sequential order, selecting "Yes" when prompted, EVERY time:
   a. ID/ADD records to CALL table
      i. Select "Yes" when prompted EVERY time
   b. ID/ADD records w.o outcomes to ASSIGNMENT table
      i. Select "Yes" when prompted EVERY time
   c. ID/REMOVE completed ASSIGNMENTS records
      i. Select "Yes" when prompted EVERY time





Revision Record
Printed 7/5/2012 3:43 PM

Current Filename:		Managing Saliva Study Participant Status ver 1.doc	
Revision No.	Date	Responsible Author	Change Description
1	7/5/12	J. Ford	Initial Development

Medical and Cancer Terminology

The following section is presented as a glossary of terminology that may be useful to the clinical research assistants and associates involved in the LTFU study.

Achondroplasia (dwarfism) - peculiar form of dwarfism, with short limbs, normal trunk, small face, normal vault, lordosis (curve in the spine), and trident hand

Acrocephalosyndactyly (Apert's syndrome) - characteristic deformity of the skull, and webbing of the digits on hands and feet

Acute Lymphoblastic Leukemia - a fast-growing type of leukemia (blood cancer) in which too many lymphoblast's (immature white blood cells) are found in the blood and bone marrow. Also called acute lymphoblastic leukemia and acute lymphocytic leukemia

Alopecia - temporary loss of hair after receiving some type of chemotherapy or radiation

Aniridia - absence of the iris

Anemia - **l**ess than normal hemoglobin or red cells in the blood

Ascites - accumulation of fluid in the abdominal cavity

Apert's syndrome (acrocephalosyndactyly) - characteristic deformity of the skull, and webbing of the digits on hands and feet

Ataxia telangiectasis (AT) - progressive failure of muscle coordination and oculocutaneous vascular lesions

Basal cell carcinoma - skin cancer that forms in basal cells (small, round cells in the base of the outer layer of skin) (non-melanoma)

Beckwith's or Beckwith-Wiederrnann syndrome - extreme cytomegaly of the fetal adrenal cortex, umbilical hernia, big tongue, hyperplasia of the kidney and pancreas, Leydigcell hyperplasia, and postnatal gigantism

Bilateral acoustic neurofibromatosis (type 2) - familial condition, characterized by the formation of multiple soft tumors of skin

Biopsy - removal of a small portion of tissue for examination

Blasts - immature white blood cells not normally found in the blood

Bloom's Syndrome - dwarfism, photosensitivity, with numerous defects of skin pigmentation

Bone Marrow - Soft tissues inside bones where blood cells are made

Bone Marrow Aspirate - the aspiration of bone marrow through a needle

Bone Marrow Transplant - a process by which bone marrow, either from a donor or oneself, is transplanted into a person who is not making enough healthy blood cells

Bone Marrow Suppression - lower than normal elements in bone marrow due to disease or treatment

Brachytherapy - A form of radiotherapy in which radioactive "seeds" are carefully placed inside of the cancerous tissue and positioned in a manner that will attack the cancer most efficiently

Broviac/Hickman Catheter - a special implanted intravenous catheter which allows medicines, fluids and blood products to be given and blood samples to be drawn

Buccal cell - the cells from the inner lining of the mouth, or cheek. These cells are routinely shed and replaced by new cells. As the old cells die, they accumulate in the saliva in the mouth and can easily be collected

CAT Scan - diagnostic x-ray procedure in which a computer is used to generate a three dimensional image

Carcinoma - cancer that begins in the skin or in tissues that line or cover internal organs

Central Nervous System - the brain and spinal cord

Chemotherapy - the use of medicine(s) to kill cancer cells.

Complete Blood Count (CBC) - a count of elements in the blood.

Congenital megacolon (Hirschpnrng's disease) - an abnormally large or dilated colon; this condition appears soon after birth

Consolidation - a stage of chemotherapy during which intensive treatment is given. It follows induction and precedes maintenance

Cystic Fibrosis (CF) - dysfunction of the endocrine glands, characterized by chronic

pulmonary disease and pancreatic deficiency

Cytotoxic - cell-killing

Dehydration - excessive loss of fluids from the body

Diagnosis - the identification of a disease

Dosimetry - measurement and calculation of dose for the treatment of cancer patients; scientific determination of amount, rate, and distribution of radiation emitted from a source of ionizing radiation

Endocrine - pertaining to hormones and the glands that make and secrete then into the bloodstream through with they travel to affect distant organs. Glands of internal secretion

Fanconi's anemia - characterized by pancytopenia, hypoplasia of the bone marrow, and patchy brown discoloration of the skin

Ewing sarcoma - A type of cancer that forms in bone or soft tissue. Also called peripheral primitive neuroectodermal tumor and pPNET

Exocrine - Pertaining to the secretion of a substance out through a duct. Salivary glands, sweat glands, glands in gastrointestianl tract. Glands of external secretion

Febrile - fever-high temperature. Above 101 degrees

Hematopoietic stem cell transplantation - *i*nvolves the intravenous infusion of autologous or allogeneic stem cells collected from bone marrow, peripheral blood, or umbilical cord blood to reestablish hematopoietic function in patients with damaged or defective bone marrow or immune systems (see bone marrow transplant)

Hemoglobin - The substance in red blood cells that carries oxygen

Hepatic - Having to do with the liver

Hodgkin disease - A cancer of the immune system that is marked by the presence of a type of cell called the Reed-Sternberg cell. The two major types of Hodgkin disease are classical Hodgkin lymphoma and nodular lymphocyte-predominant Hodgkin lymphoma. Symptoms include the painless enlargement of lymph nodes, spleen, or other immune tissue. Other symptoms include fever, weight loss, fatigue, or night sweats. Also called Hodgkin lymphoma

Immunity - defense against a particular infection

Immunosuppression - increased susceptibility to infection

Infusion - injecting fluid into a vein or artery

Induction - The first stage of a treatment protocol that aims at eliminating the cancer (remission)

Intrathecal - within or into the spinal cord

Intravenous - within or into a vein

Investigational Drugs - medications that are used for treatment in which all the side effects may not be known. These medicines will be explained by your doctor

Isolation - a special room where the child stays alone to protect others from an infection the child has or, to protect the child from infections.

Jaundice - yellowish color of the skin or whites of the eyes

Klinefelter's syndrome - associated with abnormality of sex chromosomes, characterized by small testes and sterility; males only

Leukemia - cancer that starts in blood-forming tissue such as the bone marrow and causes large numbers of blood cells to be produced and enter the bloodstream

Leukocytes - all white blood cells

Leukocytosis - A total white blood cell counts greater than 10,000

Leukopenia - total white blood cell count less than 4,000

Lumbar puncture - diagnostic procedure that involves taking (spinal tap) and examining a sample of spinal fluid

Lymph - the clear fluid that travels through the lymphatic system and carries cells that help fight infections and other diseases. Also called lymphatic fluid

Lymph nodes - a rounded mass of lymphatic tissue that is surrounded by a capsule of connective tissue. Lymph glands filter lymph (lymphatic fluid), and they store lymphocytes (white blood cells). They are located along lymphatic vessels. Also called lymph node

Lymph node mapping - the use of dyes and radioactive substances to identify lymph nodes that may contain tumor cells. Also called lymphatic mapping

Lymphocyte - a type of white cell found in the blood.

Maintenance - **a** stage of a treatment protocol to eliminate any remaining disease. The last stage of treatment

Malignant - cancerous. Malignant tumors can invade and destroy nearby tissue and spread to other parts of the body

Marfan's syndrome - congenital disorder of connective tissue characterized by abnormal length of extremities and other deformities

Melanoma - a form of cancer that begins in melanocytes (cells that make the pigment melanin). It may begin in a mole (skin melanoma), but can also begin in other pigmented tissues, such as in the eye or in the intestines

Metastasis - the spread of cancer from its original site.

Monocyte - A type of white cell found in the blood.

Morbidity - the relative incidence of a particular disease; a diseased state

MRI (Magnetic Resonance Imagery) - is a diagnostic procedure utilizing a large

magnet, radio waves, and a computer to produce a three dimensional image

Multiple exostoses - benign bony growths projecting outward from the surface of the bone

Multiple polyposis - the development of multiple adenomatous polyps, lining the mucous membrane of the intestine and colon

Myotonic dystrophy - increased muscular irritability and contractility with decreased power of relaxation, which leads to atrophy of muscles, cataracts, and other problems

Neoplasm - An abnormal mass of tissue that results when cells divide more than they should or do not die when they should. Neoplasms may be benign (not cancerous), or malignant (cancerous). Also called tumor

Neuroblastoma - cancer that arises in immature nerve cells and affects mostly infants and children. Often begins in the nerve tissue of the adrenal glands

Neuroendocrine carcinoma (skin) - skin cancer that forms in neuroendocrine cells (cells that release hormones in response to signals from the nervous system (non-melanoma)

Neurofibromatosis - familial condition, characterized by the formation of multiple soft tumors of skin; also called von Recklinghausen's disease

Neutropenia - less than 1,000 neutrophils in the blood. The patient with fewer than 500 becomes more susceptible to infection

Neutrophil ("Poly") - *a* type of white blood cell, the most important in fighting bacterial infection

Nevoid basal cell carcinoma syndrome - multiple skin cancers

Non-Hodgkin lymphoma - any of a large group of cancers of the immune system. Non-Hodgkin lymphomas can occur at any age and are often marked by enlarged lymph nodes, fever, and weight loss. There are many different types of non-Hodgkin lymphomas which can be divided into aggressive (fast-growing) and indolent (slow-growing). Also called NHL

Osteogenic sarcoma - a cancer of the bone that usually affects the large bones of the arm or leg. It occurs most commonly in young people and affects more males than females. Also called osteosarcoma

Osteogenesis imperfects - bones are abnormally brittle and subject to fractures

Pancytopenia - a decrease in all types of cells in the blood

Petechia - tiny hemorrhages of the small blood vessels underneath the skin which indicate low platelets

Plasma - the liquid portion of the blood

Platelet – a particle in the blood that helps in blood clotting

Polycystic kidney disease - polycystic disease of the kidney disorder marked by cysts scattered throughout both kidneys

Polyposis Coi, juvenile polyposis coli, or Gardner's syndrome - multiple polyps of the small bowel and colon, often leads to cancer

Porta Cath - an implanted catheter placed under the skin with the same functions as a broviac catheter

Proband - the family member through whom a family's medical history comes to light. The proband may also be called the index case, propositus (if male), or proposita (if female). An individual affected with a disorder who is the first subject in a study (as of a genetic character in a family lineage)

Prognosis - a prediction of the course of disease; the future prospects for the patient

Prophylactic - treatment to prevent a complication or an illness before it occurs

Protocol - a plan of treatment for a specific disease

Pulmonary Fibrosis - Pulmonary Fibrosis involves scarring of the lung. Gradually, the air sacs of the lungs become replaced by fibrotic tissue. When the scar forms, the tissue becomes thicker causing an irreversible loss of the tissue's ability to transfer oxygen into the bloodstream.

Radiation - treatment using high energy radiation from x-ray machines, radium, or other sources.

Reinduction – to start over (e.g., new treatment or protocol)

Relapse - the reappearance of cancer after a disease-free period

Remission - when no disease can be detected in a patient

Retinoblastoma - cancer that forms in the tissues of the retina (the light-sensitive layers of nerve tissue at the back of the eye). Retinoblastoma usually occurs in children younger than 5 years. It may be hereditary or nonhereditary (sporadic).

Rhabdomyosarcoma - cancer that forms in the soft tissues in a type of muscle called striated muscle. Rhabdomyosarcoma can occur anywhere in the body

Sarcoma – a cancer of the bone, cartilage, fat, muscle, blood vessels, or other connective or supportive tissue

Sequelae - an abnormal condition resulting from a previous disease; A secondary consequence or result

Squamous cell carcinoma - Skin cancer that forms in squamous cells (flat cells that form the surface of the skin) (non-melanoma)

Stomatitis - swelling and sores in the mouth and lips

Therapy -treatment to eliminate a disease

Thrombocytopenia - a low platelet count that may result in abnormal bleeding

Tuberous Sclerosis - familial disease characterized by tumors of the brain and light spots on skin

Turner syndrome - associated with absence of second sex chromosome, characterized by short stature, and variable abnormalities; females only

Tumor - a mass or swelling, an overgrowth of tissue (see also Neoplasm)

Virus - a group of tiny organisms than can cause an illness which cannot be treated with antibiotics. Common viral infections are chicken pox, measles and mumps

von Hippel-Lindau disease - characterized by congenital angiomatosis (tumor of the blood vessels) of the retina and cerebellum

von Recklinghausen's disease (neurofibromatosis) - familial condition, characterized by the formation of multiple soft tumors of the skin

Wilms Tumor - a disease in which malignant (cancer) cells are found in the kidney, and may spread to the lungs, liver, or nearby lymph nodes. Wilms tumor usually occurs in children younger than 5 years old

Wiscott-Aldrich syndrome - an inherited immune deficiency characterized by chronic eczema, chronic suppurative otitii media, anemia and thrombocytopenia purpura; occurs in males only

Xeroderma Pigmentosum - disease in which skin and eyes are extremely sensitive to light

Revision Record Printed 7/16/2012 1:16 PM

Current Filename:		Medical and Cancer Terminology ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development

Missed Appointment Follow-up Email Tracking

Background

Unfortunately it is not uncommon for participants to miss appointments that were scheduled to complete phone based questionnaires. For this reason, a procedure was created for the SI to send a follow-up email to participants following the missed appointment. This procedure is outlined in the SOP document titled, Sending a Missed Appointment Follow-up Email. To ensure that the SI does not overlook this procedure, a tracking system was designed for use by the Lead Survey Interviewers.

Procedure

1. The LSI checks the calendar for any missed appointments from the previous day, notating the date and time of the appointment, the CCSSID number, the SIID number, and any reason indicated for the missed appointment

2. The LSI opens the Missed Appointment Follow-up Email Tracking Excel file, located in the LSI subfolder in the Interviewer's folder, and adds this information to the spreadsheet.

	A	B	C	D	E	F	G	H	I	J
1										
2	Missed Appointment Follow-up Email Tracking									
3	DATE	CCSSID	APPOINTMENT DATE	APPOINTMENT TIME	SI ID	REASON FOR MISSED APPOINTMENT?	Participant email address available?	Did SI send Follow-Up Email	Date Email Sent	LSI ID
4	7/8/2012	01262422	7/7/2012	10:30am	119	No answer				

3. The SI procedure outlined in the Sending a Missed Appointment Follow-up Email SOP includes copying the LSIs and Coordinator, when sending a follow-up email.
   a. If the LSI ***was*** copied on the email to the Participant, the LSI completes the Tracking form, and then saves and closes the form.

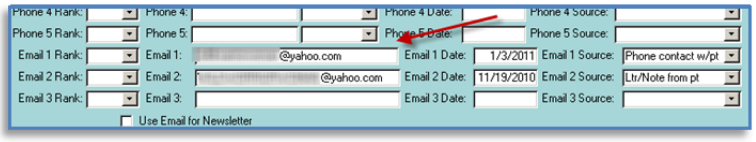
   b. If the LSI ***did not get*** an email to this regard, the LSI will then check the Participant Call Log to determine IF the SI sent a follow-up email to the Participant, and if so, complete the Tracking spreadsheet accordingly (selecting YES for Did SI Send Follow-Up Email), and send a reminder to the SI to always copy them and the Coordinator on emails to Participants.

	A	B	C	D	E	F	G	H	I	J
1										
2	Missed Appointment Follow-up Email Tracking									
3	DATE	CCSSID	APPOINTMENT DATE	APPOINTMENT TIME	SI ID	REASON FOR MISSED APPOINTMENT?	Participant email address available?	Did SI send Follow-Up Email	Date Email Sent	LSI ID
4	7/8/2012	01262422	7/7/2012	10:30am	119	No answer	Yes	Yes	7/7/2012	103
5										

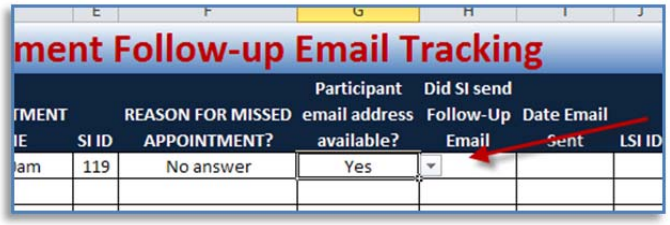
c. If the LSI ***cannot determine*** from the Participant Call Log IF a follow-up email was sent to the Participant, then the LSI will open the appropriate database or speak with the SI to determine IF the Participant has an email address in the system.

i. If there is no email address in the database, the LSI will send a reminder email to the SI to enter the CCSSID into their MS Outlook calendar a day or two in the future, (as outlined in SOP procedure, Call Center Appointment Calendar) as an electronic reminder to attempt to contact the participant in the next few days following the missed appointment. No further action is required on the part of the LSI.

ii. If there is an email address in the database for the Participant, the LSI will:



1. Enter a "Yes" in the Missed Appointment Follow-up Email Tracking spreadsheet, indicating that the Participant has an email address.



2. Send the SI an email to ask if they sent a follow-up email to the Participant, following the missed appointment.
   a. If the SI did send the email, the LSI will remind the SI to always copy them and the Coordinator on emails to Participants, and also enter a note in the Participant Call Log.
   b. If the SI did NOT send the email, the LSI will ask the SI to do so, copy them and the Coordinator, and update the Participant Call Log.
   c. Once the LSI receives confirmation that the email was sent, they will update the Tracking spreadsheet accordingly.

Revision Record

Printed 7/30/2012 4:05 PM

Current Filename:		Missed Appointment Follow-up Email Tracking ver 1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	7/10/12	D. Rinehart	Initial Development
1.1	7/27/12	Procedure Team	Content revisions

Monetary Incentive Journal

Background

Initial recruiting packets contain a two-dollar bill. We keep track of the disbursed and returned cash. Returned cash comes back when a packet containing a bill was returned to sender.

Procedure

Use the Excel file Monetary Incentive Journal (located on the server in z:\sjshare\sjcommon\ECC\CCSS\Expansion Recruiting).

Record disbursements and receipts on the tab CashIN-OUT register. This register provides a cash on hand balance by subtracting disbursements and adding back any returns to the current balance. It also displays for how many packets we have money available. When we run low on cash, we need to request a check and order the $2 from the credit union. (The top of the form documents those transactions.)

For disbursements:

- Key in the **Date** and a **description** on the next available line. The description should identify who the money was given to, and which batches it relates to.
- In the **Amount** column, enter the formula -2* the number of bills you disbursed. (E.g., see ref 467: you gave out 14 bills, so key in -2*14). The answer will compute as a negative number (in this example, it will display $(28)
- Then "copy down" the formulas for **Balance**, **init**, and **Enough left for # pkgs**. (If you are not "jb", then replace jb with your initials.

For receipts (money returned to us)

- Key in the **Date** and a **description** on the next available line. A simple description will do
- In the **Amount** column, enter the actual CASH AMOUNT you received. It will display as a positive number
- Then "copy down" the formulas for **Balance**, **init**, and **Enough left for # pkgs**. (If you are not "jb", then replace jb with your initials.

$2 per recruitment package

PURCHASES

	PURCHASE DATE	Amount	Cumulative	Covers
	10/21/2009	$ 1,600	$ 1,600	800
	2/1/2010	$ 4,000	$ 5,600	2,800
2/25/2010	picked up 2,000 bills ($4,000)-ordered 2/19/10	$ 4,000	$ 9,600	4,800
3/26/2010	picked up $4,000 (ordered 3/12)	$ 4,000	$ 13,600	6,800
8/12/2010	check for $4,000 rec'd from Abbe; (request was for $2000)	$ 4,000	$ 17,600	8,800
11/11/2010	Check request for $4,000		$ 17,600	8,800
12/10/2010	picked up $4,000 /ajm	$ 4,000	$ 21,600	10,800
1/26/2011	ORDERED 1,000 bills ($2,000); paying with $150 worn plus ck		$ 21,600	10,800
2/3/2011	returned 75 worn bills	$ (300)	$ 21,300	10,650
2/3/2011	Picked up $2,000	$ 2,000	$ 23,300	11,650

EXPENDITURES

Ref#	Date	Description	Amount	Balance	init	Enough left for # pkgs
465	4/26/2011	ret mail	$ 6	$ 3,267	jb	1,634
466	5/5/2011	ret mail-CNMC	$ 60	$ 3,327	jb	1,664
467	5/6/2011	James rec resend batches 10,11,12,13,14,15,17	$ (28)	$ 3,299	jb	1,650
468	5/6/2011	Lynn rec resend batch 3	$ (100)	$ 3,199	jb	1,600
469	5/9/2011	Twanna rec resend batch 4, 5	$ (14)	$ 3,185	jb	1,593
470	5/9/2011	Bonner rec resend batch 1 7 8	$ (16)	$ 3,169	jb	1,585
471	5/10/2011	ret to sender UCLA	$ 4	$ 3,173	jb	1,587
472						
473						
474						

To record the purchase of additional funds

- On the next available line, enter the date with the amount purchased.
- In the amount column, enter the dollar amount.
- Copy down the right-most 3 columns.
- To make purchases easy to spot, color code the purchase line (I have used GREEN).

11		12/10/2010	picked up $4,000 /ajm	$ 4,000	$ 21,600	10,800	
12		1/26/2011	ORDERED 1,000 bills ($2,000); paying with $150 worn plus ck		$ 21,600	10,800	
13		2/3/2011	returned 75 worn bills	$ (300)	$ 21,300	10,650	
14		2/3/2011	Picked up $2,000	$ 2,000	$ 23,300	11,650	
15							
16							
17		EXPENDITURES					
18	Ref#	**Date**	**Description**	**Amount**	**Balance**	**init**	**Enough left for # pkgs**
348	330	12/9/2010	Requested resends-Cheryl	$ (34)	$ 2,640	jb	1,320
349	331	12/10/2010	Purchased $4000	$ 4,000	$ 6,640	ajm	3,320
350	332	12/13/2010	UCLA-Davida minors	$ (28)	$ 6,612	jb	3,306

RECONCILING the register to the cash drawer

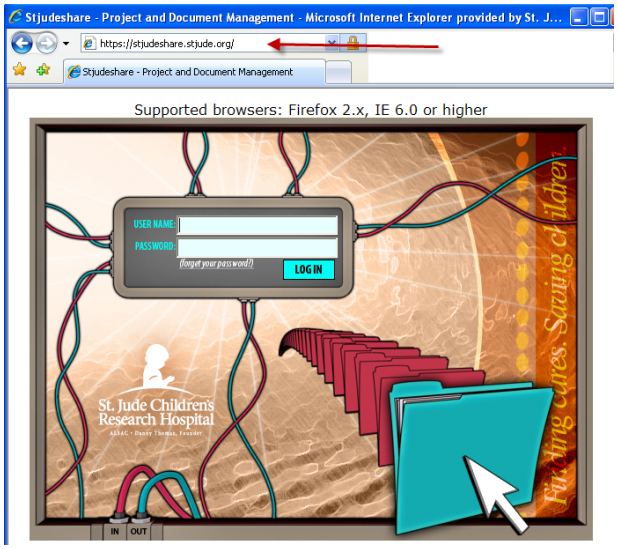
- We must periodically reconcile the register to the actual amount of cash on hand. Count the money in the safe. If they balance, enter a memo (see line 311 for an example).
- If they do not balance, then research to locate the source of the discrepancies. Backtrack through the recruitment production schedules to locate batches that may not have been recorded.
- Make adjusting entries if needed. (See lines 364-365 for an example. Lines 191 and 192 show entries identifying batches that had not been entered.)

Revision Record
Printed 7/10/2012 2:20 PM

Current Filename:		Monetary Incentive Journal ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/10/11	J.Bates	Initial Development

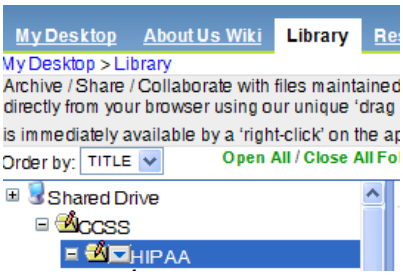
Monthly LTFU Recruitment Updates—*Information for Data Managers*

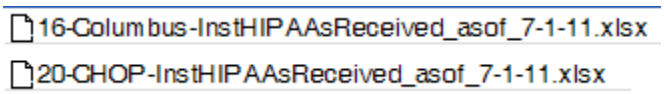
Background



Each month the LTFU Coordinating Center generates a cumulative list of individuals we recruited for each institution. We post the lists to the St. Jude share site (https://stjudeshare.stjude.org/). Each data manager has a username and password to log into the St. Jude Share site.

Data managers download their own list each month. Find the file on the Library tab, in your CCSS\HIPAA folder. The Excel file will be named "instHIPAAs Received_asof_m-d-yy." You will only see the file for **YOUR** institution. Save the file on your own computer/network.





The file contains protected health information (e.g., name, date of birth) to make it easier for data managers to identify cases. The excel file shows, for each recruited case, the following:

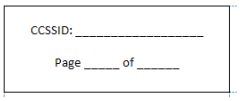
- INSTCOD
- OUTCOMEDATE (the date we received the inst HIPAA)
- DATEINSTMRSIGNED (date the individual or LAR wrote as signature date for your HIPAA medical release or online submit date/time)
- INELIGIBLE (true= not eligible)
- CCSSID
- HOSPNUM
- INSMRSTATUS (1=Recruited)
- INSTMRSOURCE (1=online, 2=paper)
- PTFIRST, PTMID, PTLAST
- DXCODE
- BIRTHDATE
- ALIVE (1=alive; 2=deceased)
- DEATHDATE

What do you do with this information?

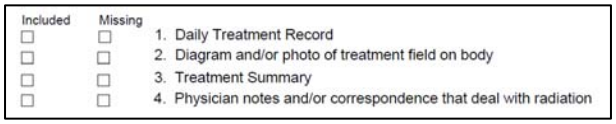
1. Review the list to identify the *new* recruits. The list comes to you sorted with the MOST RECENT "outcomedate" at the top. These are the HIPAAs we've most recently received. The list is cumulative, so it does include ALL recruits.

2. Locate the photocopied surgery and radiotherapy records for cases you have not already sent to us. Most data managers prepare the photocopies of medical records while they are submitting their MRAF entries. NOTE: if a case is INELIGIBLE ("TRUE" in the ineligible column), you do NOT need to send photocopies.

3. Verify that photocopies for each case are properly prepared and include a completed checklist:
   a. CHECKLIST
      i. Attach completed **checklist** to the photocopies for the case with a paper clip or binder clip. See the Procedure Manual for Data Managers for more information on checklist preparation.
      ii. Keep surgery and radiotherapy packets separate. (Do not clip survey and radiotherapy records for the same case together.)
   b. **Number** the pages, using "Page x of Total#". The Checklist is always page 1.
   c. Mark each photocopied page with both the **Page x of Total** AND the **CCSSID**. (Many data managers print labels with the CCSSID and blanks to fill in for page numbering. If you use this method, take care to place label on a blank part of the page.)



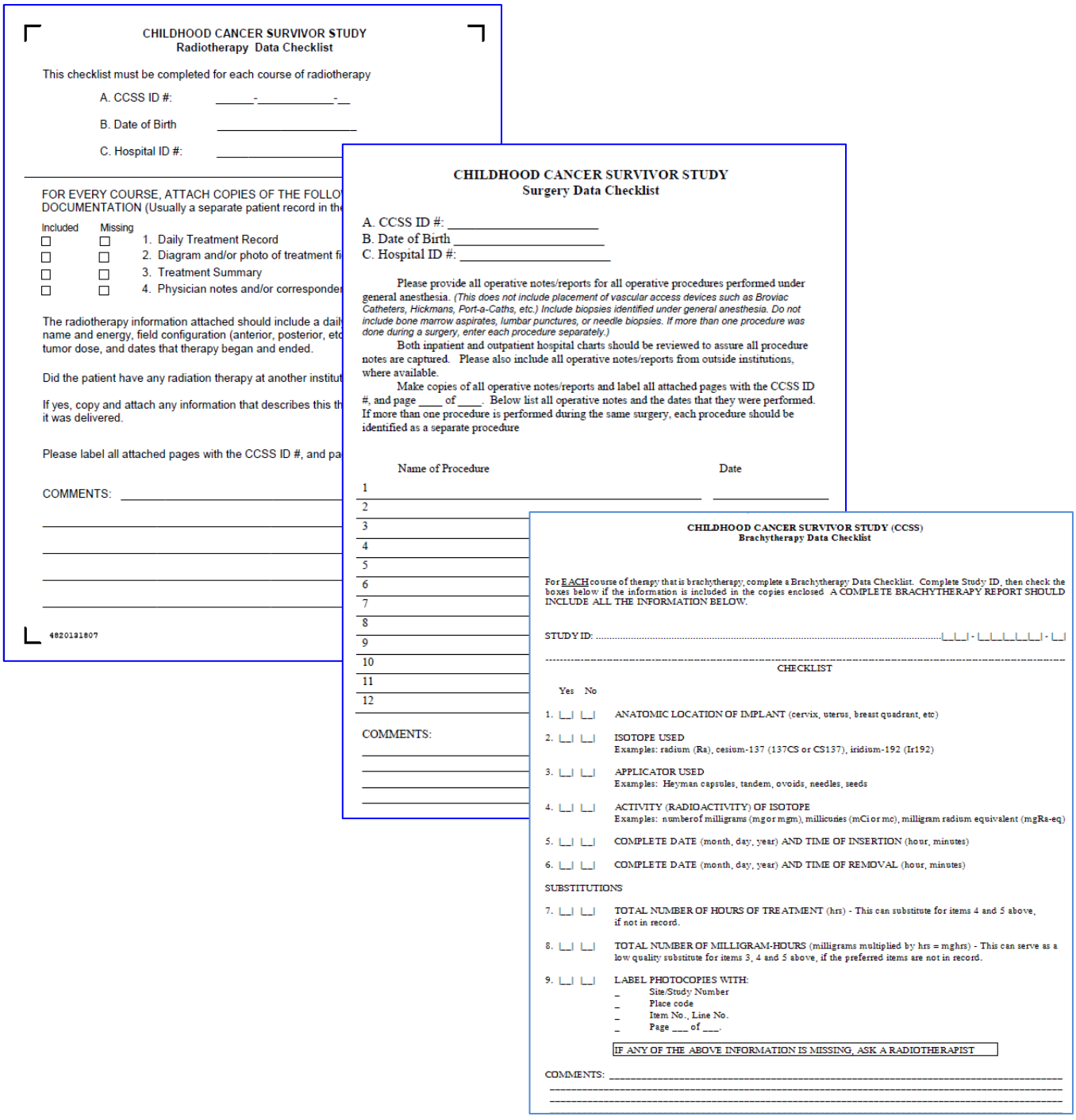
   d. **De-identify protected health information** (notably names and social security numbers) before you send the copies to us, to adhere to HIPAA regulations.
   e. Use **COMMENTS** area to add additional information you believe appropriate. For example:
      i. If you are sending more than one set of surgery (or radiotherapy) records for a case, indicate "set x of y" in the comments.
      ii. If there was treatment at an outside institution, and you have requested but not yet received those records, indicate this in the comments. When you do receive the records, send them with a new checklist.
      iii. If a case received surgery but no radiotherapy, you can make that note in the Comments section of the surgery checklist (and vice versa: if radiotherapy but no surgery, add the note on the radiotherapy checklist).
   f. For **Radiotheraphy/brachytherapy** packets:
      i. **Use ONLY black ink** to label the pages with the CCSSID and page number.
      ii. **Radiotherapy records** should include 4 different types of documents, as listed on the checklist. Be sure to check EITHER "included" OR "missing", to clearly indicate what is (or is not) included in the packet.



4. Send (mail or FedEx) photocopied records (surgery, radiotherapy and brachytherapy) for individuals on the list to

   Jerry Bates/Lynn Harrison
   Epidemiology and Cancer Control
   St. Jude Children's Research Hospital
   262 Danny Thomas Place, Mail Stop 735
   Memphis TN 38105-2794

5. Be sure to keep a list of the CCSSIDs whose photocopies you have sent. We also recommend that you maintain your own photocopy of the records, especially if requesting medical records incurs a charge to your department!



CHILDHOOD CANCER SURVIVOR STUDY
Radiotherapy Data Checklist

This checklist must be completed for each course of radiotherapy

A. CCSS ID #: _____-_____-__

B. Date of Birth _____

C. Hospital ID #: _____

FOR EVERY COURSE, ATTACH COPIES OF THE FOLLO
DOCUMENTATION (Usually a separate patient record in th

Included	Missing	
☐	☐	1. Daily Treatment Record
☐	☐	2. Diagram and/or photo of treatment fi
☐	☐	3. Treatment Summary
☐	☐	4. Physician notes and/or correspondet

The radiotherapy information attached should include a dail
name and energy, field configuration (anterior, posterior, etc
tumor dose, and dates that therapy began and ended.

Did the patient have any radiation therapy at another institut

If yes, copy and attach any information that describes this th
it was delivered.

Please label all attached pages with the CCSS ID #, and pa

COMMENTS: _____

4820121807

CHILDHOOD CANCER SURVIVOR STUDY
Surgery Data Checklist

A. CCSS ID #: _____
B. Date of Birth _____
C. Hospital ID #: _____

Please provide all operative notes/reports for all operative procedures performed under general anesthesia. *(This does not include placement of vascular access devices such as Broviac Catheters, Hickmans, Port-a-Caths, etc.) Include biopsies identified under general anesthesia. Do not include bone marrow aspirates, lumbar punctures, or needle biopsies. If more than one procedure was done during a surgery, enter each procedure separately.)*

Both inpatient and outpatient hospital charts should be reviewed to assure all procedure notes are captured. Please also include all operative notes/reports from outside institutions, where available.

Make copies of all operative notes/reports and label all attached pages with the CCSS ID #, and page ____ of ____. Below list all operative notes and the dates that they were performed. If more than one procedure is performed during the same surgery, each procedure should be identified as a separate procedure

	Name of Procedure	Date
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		

COMMENTS:

CHILDHOOD CANCER SURVIVOR STUDY (CCSS)
Brachytherapy Data Checklist

For EACH course of therapy that is brachytherapy, complete a Brachytherapy Data Checklist. Complete Study ID, then check the boxes below if the information is included in the copies enclosed. A COMPLETE BRACHYTHERAPY REPORT SHOULD INCLUDE ALL THE INFORMATION BELOW.

STUDY ID: .....|__|__| - |__|__|__|__|__|__| - |__|

CHECKLIST

Yes No

1. |__| |__| ANATOMIC LOCATION OF IMPLANT (cervix, uterus, breast quadrant, etc)
2. |__| |__| ISOTOPE USED
Examples: radium (Ra), cesium-137 (137CS or CS137), iridium-192 (Ir192)
3. |__| |__| APPLICATOR USED
Examples: Heyman capsules, tandem, ovoids, needles, seeds
4. |__| |__| ACTIVITY (RADIOACTIVITY) OF ISOTOPE
Examples: numberof milligrams (mgor mgm), millicuries (mCi or mc), milligram radium equivalent (mgRa-eq)
5. |__| |__| COMPLETE DATE (month, day, year) AND TIME OF INSERTION (hour, minutes)
6. |__| |__| COMPLETE DATE (month, day, year) AND TIME OF REMOVAL (hour, minutes)

SUBSTITUTIONS

7. |__| |__| TOTAL NUMBER OF HOURS OF TREATMENT (hrs) - This can substitute for items 4 and 5 above, if not in record.
8. |__| |__| TOTAL NUMBER OF MILLIGRAM-HOURS (milligrams multiplied by hrs = mghrs) - This can serve as a low quality substitute for items 3, 4 and 5 above, if the preferred items are not in record.
9. |__| |__| LABEL PHOTOCOPIES WITH:
_ Site/Study Number
_ Place code
_ Item No., Line No.
_ Page ___ of ___.

IF ANY OF THE ABOVE INFORMATION IS MISSING, ASK A RADIOTHERAPIST

COMMENTS: _____

Revision Record Printed 7/6/2012 10:57 AM

Current Filename:		Monthly LTFU Recruitment Updates-Information for Data Managers v5.doc	
Revision No.	Date	Responsible Author	Change Description
4	6/30/11	J. Bates	Minor formatting
5	7/21/11	J.Bates	Major reorganization

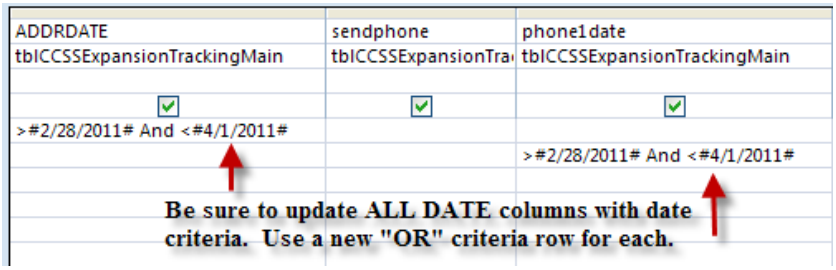
Monthly Updates to Cancer Center

Background

We send monthly updates to the St. Jude Cancer Center to inform them of changes to the contact information we have obtained for St. Jude CCSS participants. There is a query called ***QryCancerCenterUpdate15_Step1*** in both the Reg and Expansion databases that is used to obtain the needed information.

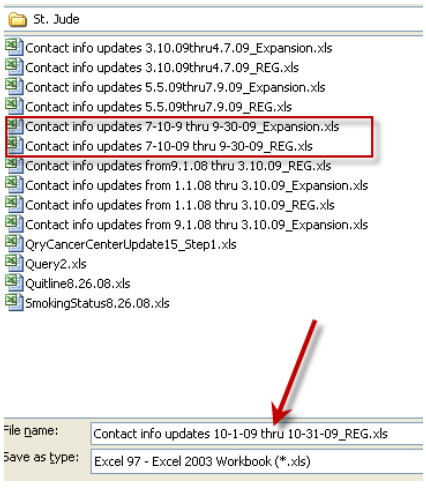
Procedure

1. Open the REG (original cohort) database.
2. Click once on the query called ***QryCancerCenterUpdate15_Step1***.
3. Open the query in design view and update the date range (based on the last date information was sent). *Be sure to change the dates on ALL the date fields in the query (phonedate, sendphone2date, sendphone3date, addrdate, emaildate, email2date), each on a new "or" line in the query design view).* This will give you a list of anyone who has had an update to *any* contact field within the specified date range.



   a. Hint: tab to the first date column showing the criteria left over from the last time the query was run. Change the dates inside the pound signs. Then copy the criteria, tab to the next date column, arrow down to the cell with the criteria, and paste the copied criteria. Continue until you have put the new criteria in each of the date columns. You will be updating 6 date fields.
   b. 10/1/09: the queries have been updated so that ONLY instcod=15 (St Jude) are included.

4. Save the query as an Excel file (Tools-> Office links ->Analyze it with Microsoft Office Excel). Save the file in the *folder* …\ECC\CCSS\CCSS Site Request\St. Jude. This is where past updates are stored.
   a. In the file name, identify the database (by adding "_REG" or "_Expansion:) to the end of the file name.
   b. Also add the from/thru dates (mm-dd-yy) to the file name
   c. E.g.,
      i. "*Contact info updates from 07-10-09 thru 09-30-09_REG*"
      ii. "*Contact info updates from 07-10-09 thru 09-30-09_Expansion*"



5. Now open the Excel file
    a. *(File will only have Instcod of "15" (St. Jude), as of the 10/1/09 update to the query. So it is no longer necessary to* sort and delete cases that are not "15" which was the manual way in Excel to limit the data to only include those who have updated contact info who are from St. Jude.)

    b. Sort by shareCCSS and delete anyone with a 2 in shareCCSS. These are the people who will not allow us to share their information with their treating institution.

    c. Making the "alive" codes clear (Tip: use Excel's find/replace function for each of these.)
        i. EXPIRED:
            1. Change the 2's in the alive column to the word "EXPIRED" so that they know the patient has died.
        ii. ALIVE
            1. In REG, change the 1's in the alive column to "Alive."
            2. In Expansion, change the blanks in the alive column to "Alive."

    d. Delete the columns for shareCCSS, instcode , addresscode, and outcome as the Cancer Center does not need those.

6. Now **Repeat this process** with the other database (e.g., Expansion)

7. Once you have the files compiled of updates, send them to Jeana Cromer in the Cancer Center at Jeana.Cromer@stjude.org. Also include Kerry Wilson (Kerry.Wilson@stjude.org).

Revision Record Printed 7/10/2012 1:19 PM

Current Filename		Monthly Updates to Cancer Center ver 1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/25/09	J. Lanctot	Initial Development
1.1	10/1/09	J. Bates	Minor detail elaboration; noted qry modification to include only instcod 15's
1.2	12/1/09	J.Bates	Add Kerry Wilson to distribution list
1.3	4/12/11	J.Bates	Specificity
1.4	5/3/11	J.Bates	Delete addresscode before sending

MRAF - Updates to Data Managers

Background

Data managers are responsible for providing us photocopies of surgery and radiotherapy/brachytherapy records for patients recruited to the LTFU study. We review the records as we receive them, and record the receipt in the MRAF portion of our database. Periodically we provide each institution's data manager with a comprehensive list of the cases from that institution.

It is possible that we have Surgery without RT, and vice versa. It should be noted that notes are not always available. If there is NOTHING given for a record, then we have not received anything.

Data managers will be asked to check their records, to see what records we still need, and identify any discrepancies between their and our records.

Procedure

For each institution (except 05)

1. In Expansion Tracking database, open **qry_JBx_Sgy_RT_photocpies_Received_Status_ALL** in design view.
2. Set the value for InstCod.
3. Save the query design
4. Export file to Excel.
   a. Name file with **InstCod-InstName- _Sgy_RT_photocopies_Received_Status _ALL**
   b. Save in **z:\SJShare\SJCOMMON\ECC\CCSS\MRAF\InstitutionLists-PhotocopiesReceived** , in a folder dated according to the date you ran the report.
5. Send an encrypted email to the data manager (sample text below)
6. Run SPECIAL query for DanaFarber: **qry_JBx JBx_Sgy_RT_photocpies _received_Status_DanaFarber**. This includes expbasemrStat. We must provide scanned HIPAAs to DF before they can send records.

Email sample:

Your bi-monthly Surgery/RT photocopy status list is attached to this email.

This list is provided as a double-check for you.

- Compare it to your record of photocopies you have already sent.
- Use it to identify cases you still need to send to us.

The file has the following layout. (PtFirst and PTLast are also included.)

COL A	COL B	COL C	COL D	COL E	**COL F**	COL G	COL H	**COL I**	COL J	COL K
INST COD	ccssid	HOSP NUM	PTFirst	PTLast	**RT_ records**	RT_Date Received	RT_ notes	**Sgy_ records**	Sgy_Date Received	Sgy_ notes
##	#######	####			Yes/**No/ Incomplete,**	Mm/dd/yy		Yes/**No/ Incomplete/ Not**	Mm/dd/yy	

	#				**Pending/ Incomplete, Final/ blank**			**Available/ blank**		

For Column F:

Yes = RT file has been received and thus far MD Anderson has not asked for more information
No = there was no radiation therapy for this participant
Incomplete, Pending = the file is incomplete and we have requested more information/better copies, etc.
Incomplete, Final = the file is missing information but all information has been sent; no further information will be forthcoming
Blank = we have not received a file or notification that the participant did not have radiation

For Column I:

Yes = A surgery file has been received
No = the participant did hot have surgery related to their initial diagnosis
Not Available = attempts were made to locate a surgery file, but there is no operative information available
Thank you again for your hard work in the data collection process.

The document **Monthly Recruitment Updates-Information for Data Managers** (intended for data managers) outlines the structure of the uploaded file, indicates where to send the photocopies, and provides notes on how to prepare the photocopies. This document is available in the procedure library.

Revision Record Last Printed: 7/2/2015 10:15 AM

[39]Current Filename:		MRAF Updates to data managers ver 1_7.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/4/10	J. Bates	Initial Development
1.1	11/12/10	J.Bates	New query; sample language
1.2	12/1/10	J.Bates	DanaFarber handling; email language
1.3	5/12/11	J.Bates	Alter email language
1.4	6/20/11	J.Bates	Refer to separate DM doc
1.5	7/27/11	J.Bates	Update qry names; storage location
1.6	5/30/12	J.Bates	Update list of insts being recruited
1.7	7/30/12	J.Bates	Fix typos; reference SOP library
2.0	7/2/2015	L.Harrison	Change method of transmission from Sharesite to encrypted email; revise sample email

MRAF Institution Monthly Update Totals

Background

At the first of each month, data managers from each participating institution email a report to update the Coordinating Center regarding MRAF completion progress. The reports are saved to the server and also used to update running totals in a master spreadsheet. An email reminder is used to notify data managers who have not submitted their monthly updates.

*Note - To create a new monthly spreadsheet, follow steps 1-8. To enter the information for an institution, start at step 9.

1. Open the spreadsheet called Institution Update MRAF Total that is saved in the following path: …\ECC\CCSS\MRAF\Totals worksheet by site
2. Create a new worksheet
    a. Insert/Worksheet
3. Copy last month's spreadsheet (click on upper left hand corner to highlight the worksheet)
4. Paste into the new worksheet that you created
5. Rename the worksheet (the Worksheet should currently be named Worksheet 1)
    a. Right click on the bottom worksheet tab
    b. Choose Rename
    c. Rename as MRAF (Month) Totals
6. Change the Month (and year if needed) in cell B1
7. Remove the Green from the institution names. Leave the blue (see note below).
8. Remove last months comments (Column W)
9. Enter the new information in each cell for each institution based on the monthly report they have sent.
    a. If an institution has completed 100% of their MRAF's, then leave the numbers the same (that institution usually will not send a monthly report after they reach 100%); the fill color in the institution name should be blue if at 100%
    b. Change the fill color to green for the institutions that are updated.

BLUE = 100%	GREEN = received	RED = do not contact	WHITE = report not yet received

10. *Note:* We do not do anything with the "Ineligible Participants" information. Instead, the data manager is supposed to contact Rich Pender to convey this information.
11. Go to the Log worksheet (2nd to last in the list)
    a. Put an X to denote if you received the monthly report from an institution
12. Look at the names and contact information listed for the Data Managers. Compare this with the information on the Data Mgrs worksheet AND the Data Manager spreadsheet saved at …:\ECC\CCSS\Addresses & Names
    a. Make updates as needed
13. After all of the information has been entered, save the original monthly report (usually a Word file sent from the institution) to the server: …\ECC\CCSS\MRAF\Totals worksheet by site\(Month)

Notes

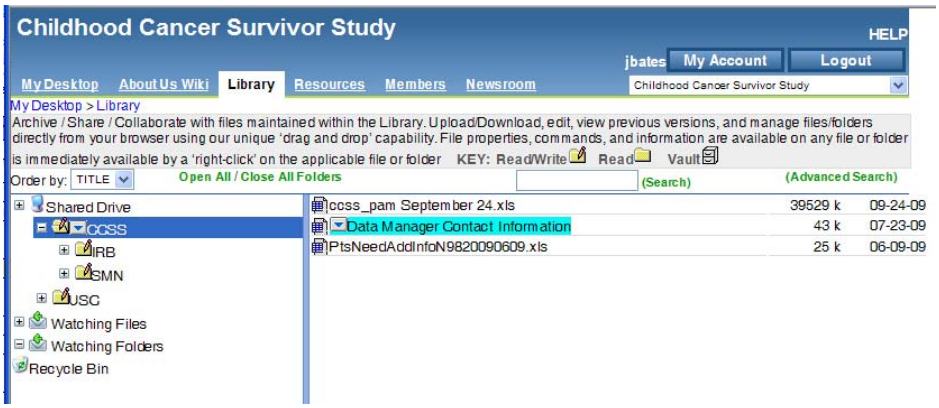
1. Institution Name cell is green for those that have sent a report; and blue for those at or above 100%. Those with no color need to send their monthly report (the numbers will not be current because they have been copied and pasted from a previous month).
2. The column headers are "frozen" (e.g., Window/Freeze Panes). You may have to scroll up or down to find an institution name.

Monthly email reminders to data managers

On the fifth of the month, send an email to data managers from whom we have not yet received a needed MRAF update. (Remember that those who have completed the process no longer need to send the updates. Similarly, those color coded "red" will not receive a monthly reminder.)

The shared master list of email addresses for data managers (which data managers may update) is located on the St. Jude share site. To access it:

- Log into the St. Jude share site located at https://stjudeshare.stjude.org/.
- Select the Library tab.
- In Library, select the CCSS folder.
- You will see an Excel file named Data Manager Contact Information.xls



This is the same file you update, should any data manager send new contact information as part of the monthly update process. (You may add the file to the "Watching Files" so that you will be auto-notified when anything is changed in the file.)

Revision Record

Printed 7/6/2012 10:45 AM

Current Filename:		MRAF Institution Monthly Update Totals ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/1/09	A. McDonald	Initial Development/Refinement for manual
1.1	10/1/09	J. Bates	Ineligible participants; monthly reminder email.

myLTFU and Follow-Up 7 Survey Non-Responder Calls

Background

A new, mobile-friendly web portal called **myLTFU** is now available for Long-Term Follow-Up (LTFU) Study childhood cancer survivors (case participants) and the sibling cohort (sibling participants) that can be accessed anywhere an internet connection is available, from a smartphone, tablet, or PC. From the **myLTFU** portal, the participant can:

- Complete follow-up surveys online
- Access a comprehensive list of study resources
- Learn about new studies they are eligible for

The goal of the Survey Interviewer (SI) is to:

- ✓ Invite the participant to use the new **myLTFU study portal** to complete the Follow-Up 7 (FU7) survey
- ✓ Answer questions
- ✓ Assist the participants with portal activation and
- ✓ Help the participant complete the Follow-Up 7 survey via phone interview or reminders calls

Incentives

1. Smartwatch drawing and post-Follow-Up 7 survey $10 gift card
    - From the first invite sent to the participant through the first paper survey mailing, the participant will receive an online $10 gift card at Follow-Up 7 survey completion and automatic entry into a drawing to win a Smartwatch.
2. Second paper Follow-Up 7 survey mailing, $10 cash
    - The second Follow-Up 7 survey mailing includes a $10 bill attached to the survey. Once the second paper survey has been mailed, the participant is no longer eligible for the Smartwatch drawing.

Tools Needed (*See Appendix for Locations*):

1. **Databases:**
    i. **CCSS SI LTFU Assignments**
    ii. **CCSS LTFU Participants Database**
    iii. **CCSS Follow-Up Survey Tracking Database**
    iv. **LTFU Datstat portal**
2. **Standard Operating Procedures (SOPs)**
    i. Reconsenting During Follow-Up 7 Survey Calls
    ii. **CCSS LTFU Participant Database Data Entry**
    iii. **Call Center Appointment Calendar**
    iv. **Emailing Follow-Up 7 Survey Links**
3. **Guidance Documents, Forms, and Templates**
    i. Pre-Post Call Checklist – Follow-Up 7 Survey Calls
    ii. **Follow-Up 7 Survey (paper copies)**
    iii. **Expired Participant Information Sheet**
    iv. **myLTFU_FU7 Invite Email Template_SI.docx**

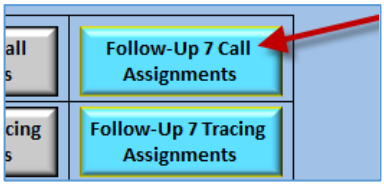
v. **myLTFU_FU7 Invite Email Template_SI_No Incentive.docx**
vi. **myLTFU_Temporary Password Email Template_SI ajm**
vii. **myLTFU_Temp_Password_Email_Reset_No_Incentive.docx**
viii. **Post Activation FU7 Email Template_No Incentive.docx**

4. **Scripts:**
   i. **Outgoing Call Script, FU7 Survey Non-Responders**
   ii. **Age of Majority Reconsent Script jf**
   iii. **LTFU Study Age of Majority Reconsent Form_r1am**

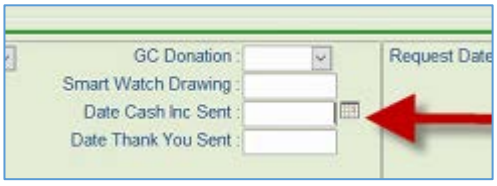
Procedures

PRE-CALL PROCEDURES

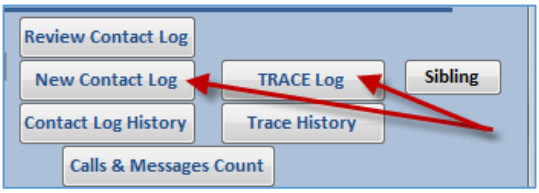
1. Open the databases listed in the "**Tools Needed**" section.
2. Open the list of non-responders to call. In the database, **CCSS SI LTFU Assignments**:
   A. Click on the **Follow-Up 7 Call Assignments** button.
   B. At the **SI ID:** prompt, enter your ID and click the **OK** button.
   C. The assignments display. The first participant to call will display at the top of the list, based on the date of the last FU7 call.



3. Locate the first assigned participant in the **CCSS LTFU Participant Database** :
   A. Using the **Pre-Post Call Checklist – Follow-Up 7 Survey Calls**, review all appropriate fields in the database to build a *pre-call profile* of the participant.
   B. Review the **Age of Majority** fields on the **HIPAA-PARTICIPATION HISTORY** tab to determine if the participant will need to be reconsented before activating the myLTFU portal or completing the Follow-Up 7 survey. (See the SOP titled **Reconsenting During Follow-Up 7 Survey Calls** for more information.)
4. Review any previous call history: Click on the **Review Contact Log** button or the **Contact Log History** button.
5. Review all **Notes:**
   A. Participant tab
   B. Associates tab
   C. HIPAA – Participation History tab
   D. App-Text Tab – Review the **DatStat Connect** fields to see if participant has already been activated by an SI.
6. Locate the participant in the **CCSS Follow-Up Survey Tracking Database**.
   A. In FU7 Tracking tab – Check **Opened Invite Email**, **Clicked Invite Email**, and **Notes** fields for any updates.
   B. Check the **Date Case Inc Sent** field to see if the participant has been mailed the survey packet that included the $10. NOTE: Do not mention the incentive during the call. If the participant affirms that they never received the packet, send an email to the Research Scientist for consideration of a packet resend with incentive.



7. Click the **Calls & Messages Count** button to see the number of calls and messages previously recorded in the CCSS LTFU Participant Database for each telephone number in the past 60 days.
8. Document each call:
   A. If calling a previously confirmed number:
      i. Click on the **New Contact Log** button in the header of the participant's record.
      ii. Populate the **Contact Mode** field with "1. Phone".
      iii. Populate the **Phone** field with the telephone number being dialed.



   B. If calling an unconfirmed number from Tracing:
      i. Click on the **Trace Log** button, then on the **New Record** button.
      ii. Populate the **Contact Mode** field with "1. Phone".
      iii. Populate the **Phone** field with the telephone number being dialed.

DURING THE CALL PROCEDURES - General

1. Verify the identity of the person to whom you are speaking using standard procedures (name, DOB, etc.). Do NOT provide protected information to anyone other than the participant (case or sibling) or his/her legally authorized representative (LAR).
2. Follow the **Outgoing Call Script, FU7 Survey Non-Responders**, located at *Z:\...\Interviewers\FU7\Scripts*.
3. If the participant **refuses** to complete the FU7 survey:
   A. Clarify if the participant is refusing only FU7 or refusing all further participation in the LTFU Study.
   B. Try to capture a reason for the refusal. If the participant's concerns can be addressed, do so. Offer a hold if more appropriate.
4. If the participant indicates s/he has **already returned the FU7 survey**:
   A. Ask the method of return (online vs. hardcopy).
   B. Ask the approximate date of return.
      i. If a paper copy was returned more than one month ago, it may be lost in the mail. Offer to complete the survey over the telephone to avoid further losses.
      ii. If a paper copy was returned less than one month ago, it may still be in route. Thank the participant for their involvement and advise that the study team will follow up if the survey is not received.
      iii. If an online survey was returned before today but the **Date Survey Received** field is blank, we did not receive the survey. EXCEPTION: Surveys completed on Friday, Saturday, or Sunday will have the **Date Survey Received** field populated the following Monday.
         a. Confirm the participant is referring to the LTFU Study's FU7 survey. The participant could be thinking of another study in which s/he participates.
         b. Try logging in to the online survey to determine the survey status. It may be that the participant neglected to click the **Submit** button.

iv. If an online survey was returned today, the **Date Survey Received** field will be populated on the next business day (Monday through Friday). Thank the participant for his/her involvement and advise that the study team will follow up if the survey is not received.

C. Confirm all contact information (address, phone numbers, email address, additional contacts).

5. If we learn the participant is now **incarcerated**:
   A. Attempt to obtain the anticipated release date. (In a few months? Several years?)
   B. If the participant is expected to be available again in a reasonable period of time, ask what the best number will be to reach him/her when s/he is released.
6. If we learn that the case or sibling is now **deceased**:
   A. Offer condolences.
   B. Complete the **Expired Participant Information Sheet** with as much information as the party is able/willing to provide.
   C. Obtain contact information for an appropriate proxy.
   D. Thank the party for providing the information.
   E. NOTE: There is not a FU7 survey for deceased participants. Do not pursue a FU7 survey with the proxy.
7. If we learn that the participant has a legally authorized representative (**LAR**) or proxy (See a member of the LSI team or the Coordinator for assistance determining an authorized proxy for a non-deceased adult participant.):
   A. Gather the name(s) and contact information for the LAR(s)/proxy.
   B. Determine if the participant has a disability and if the participant is able to legally represent himself or herself (e.g. Mother is a legal representative due to participant's hearing disability, but the participant is a cognitively able adult).
8. If the participant prefers to do the FU7 survey in **Spanish**, non-Spanish-speaking SIs should refer the participant to a Spanish-speaking SI. If there is not a Spanish-speaking SI available:
   A. Whenever possible, the non-Spanish-speaking SI should attempt to secure a survey appointment with the participant at a time when a Spanish-speaking SI will be available. It may be best to take a message and allow the Spanish Speaking SI to call back instead of making the appointment for the Spanish-speaking SI.
   B. Non-Spanish-speaking SIs can refer to the document titled **Basic Spanish Words**, located at *Z:\...\Interviewers\Spanish*.
9. If the participant wants to **complete the survey on the telephone**, proceed to the section of this document titled *DURING THE CALL PROCEDURES – Completing the FU7 Survey*.

DURING THE CALL PROCEDURES – Completing the FU7 Survey

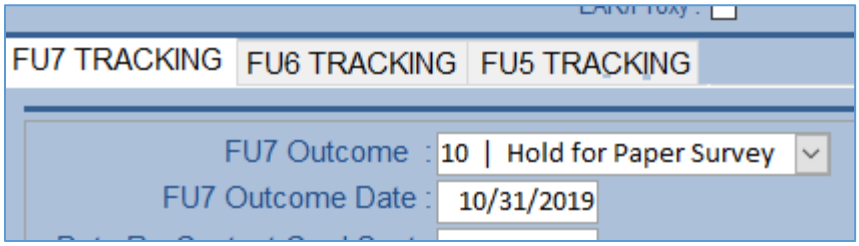
1. Activate the participant's account for them. (*Note: If the participant's myLTFU account is already activated, proceed to the next step*).
   A. Open the webpage, **https://ltfu.stjude.org/myltfu.html**.
   B. Click the **Activate myLTFU** button on this page.
   C. Activate the pt's account by entering their **DOB** and **personalized key code** (*Password, LTFU Pt db*).

D. Create their account by entering their email address and creating the temporary password, "**LTFU1234**" (*use all caps*).
E. Click the **I am not a robot** box.
F. Click **Activate**.

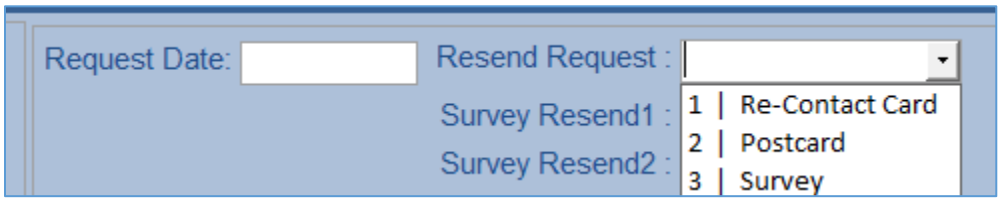
2. Access the Follow-Up 7 survey:
   A. Open the webpage, **https://ltfu.stjude.org/myltfu.html**.
   B. At bottom of webpage, click on "Log in" which will take you to myLTFU homepage.
   C. On "**myLTFU**" home page click on right top "**Log In**".
   D. Type in participant's email address and password.
   E. Click on "**Follow-Up Survey**".

3. Complete Survey over the phone with participant.

4. If the participant insists on completing FU7 on paper:
   A. Say, "No problem" and Inform the pt that a new paper survey will be mailed out to them.
   B. Educate the pt about the benefits of the new portal.
   C. Let them know that they can enjoy access to the resources for participants on the portal without having to complete their survey on the portal. They can still do their survey on paper.
5. Ask if they are interested in activating:
   A. If "***YES***", ask if we can assist.
   B. If "***NOT NOW***",
      i. Let them know that they will receive occasional automatic reminders about the portal that they can ignore until they are ready to activate.
      ii. Update the FU7 Outcome field, "**10. Hold for Paper Survey**".

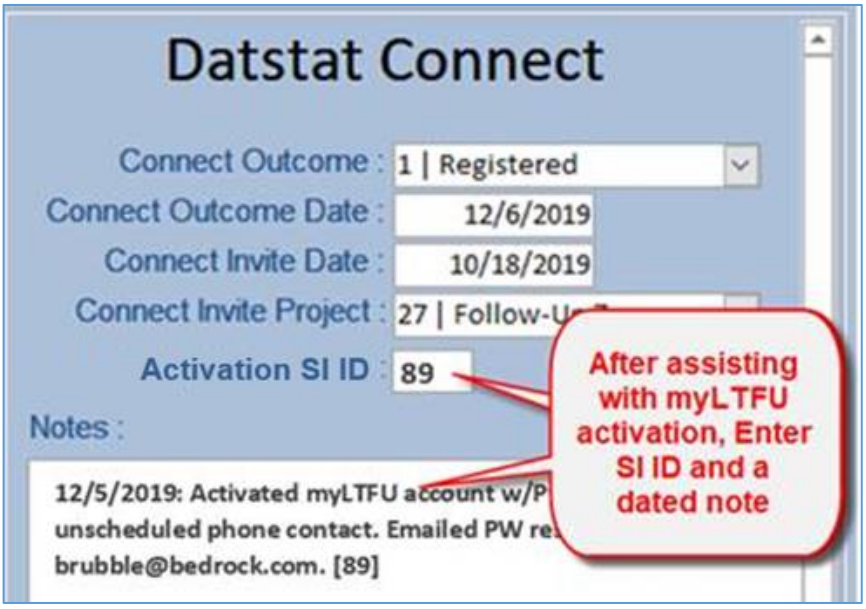


   C. If "***NEVER***",
      i. Say, "No problem", and ask, *"Would you mind sharing your reasons for choosing not to activate the **myLTFU** study portal?"*
      ii. Update the **FU7 Outcome** field, "10. Hold for Paper Survey."
      iii. If it is clear that they are against registering or doing their survey online, send an email to AJM, JF, DR, RD, and AC requesting to turn off reminders in DatStat.
      iv. NOTE: If a paper survey has already been mailed, then do not add this outcome code. Instead, use the resend request fields and leave the **FU7 Outcome** fields <null>.



POST-CALL PROCEDURES - General

1. **Complete the contact or Trace Log** record initiated in the pre-call procedures by populating the remaining fields. See the SOP titled **CCSS LTFU Participant Database Data Entry** for full details.
2. If **contact information** for the participant or his/her associate(s) was **confirmed or updated** during the call, update the CCSS LTFU Participant Database. See the SOP titled **CCSS LTFU Participant Database Data Entry** for details on documenting participant and associate contact information.
3. For confirmed updates to the **participant's name**, **Spanish status**, **date of birth**, **gender**, **incarceration status**, **vital status**, **LAR/proxy status** (including "no proxy available" situations), **hold status**, **tracing status**, **preferred contact time**, or **eligibility status**, see the SOP titled **CCSS LTFU Participant Database Data Entry** for details on documenting the changes.
4. For changes in **associate contact status** or **associate vital status**, see the SOP titled **CCSS LTFU Participant Database Data Entry** for details on documenting the changes.
5. If you activated the **myLTFU** portal for the participant during the call, update the **DatStat Connect** fields on the **APP-TEXT** tab. Enter your **SI ID** and a dated note with SI ID in the **Notes** field.



6. For survey outcomes, continue to the section of this document titled ***POST-CALL PROCEDURES – FU7 Survey Outcomes***.

POST-CALL PROCEDURES – FU7 Survey Outcomes

1. **Participant Indicated Paper Survey Previously Returned** – Enter a reminder in your MS Outlook calendar (*not* the Call Center appointment calendar) to follow-up with the participant 4 weeks from the approximate date of return.
2. **Appointment Made** –
   A. Write the appointment on the Call Center appointment calendar. See the SOP titled **Call Center Appointment Calendar** for details on how to document the appointment.

B. If you will be covering the appointment, add the appointment to your personal MS Outlook calendar on the appropriate date/time.

C. If the appointment needs to be assigned to another SI, send an email with the CCSSID/SIBID and the appointment type/date/time to the LSI team, copying the Coordinator, requesting that the appointment be reassigned. If there is no time to follow this procedure (e.g. The appointment is scheduled for the same day, and the LSI team and Coordinator are out or unavailable before the appointment.):

i. Coordinate with another SI to handle the appointment.

ii. Document the covering SI's number with the appointment on the Call Center calendar according to the SOP titled **Call Center Appointment Calendar**.

iii. Email details about the appointment and who will cover it to the LSI team, the Coordinator, and the covering SI.

3. **Request for Paper Survey Resend** – From the **CCSS Follow-Up Survey Tracking** Database:

A. **Resend Request** – Populate with 3-Survey.

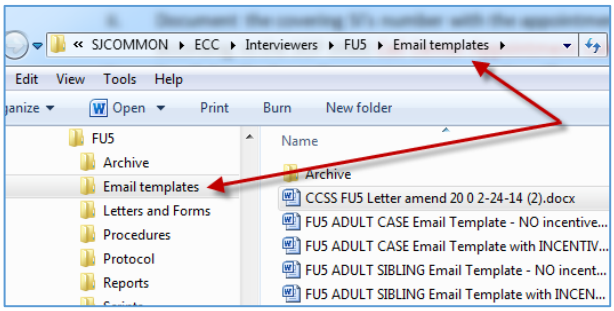
B. **Request Date** – Populate with the current date.

C. **Notes** – Add a dated comment with your SI ID documenting the field changes.

D. Note that Spanish-language surveys must be done on the telephone with an SI. Please check the **Spanish Status** field in the participant's header prior to requesting a resend of the paper survey.

4. **Request for FU7 Email** to access **myLTFU** account and complete FU7 study

*Note: **Spanish-language surveys can only be done on the telephone with a Spanish-speaking Survey Interviewer.** Please check the **Spanish Status** field in the participant's header prior to sending a survey link.*



A. Send the email to access myLTFU account using the appropriate email template located at *Z:\...\Interviewers\FU7\Email templates*. See the **myLTFU Temporary Password Email Template_SI** for details on this procedure.

B. Document the email communication in the Contact Log. The email sent to the participant should be documented separately from the telephone call. See the SOP titled **CCSS LTFU Participant Database Data Entry** for details on this procedure.

5. **Refusal** –

A. Refused FU7 but agreed to stay in the LTFU Study:

i. Document the FU7 refusal in the **Outcome** field of the Contact or Trace Log. See the SOP titled **CCSS LTFU Participant Database Data Entry** for details on using the Contact and Trace Logs.

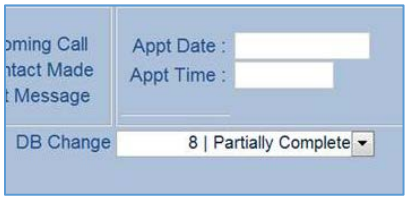
ii. Update the CCSS LTFU Participant Database with the FU7 refusal:

a. On the Participant tab, click on the **Notes** button. Enter a dated note with your SI ID documenting the refusal; specify that the participant refused FU7 only. Before closing the **Notes** form, copy the entire refusal note.
b. In the **CCSS Follow-Up Survey Tracking Database**, update the fields,
   1. **Notes** – Paste the refusal note into the field at the bottom of the screen.
   2. **FU7 Outcome Code** – Populate with 1-Refused FU7. If this field is already populated, consult a member of the LSI team prior to modifying the value.
   3. **FU7 Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.

B. Refused All Else:
   i. Document the refusal in the **Outcome** field of the contact or Trace Log. See the SOP titled **CCSS LTFU Participant Database Data Entry** for details on using the **Contact** and **Trace Logs**.
   ii. Update the CCSS LTFU Participant Database with the refusal:
      a. On the Participant tab, click on the **Notes** button. Enter a dated note with your SI ID documenting the refusal; specify that the participant refused all else. Before closing the **Notes** form, copy the entire refusal note.
      b. On the Open CCSS Follow-Up Survey Tracking Database:
         1. **Notes** – Paste the refusal note into the field at the bottom of the screen.
         2. **FU7 Outcome Code** – Populate with 2-Refused All Else (CCSS). If this field is already populated, consult a member of the LSI team prior to modifying the value.
      c. **FU7 Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.

      In the header:
         1. **CCSS Study Outcome** – Populate with 37-Refused all else. If this field is already populated, consult a member of the LSI team prior to modifying the value.
         2. **CCSS Outcome Date** – Populate with the current date. If this field is already populated, consult a member of the LSI team prior to modifying the value.

6. **Partial FU7 Surveys** –
   A. Using the **Previous** and **Next** buttons on the online survey (NEVER use the back/forward buttons from your internet browser.), **review every completed page** of the online survey for accuracy and check for missing information or fields erroneously left blank. Complete any missing information on these pages before closing the survey.
   B. **Complete the Contact or Trace Log** for the call, specifying 8-Partially Complete in the **DB Change** field.
   C. **Update the CCSS LTFU Participant Database** with any confirmed contact information using the SOP titled **CCSS LTFU Participant Database Data Entry**.
   D. Update the **CCSS Follow-Up Survey Tracking Database:**



i. **Notes** – **Enter a dated note** with SI ID documenting the partial survey. Specify if Spanish was used. *Example: 6/7/2017: Partially completed FU7 survey through question C.4. with Martha Stewart, mother and LAR of adult case. [162]*

ii. **Survey Source**, **Survey Interviewer ID**, **Interview Status** – DO NOT populate these fields. The database update team will populate these fields when appropriate.

E. For **scheduled** surveys, note the partial survey outcome on the Call Center appointment calendar according to the SOP titled **Call Center Appointment Calendar**.

F. For **unscheduled** partial surveys, email the participant ID to the closing monitor to include the partially completed survey in the closing report.

G. **Update the Dry Erase Board** (DEB) FU7 survey tally to indicate the partial survey by writing a "p" instead of a tally mark.

7. **Completed FU7 Surveys** –

A. Using the **Previous** and **Next** buttons on the online survey (NEVER use the back/forward buttons from your internet browser.), **review every page of the online survey** for accuracy and check for missing information or fields erroneously left blank. Complete any missing information.

B. **Complete the Contact or Trace Log** for the call. If the participant has requested to NOT receive LTFU Study newsletters, document the request in the **DB Change** field of the contact or Trace Log, and an LSI or designee will make the appropriate entries in the record. See the SOP titled **CCSS LTFU Participant Database Data Entry** for details on using the Contact and Trace Logs.

C. **Update the CCSS LTFU Participant Database** with any confirmed information using the SOP titled **CCSS LTFU Participant Database Data Entry**.

D. Click the "**Submit"** button on the last page of the survey. Click the "**Close"** button on the next page, and then choose "**Yes"** at the next prompt to close the browser instance.

E. in the **CCSS Follow-Up Survey Tracking Database:**

i. **Survey Interviewer ID** – Populate with your SI ID.

ii. **Notes** – Add a dated note with your SI ID documenting completion of the FU7 survey. If the survey was completed in Spanish, specify this.

iii. **Date Survey Returned, Survey Source**, **Interview Status** – DO NOT populate these fields.

F. For a completed **scheduled** survey, place a check mark on the Call Center appointment calendar to indicate the kept appointment. See the SOP titled **Call Center Appointment Calendar** for full details.

G. For a completed **unscheduled** survey, email the participant ID to the closing monitor to include the completed survey in the closing report.

H. Note the completed FU7 survey with a tally mark on the **Dry Erase Board** (DEB).

I. If the survey was completed with the participant over the phone in **Spanish**:

i. Document the Spanish survey completion in the **DB Change** field of the database **Contact** or **Trace Log**, and an LSI or designee will make the appropriate entries in the record. See the SOP titled **CCSS LTFU Participant Database Data Entry** for details on using the **Contact** and **Trace Logs.**

ii. Complete all online and database data entry, as indicated above.

iii. Confirm the **Spanish Status** field in the header is properly updated. See the SOP titled **CCSS LTFU Participant Database Data Entry** for details.

iv. Send an email to CRA2s in charge of the study, copying the LSI team and the Call Center Coordinator, that a FU7 survey has been completed in Spanish. Include the CCSSID or SIBID in the **Subject** line and in the body of the email.

v. Create a personalized Spanish thank-you card insert to the participant. See the SOP titled **Sending Spanish Thank You Notes** for details.

vi. Deliver the thank-you card insert to the CRA2 team. See the SOP titled **Sending Spanish Thank You Notes** for details.

Revision Record Printed

Current Filename:		myLTFU and Follow-Up 7 Survey Non-Responder Calls ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/25/2020	A. Cobble, D. Rinehart, R. Daniels, L. McKinney, Y. Booth; M. Sanchez	Initial Development

Newsletter Distribution

Background

The LTFU Education Committee produces a newsletter four times a year (3 Brief Updates and 1 full newsletter) which is distributed to participants and other designated individuals. Distribution involves generating a data file from the respective databases, determining needed quantities, coordinating with the St. Jude Print Shop for envelope production, notification of St. Jude mailroom to ensure the account has adequate postage available, initiating purchase procedures with outside vendors and direct mailing, coordinating delivery of materials to direct mail company, ensuring return of unused newsletters/envelopes to the LTFU Coordinating Center.

Who receives the Newsletter?

- Cases (Original cohort of CCSS and Expansion cohort)
- Siblings
- Steering Committee, Advisory Committee, Principal Investigators
- Miscellaneous recipients (random requests for the newsletter)

Generating the newsletter content

The LTFU Education Committee brainstorms for topics. Drafts are distributed for feedback from LTFU staff, revised, and then to the steering committee for feedback/approval. When the final approved document is presented, the production/distribution process begins. Catherine Moen at the University of MN serves as the editor and designer of the newsletters.

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Email: moenx004@umn.edu

Location of files

Files for the Newsletter are located in S:\ECC\CCSS\Newletter, in folders separated for each issue of the newsletter.

Procedure

1. *Generate the mailing list(s)*
   - **a.** Produce (or re-use after verifying) a query from the **Original cohort (Reg database)**
     - i. Use the Quest and Reg tables
     - ii. Use these fields: CCSSID, sendname, send care of, send city, send state, zipsort, country
     - iii. Also include these 3 fields and selection criteria: Alive (=1), outcome (is null or 40), Address code (is null or 19 or 21 or 83 or 83 or 85). Set these criteria field to not display (uncheck the "Show" check box)
     - iv. Export the query (Tools|Analyze with Excel), saving accordingly:
       1. In …\ECC\CCSS\Newsletter\[Folder named for issue/year Newsletter]

2. Filename: [Issue Newsletter YEAR_source]. E.g., FallNewsletter2009_Cases (.xls)

v. IF the database has not yet been corrected for international addresses, you will need to locate the potential international addresses, identify the country, and enter the country name in the country field. (Later, update the database with the Country field.)

b. Produce (or re-use after verifying) a query from **Siblings (orig cohort)**
   i. Use the Sibling Table
   ii. Uses these fields: SibIDNo, SibSendName, SibSendCareOf, SibSendAddress, SibSendCity, SibSendState, SibSendZip, {SibSendCountry…or whatever the country field name is}.
   iii. Also include the following fields and criteria in the query: SAddressCode = IsNull or 19 or 21 or 82 or 83 or 85; SibOutcome = IsNull or 40; SAlive = 1. Set these criteria fields to not display (uncheck the "Show" check box).
   iv. Export the query (Tools|Analyze with Excel), saving accordingly:
      1. In …\ECC\CCSS\Newsletter\[Folder named for issue/year Newsletter]
      2. Filename: [Issue Newsletter YEAR_source]. E.g., FallNewsletter2009_Siblings (.xls)
   v. IF the database has not yet been corrected for international addresses, you will need to locate the potential international addresses, identify the country, and enter the country name in the country field. (Later, update the database with the Country field.)

c. Produce (or re-use after verifying) a query from **Expansion**
   i. Use the tblCCSSExpansionTrackingMain table and the tblDeathData (use an outerjoin)
   ii. Use the following fields: CCSSID, Name, Sendaddr, Sendcity, Sendstate, Zipsort
   iii. Include the following fields and criteria in the query: SAddressCode Alive=IsNull; Outcome=IsNull or 40; AddressCode = IsNull or 19 or 21 or 83 or 82 or 85. Set these criteria fields to not display (uncheck the "Show" check box).
   iv. Export the query (Tools|Analyze with Excel), saving accordingly:
      1. In …\ECC\CCSS\Newsletter\[Folder named for issue/year Newsletter]
      2. Filename: [Issue Newsletter YEAR_source]. E.g., FallNewsletter2009_Expansion (.xls)
   v. IF the database has not yet been corrected for international addresses, you will need to locate the potential international addresses, identify the country, and enter the country name in the country field. (Later, update the database with the Country field.)

d. OTHER RECORDS
   i. Copy the file called LTFU Newsletter Additional Names from …\ECC\CCSS\Newsletter and put it in the appropriate Newsletter folder
   ii. Locate a list of the Principal Investigators, Steering Committee, and Advisory Committee. (Make a copy of the file used for the last newsletter, then ask Ed Sandy to confirm the names/addresses. Save the updated file in the folder for the current newsletter.)

2. ***Determine needed quantity***
    a. Using the separate lists, subtotal number of newsletters needed.
    b. ADD approximately 300 to the subtotal, to have additional available to accommodate later requests and resends.
    c. This grand total is for the number of newsletters to print as well as the number of envelopes needed.
    d. Determine the count of domestic mail pieces and international pieces. If non-indicia envelopes are to be used for international pieces, differentiate the envelope counts above.

3. ***Standardizing the mailing data files: collating files and fixing the sendname for minors***
    a. Collate the DOMESTIC sibling, expansion, and original cohort cases into a single excel file.
        i. Make sure the files have the same columns and in the same order. See sample. You may need to insert a sendcareof column.

	A	B	C	D	E	F	G	H
1	ccssid	sendname	sendcareof	sendaddr	sendcity	sendstate	zipsort	sendCountry

    b. Do the same for the INTERNATIONAL data file for cases.

    c. Some of the "Sendname" data will say "Dear Parents of [John Doe]". Do a search and replace in the Sendname column to Search for "Dear parents of" and replace it with "The Parents of".

4. Ordering the **Newsletter** print job: Argo & Associates
    a. Contact person: Kevin [(Kargo9@comcast.net, 751-0786 or 497-0728 (cell)]
    b. Request a price quote and job timeline for printing the total quantity of newsletters.
    c. Specify paper quality, etc. Determine whether the printer does the folding or whether the mass mailer folds.
    d. Send the price quote to Abbe Anderson and request a Purchase Order number.
    e. Send the purchase order # to Kevin, and give him the authorization to proceed
    f. Determine where the finished job needs to be delivered (St. Jude or the mailing company).
    g. Make sure Kevin knows to send us a review proof before printing the full job.

5. **Envelopes**
    a. Determine current quantity on hand; compare to total pieces to distribute; compute balance needed.
    b. Contact Print Shop to order needed quantity (typically use white #10 envelopes).
        i. Determine how the finished envelopes will be transported to the mailing company.
    c. Copy Abbe on the email so she can approve the cost involved with the print requisition.

6. **Assembly and shipping (mass mailer)**
    a. Contact Jaco-Bryant (mass mailer), with job request
    b. Contact person is Cheryl Patrick (cheryl@jaco-bryant.com); 901.546.9600
    c. Send mailing lists via encrypted email to Cheryl.

Lead CRA

d. Get a quote and timeline for the job.
e. Email this to Abbe so she can get purchase order for the job estimate
    i. **IMPORTANT: Ask for an estimated postage for the domestic mail. This will be paid out of our permit account (i.e., Jaco-Bryant will not charge us for domestic postage), but we need to ensure we have enough money in our account.
    ii. Send the postage estimate to Samantha Watson in the SJ mailroom. She will let us know if money needs to be added to the account. If so, work with Abbe to get funds added.
    iii. Jaco-Bryant will charge us for the international postage.
f. Coordinate the delivery/pickup of the Newsletters (Argo), envelopes (printshop), so Jaco has the needed materials.
g. Provide Jaco with sample imprint indicating what is to be in the address. (Notably, the CCSSID is to appear on the label.)
h. Jaco-Bryant prints the addresses on the envelopes, stuffs envelopes, seals, and bundles for postal pickup.
i. Jaco-Bryant notifies CCSS as the shipment(s) are being sent.
j. Jaco-Bryant returns unused stock to St. Jude (envelopes, newsletters, etc.)

Revision Record Printed 7/9/2012 3:00 PM

Current Filename:		Newsletter Distribution ver 2_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/2/09	J. Bates	Initial Development
2	2/21/11	A. McDonald	Updating contacts and steps

Newsletter List

**Note – the bulk mailer asked that we also list the country name in the International file. I did this by hand (see spring 2009 mailing lists). There may be a method to include this in the query next time. Also, some of the city and/or state names actually include the international country name too. The country name should be moved to the country name field (manually).

Original Cohort Cases and Siblings

1. Create query in Reg database to generate participant lists
2. Query (Cases)
    a. Add Quest and Reg Tables
    b. CCSSID
    c. Sendname
    d. Send Care of
    e. Send City
    f. Send State
    g. Zipsort
    h. Alive =1
    i. Outcome = Is null or 40
    j. Address Code = Is Null or 19 or 21 or 82 or 83 or 85
        i. Include these last three in the query, but hide them (deselect checkbox) before exporting the list to excel. Use this information to make sure query is pulling correct people
3. Export to Excel (Tools/Analyze with Excel)
4. Save the file in the appropriate newsletter folder
    a. …\ECC\CCSS\Newsletter\(Spring 2009 Newsletter)
    b. Save as naming convention such as Spring Newsletter 2009_Cases
5. Cut and paste the international addresses to a new file
    a. Sort by zipcode (cut and paste as needed)
    b. Then sort by state (cut and paste as needed)
6. Save this file in the folder using a naming convention such as Spring 2009_International
7. Query (Siblings)
    a. Add Sibling Table
    b. SibIDNo
    c. SibSendName
    d. SibSendCareOf
    e. SibSendAddress
    f. SibSendCity
    g. SibSendState
    h. SibSendZip
    i. SAddressCode = Is Null or 19 or 21 or 82 or 83 or 85
    j. SibOutcome = Is Null or 40
    k. SAlive = 1
        i. Include these last three in the query, but hide them (deselect checkbox) before exporting the list to excel. Use this information to make sure query is pulling correct people
8. Follow steps 3 – 6

   a. Name the sibling file using convention such as Spring Newsletter 2009_Siblings
   b. Add the international addresses to the previous file you created for the cases
9. Copy the file called LFTU Newsletter Additional Names from …\ECC\CCSS\Newsletter and paste it into the appropriate Newsletter folder
   a. You will now have 4 Excel files in the folder

Expansion Cohort Cases

10. Create query in Expansion database to generate participant lists
11. Query (Cases)
    a. Add tblCCSSExpansionTrackingMain
    b. CCSSID
    c. Name
    d. Sendaddr
    e. Sendcity
    f. Sendstate
    g. Zipsort
    h. Alive = Is Null (Have to use an outer join with tblDeathData)
    i. Outcome = Is Null or 40
    j. Address Code = Is Null or 19 or 21 or 83 or 82 or 85
       i. Include these last three in the query, but hide them (deselect checkbox) before exporting the list to excel. Use this information to make sure query is pulling correct people
12. Follow steps 3 – 6 above

*Note – there are currently no sibs or international addresses in the Expansion cohort. When these are added, then the procedure will be modified to match the "original cohort."

13. Use the FTA program to send the Excel files to the Rush Street mailing POC and Margaret Carbaugh
    a. Rick@Jaco-Bryant.com
    b. rcooper@street-rushing.com
    c. ~~Margaret.Carbaugh@stjude.org~~

Revision Record — Printed 7/9/2012 3:03 PM

Current Filename:		Newsletter List ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	3/23/09	A. McDonald	Initial Development

Notifications from Form Submission about Contact Information Update

Background

Study participants may log into either of the study websites to update their contact information or send comments to the system manager. (See ccss.stjude.org and ltfu.stjude.org). This generates an automated email message to LTFU. The message does *not* identify the cohort (original or expansion) or status (case or sibling) but does allow respondent to indicate they are a study participant. They may also indicate they want to receive the LTFU newsletters by email.

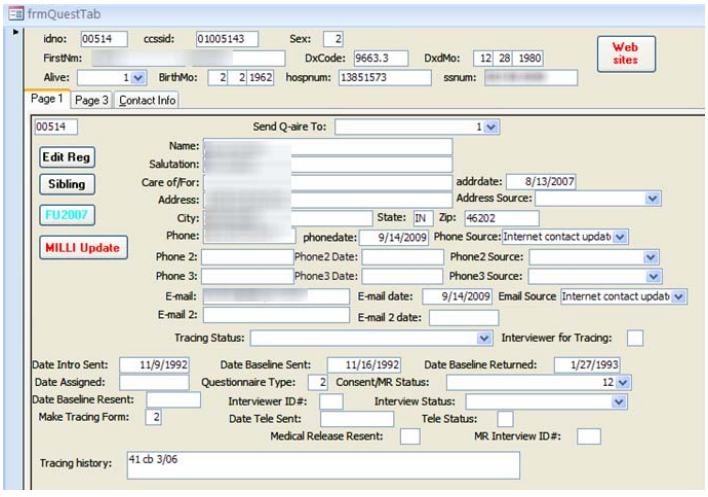
Long-term Follow-up Contact Information Update

- **Check here if you are a LTFU study participant.** Yes
- First Name*:
- Middle Initial:
- Last Name*:
- Date of Birth:
- Previous Name (if applicable):
- Address 1*:
- Address 2:
- City*:
- State/Province*:
- Country:
- Zip code*:
- Telephone*:
- Alternate Phone:
- Email Address*:
- Check if you would you like to receive the LTFU newsletters by email.: Yes
- Comments:

Procedure

1. When we receive the email Contact Information Update, first locate the individual in the database. You may need to search both the original and expanded cohort databases as well as the sibling groups. (If not found, the individual might not be a study participant. Refer these to the CRA2 to pursue.)
2. After locating the record, first archive the current contact information (if the function is available in that database). Then update the information as indicated.
3. Update the information source and date. If the database supports phone and email ranking, use rank #1 for the email address provided (rerank any other email addresses) and rank 1 for the Telephone and 2 for the Alternate Phone.
4. For expansion cohort cases, after updating the information, use the save function to save the information and then the Update Print Table Address function.
5. If the name in the update differs from the name currently on file, refer to **Changing Maiden Name to Married Name** for guidance.

Original Cohort Cases



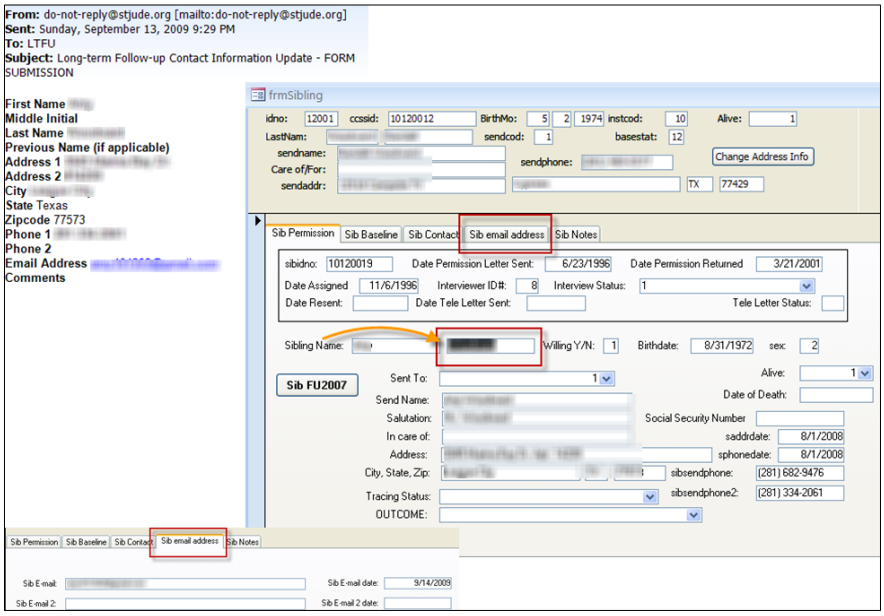
1. Open Reg Database
2. Click the Check-in Questionnaires button
3. Click Open frmQuest Tab
4. Search for participant by last name
5. Use the Tracing History field to document the CURRENT address (if different from new address) e.g., "**m/d/y: prev adrs 999 AnywhereStreet, City, ST ZIP [inits]**" *before* updating the existing address.
6. Update the information.
7. For each updated (or re-confirmed) field, enter the associated date and the source fields (Internet contact update).
8. *For multiple phone/e-mail information*
   a. If a new phone number or e-mail address is received, *and* there is an unused phone/e-mail field, simply *add* the new data (rather than replacing the existing data).
   b. If email and/or phone information is the *same* as on file, enter the update date in the appropriate date field. (This indicates that the information is "still good" as of the date you enter.)

Everyone

Siblings

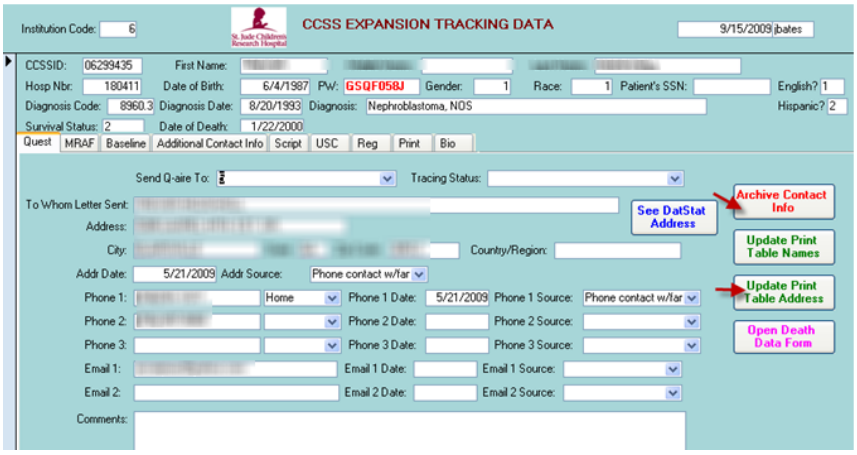
If the update does not come from an original or expansion case, it is likely from a sibling. Sibling information is currently in the Reg database (original cohort), as siblings for the expanded cohort have not yet been identified.

1. Open Reg Database
2. Click the Check-in Questionnaires button
3. Click the Sibling button
4. On the Sib Permission tab, search for last name in the Sibling Name area.
5. Update the information, including relevant date fields.
6. Enter sibling e-mail address on the Sib email address tab, indicating the date the e-mail address was received/confirmed. If requesting newsletters by email, check the **Use Email for Newsletter** check box..



Expansion cohort case

1. Open Expansion Tracking Database
2. Search for participant by last name
3. Click the Archive Contact Info button (to ensure the current information is archived)
4. Update the information (as with original cohort case)
   a. Make sure you post the date and source fields
   b. Adjust the phone ranks, using the phone numbers provided in the email as rank 1 (and 2, if 2 phones provided). Adjust other ranks as needed.
   c. If an email address is provided in the notification, RANK the specified email address as rank #1, reranking any other address that might have been ranked #1.
   d. Click the Save button on the toolbar to save the new information.
5. Click the Update Print Table Address button (so the survey print tables will be updated).

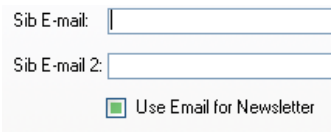


Everyone

Handling Comments

Individuals may also provide comments to the data manager through this same follow-up contact information process. Review the comments, consult to determine what action may need to be taken, and then process accordingly.

Use Email for Newsletters



If the form indicates the person wants to receive newsletters via email, check the box for Use Email for Newsletter on the Quest tab (Expansion Tracking) or Page 1 of frmQuest (Reg database) or Sib Email Address tab for original cohort siblings. Be sure you have also set the rank for the email address provided in the notification.

Revision Record

Printed 2/8/2013 11:24 AM

[119] Current filename:		Notification from Form Submission-Contact Information Update ver1_3.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/15/09	J. Bates	Initial Development
1.1	11/18/10	J. Bates	formatting
1.2	7/28/11	J.Bates	Add Use email for newsletters
1.3	2/8/13	J.Bates	Phone/Email ranking; refresh screens

Notifications from Mail Carrier about Participant Correspondence

Background

Correspondence is mailed to participants via the U.S. Postal Service (USPS) with "Address Service Requested" preprinted on the envelope. As a result of this request, when the USPS has a new address for a participant, they will either (1) forward the correspondence to the participant's new address and mail us a separate notice of the new address or, (2) if the forwarding time has expired, return the correspondence with the new address attached. The CCSS Coordinating Center also receives other communication (e.g. deceased, undeliverable) from the USPS.

All updates and communication received from the USPS must be documented in the appropriate database. This procedure describes how to process the different types of updates and communication typically received from the USPS.

Procedure

NOTE: **Newsletters** are mailed by an external vendor. The printing company will search for new addresses prior to mailing and may send the newsletter to an address other than the one on file at the CCSS Coordinating Center. If an item was not mailed to the address in the CCSS database or to a recently archived address in the database, do not make any changes to the database address and/or tracing code. Instead, make a dated note with your initials in the comments or notes field documenting where the item was mailed and the subsequent action (either returned to sender or forwarded to different address) and see the Senior Coordinator-Clinical Research Operations or a CRA2 for a directive.

Forwarded Mail or New Address Notification – Updating Addresses

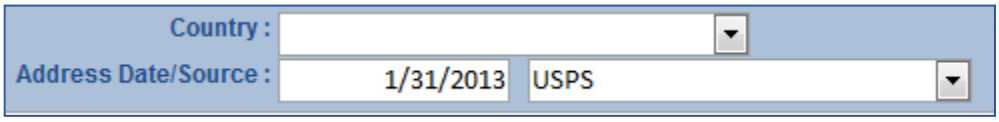
When a **notice of a new address** is received, either via a forwarded mail notice or new address information on returned mail, the participant's new address should be updated in the appropriate database and, where appropriate, a resend of the materials should be requested. There are different procedures for updating each database, as outlined below.

IMPORTANT: Always start with the LTFU Participants database when searching for a participant record. If the individual is not found in the LTFU Participants, Expansion Tracking, or Recruitment databases, see the Senior Coordinator-Clinical Research Operations or a CRA2 for a directive.

LTFU Participants Database

1. Open the CCSS LTFU Participants Database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. **Locate the participant's record** using the search screen and the participant ID printed on the mailing label.
   A. If the participant ID is not visible/available, search by first and/or last name.
   B. If the individual is not found in the LTFU Participants database, proceed to the section of this document titled *Expansion Tracking Database*, below.
3. **Verify that the participant's name and address** printed on the correspondence are the *same* as those on the PARTICIPANTS tab (or match recently archived data). If they do not match, see the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.

4. **Determine if the database's information is *more current*** than the forwarding notice or returned mail by reviewing the **Address Date** field on the PARTICIPANT tab.
   A. If the *database is more current* than the forwarding notice or returned mail, DO NOT update the database. Instead:
      i. If the participant ID does begin with "15" AND does not end with "9", this is a St. Jude case. Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2 for follow-up with a member of the St. Jude Life team.
      ii. If the participant ID does not start with "15" OR does end with "9":
         a. Forwarding notices – Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2.
         b. Returned mail - See the section of this document titled *Processing Returned Correspondence after Updating the Database*.
   B. If the *forwarding notice or returned mail is more current* than the **Address Date**, then:
      i. Click the **Archive Info** button.
      ii. Update appropriate address fields. NOTE: The **Country** field is ONLY populated for addresses that are *not* in the USA. Leave this field blank for U.S. addresses.



      iii. **Address Date/Source** – Update with the date of the notification and source as "USPS."
      iv. Move to a new field, then click the **Update Print Tables** button.
      v. **Notes** – Record a dated note documenting what was returned and what action, if any, was taken. (e.g., "*mm/dd/yy: FU5 survey sent 11/17/15 was forwarded by USPS on 11/18/15 to 123 Main St. Database already updated. [inits]")*
      vi. If the mail was not forwarded by the USPS, record a resend request using the appropriate fields. See the Senior Coordinator-Clinical Research Operations or CRA2 for assistance determining what to resend or how to record the request.
      vii. Route the forwarding notice or returned mail for further processing.
         a. If the participant ID starts with "15" AND does not end with "9", this is a St. Jude case. After the address is updated, return the mail to the Senior Coordinator-Clinical Research Operations or CRA2 for follow-up with a member of the St. Jude Life team.
         b. If the participant ID ends with "9" OR does not start begin with "15",
            1) Forwarding notices – Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2.
            2) Returned mail – See the section of this document titled *Processing Returned Correspondence after Updating the Database*.

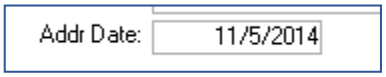
Expansion Tracking Database

1. After confirming that the participant is NOT found in the CCSS LTFU Participants Database, open the CCSS Expansion Tracking database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx. Choose the **Cases** (if the last digit of the participant ID is NOT "9") or **Siblings** (if the last digit of the participant ID is "9") button on the main switchboard screen.

2. **Locate the participant's record** using the Find feature and the participant ID printed on the mailing label.

   A. If the participant ID is not visible/available, search by first and/or last name.
   B. If the individual is not found in the Expansion Tracking database, proceed to the section of this document titled *Recruitment Database*, below.
3. **Verify that the participant's name and address** printed on the correspondence are the ***same*** as those in the Quest tab (for cases) or SibInfo tab (for sibling participants) or that they match recently archived data. If they do not match, see the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.
4. **Determine if the database's information is *more current*** than the forwarding notice or returned mail by reviewing the **Addr Date** field on the Quest (for cases) or SibInfo (for sibling participants) tab.
   A. If the *database is more current* than the forwarding notice or returned mail, DO NOT update the database. Instead:
      i. If the participant ID does begin with "15" AND does not end with "9", this is a St. Jude case. Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2 for follow-up with a member of the St. Jude Life team.
      ii. If the participant ID does not begin with "15" OR does end with "9":
         a. Forwarding notices – Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2.
         b. Returned mail – See the section of this document titled *Processing Returned Correspondence after Updating the Database*.
   B. If the *forwarding notice or returned mail is more current* than the date in the **Addr Date** field, then:
      i. Click the **Archive Contact Info** (for cases) or **Archive Information** (for siblings) button.

      ii. Update the appropriate address fields. NOTE: The **Country** field is ONLY populated for addresses that are *not* in the USA. Leave this field blank for U.S. addresses.
      iii. **Addr Date** – Update with the date of the notification.



      iv. **Addr Source** – Update to "USPS".
      v. **Comments** – Record a dated note documenting what was returned and what action, if any, was taken. (e.g., "*mm/dd/yy: Baseline survey sent 11/17/15 was forwarded by USPS on 11/18/15 to 123 Main St. Updated address. [inits]")*
      vi. If the mail was not forwarded by the USPS, update the **Tracing Status** and **Tracing Date** fields to request a resend. See the Senior Coordinator-Clinical Research Operations or CRA2 for assistance determining what to resend or how to record the request.
      vii. Save the changes to the record by either (1) navigating to the next record in the database and then navigating back again to the record in question or by (2) moving to a new field and clicking the Save icon in the Records group of the Ribbon's Home tab.

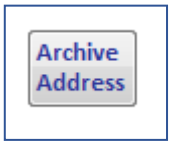
      viii. Click the **Update Print Table Address** (for cases) or **Update Sibling Print Table** (for siblings) button.
      ix. Route the forwarding notice or returned mail for further processing.

a. If the participant ID starts with "15" AND does not end with "9", this is a St. Jude case. After the address is updated, return the mail to the Senior Coordinator-Clinical Research Operations or CRA2 for follow-up with a member of the St. Jude Life team.
b. If the participant ID ends with "9" OR does not begin with "15":
   1) Forwarding notices – Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2.
   2) Returned mail – See the section of this document titled *Processing Returned Correspondence after Updating the Database*.

Recruitment Database

1. After confirming that the participant is NOT found in the CCSS LTFU Participants Database NOR in the CCSS Expansion Tracking database, open the CCSS Recruitment Database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. **Locate the case's record** using the Find feature and the CCSSID printed on the mailing label.
   A. If the CCSSID is not visible/available, search by first and/or last name.
   B. If the individual is not found in the Recruitment database, see the Senior Coordinator-Clinical Research Operations or a CRA2 for a directive.

3. **Verify that the case's name and address** printed on the correspondence are the *same* as those in the Quest tab or that they match recently archived data. If they do not match, see the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.
4. **Determine if the database's information is *more current*** than the forwarding notice or returned mail by reviewing the **ADDRESS DATE** field on the Quest tab.
   A. If the *database is more current* than the forwarding notice or returned mail, DO NOT update the database. Instead:
      i. If the participant ID does begin with "15", this is a St. Jude case. Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2 for follow-up with a member of the St. Jude Life team.
      ii. If the participant ID does not begin with "15":
         a. Forwarding notices – Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2.
         b. Returned mail – See the section of this document titled *Processing Returned Correspondence after Updating the Database*.
   B. If the *forwarding notice or returned mail is more current*, then:
      i. Click the **Archive Address** button.
      ii. Update the appropriate address fields. NOTE: The **Country** field is ONLY populated for addresses that are *not* in the USA. Leave this field blank for U.S. addresses.



      iii. **ADDRESS DATE** – Update with the date of the notification.
      iv. **ADDRESS SOURCE** – Update to "USPS".
      v. **Comments** – Record a dated note documenting what was returned and what action, if any, was taken. (e.g., "*mm/dd/yy: Recruitment packet sent 11/17/15 was forwarded by USPS on 11/18/15 to 123 Main St. Updated address. [inits]")*

vi. If the mail was not forwarded by the USPS, update the **Resend Request** and **Date Resend Request** fields to request a resend. See the Senior Coordinator-Clinical Research Operations or CRA2 for assistance determining what to resend or how to record the request.

vii. Save the changes to the record by either (1) navigating to the next record in the database and then navigating back again to the record in question or by (2) moving to a new field and clicking the Save icon in the Records group of the Ribbon's Home tab.

viii. Route the forwarding notice or returned mail for further processing:
   a. If the CCSSID begins with "15", this is a St. Jude case. Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2 for follow-up with a member of the St. Jude Life team.
   b. If the CCSSID does not begin with "15":
      1) Forwarding notices – Return the mail to the Senior Coordinator-Clinical Research Operations or CRA2.
      2) Returned mail – See the section of this document titled *Processing Returned Correspondence after Updating the Database*.

Mail Returned as Undeliverable

If the USPS does not have a new address for a relocated party or if the correspondence cannot be delivered (for a variety of reasons), then the correspondence will be returned as undeliverable. When the undelivered correspondence is received, update the appropriate database to note that we do not have a valid, current address for the participant.

1. Open CCSS LTFU Participants database, and use the participant ID, first name, or last name on the returned mail to locate the participant's record.
   NOTE: If the participant is not located in the LTFU Participants database, try the CCSS Expansion Tracking database. If the participant is not located in either of these databases, try the CCSS Recruitment database. If the individual is not found in any of these databases, see the Senior Coordinator-Clinical Research Operations or a CRA2 for a directive. All databases are located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. **Verify that the case's name and address** printed on the correspondence are the *same* as those in the Quest/SibInfo/Participant tab or that they match recently archived data. If they do not match, see the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.
3. **Verify that updated address information has not already been obtained and recorded.**
4. **Enter the appropriate code** in the **Tracing Status** or **Tracing Code** field. This will usually be one of the following:
   A. 18 – Search new address
   B. 13 – Needs tracing (use 13 if tracing code 19-Disconnect is already recorded)
   C. 81 – newsletter returned without new address
   D. 85 – Bad Lexis Nexis Address (use 85 if tracing code 18-Search new address or 81-newsletter returned without address is already recorded and the address source is "Lexis Nexis")
   E. 86 – Bad Lexis Nexis Address & Phone(s) (use 86 if tracing code 13-Needs tracing is already recorded and the address source is "Lexis Nexis")
5. **Enter today's date** in **Tracing Date**.
6. **Record a dated note** with your initials documenting what was returned (e.g., newsletter, thank you note, survey), the date on the USPS label, and the USPS information (e.g., returned to

sender, undeliverable, unable to forward, forwarding address expired) in the appropriate comments or notes field:

A. LTFU Participants database – **Notes** field, Participant tab
B. Expansion Tracking database (cases) – **Comments** field, Quest tab
C. Expansion Tracking database (siblings) – **Comments** field, SibInfo tab
D. Recruitment database – **Recruit Notes** field, Tracking tab

7. **Route the returned mail for further processing**. See the section of this document titled *Processing Returned Correspondence after Updating the Database*.

Mail Returned as Deceased

If the postal service is notified that someone is deceased, they will return correspondence stamped as "Deceased." Update the address information, as appropriate, and then return the mail to the Senior Coordinator-Clinical Research Operations or CRA2 for further processing. Efforts will be made to confirm the change in vital status.

Processing Returned Correspondence after Updating the Database

After the appropriate database has been updated (or after it has been determined that the database does not need to be updated), as directed above, process the physical correspondence as follows:

1. Original mailing envelope – Review the participant ID associated with the mailing.
   A. If the participant ID starts with "15" AND does not end in "9", this is a St. Jude case. Return the envelope to the Senior Coordinator-Clinical Research Operations for follow-up with the St. Jude Life team.
   B. If the participant ID does not start with "15" OR ends with "9", the original mailing envelope must be *shredded*.
2. Envelope contents – Review the contents of the envelope to determine if each item is personalized.
   A. Personalized insert (e.g. most letters, memos, questionnaires, etc.) – Shred.
   B. Non-personalized inserts (e.g. newsletters, postage paid return envelopes or BREs, participant copies, etc.) – Return to the storage room for reuse.

Revision Record Printed 10/28/2015 11:34 AM

Current Filename:		Notifications from Mail Carrier about Participant Correspondence ver 3_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/3/09	A. McDonald	Initial Development
2	7/28/09	A. Molina	Revisions to update
2.1	12/30/09	J. Bates	Annotating reasons for returned mail
2.2	3/24/11	J. Bates	Returned newsletters
2.3	7/8/11	J. Bates	Add recruitment, ancillary cases
2.4	5/30/12	J. Bates	Reg note prev adrs
2.5	10/5/12	J. Bates	Repl Nina Tinner w/ generic title for 15 chgs
2.6	11/27/12	J. Bates	Actions before Updating Print Table
2.7	12/23/13	J. Ford	Revised and added Expansion Sibling procedures
2.8	1/6/14	L. Harrison	Added update print table directive
2.9	1/16/14	L. Harrison	Added note about printing comp. changing address
3.0	4/16/14	L. Harrison	Added note about SJL addresses and deceased updates
3.1	11/3/14	J. Ford & L. Harrison	Removed Reg procedure, consolidated Expansion & expanded Recruitment database procedure, & added LTFU Participants database procedures
3.2	10/28/15	R. Massey, J. Ford	Add archive directive, update print tables, new tracing codes

Obtaining Signed HIPAA for Dana Farber (DFCI) Cases-Batch Process

Background

Obtaining a signed LTFU HIPAA (medical release) from Dana Farber study participants is required. When a survey interviewer completes the baseline survey with the participant over the phone, the MR Status is coded "6" (send medical release), and the interviewer's ID number is posted in the database. Each month the CRA2 polls the database for Dana Farber cases that need to have a medical release sent, generates and mails the necessary documents, and documents the activity in the database. (We use a real-time process to obtain signed HIPAAs from Dana Farber participants who return a printed survey without a signed HIPAA. See *Dana Farber Surveys with Incomplete HIPAA* for more information.)

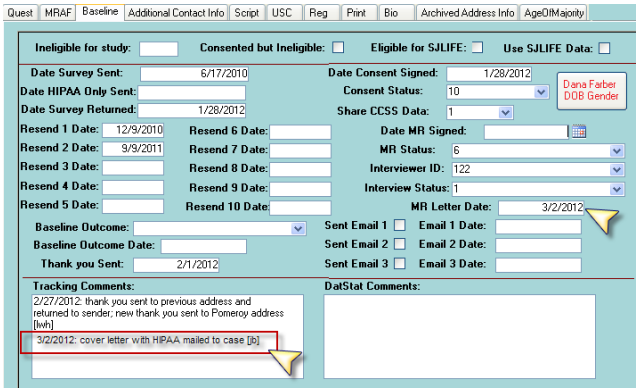
Procedure

Request MR Signature

Each month, check the database for DFCI cases without a completed MR who have not yet been mailed an MR letter. Use the **qry_JB_Need_MR_DFCI** to do this. The query (1) presents fields needed to mail merge the cover letter, the envelope, and the personalized LTFU HIPAA form; and (2) indicates whether the letter is to be sent to the participant, the minor participant's parents, or the deceased participant's family (sendcareof). We use slightly different LTFU HIPAA forms for living and for deceased individuals.

1. Run the query **qry_JB_Need_MR_DFCI** and output to excel. If appropriate, exclude those to whom a letter has already been sent. (NOTE: there may be times when mass resends are called for.)

2. Generate and mail the letters with the MR form.
   a. Mail merge documents found at **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\Consent Resends\DanaFarber 2010 ff\MERGEdocuments\DFCI MR only**
      i. EnvelopeOnly-MergeFields (or ShippingLabels-MERGE.docx)
      ii. LetterOnly-DFCI MR only-MergeFields
      iii. The appropriate HIPAA document
         1. LTFU HIPAA **Deceased**-MergeFields
         2. LTFU HIPAA **Living**-MergeFields
         3. LTFU HIPAA only-merge codes-Adult-Minor **SPANISH**
      iv. !!Contact Information Update Sheet-merge codes – Expansion Fields
   b. In each mail merge, filter for records that have NOT YET been mailed a letter.
3. Print letters on St Jude letterhead; envelopes on StJude envelopes. Print Contact information sheet. Print HIPAA in color. Staple Contact information sheet to HIPAA (HIPAA on top).
4. Print additional copy of the letters on plain paper, for file purposes.
5. Document that material was sent, on Baseline tab:
   a. Post letter date in **MR Letter Date**.
   b. Post note in **Tracking comments** (e.g., *mm/dd/yy: MR letter sent [inits]).*
   c. If an **MR Letter Date** is already on file, make sure date is captured in Tracking comments, and then replace the MR Letter Date with current date, annotating in Tracking Comments that "MR ltr resent"



LeadCRA

Filing

1. Place the copy of the printed letter in the Open Signature Request Letters folder in the DanaFarber standing desk file.

2. Electronic files:

   a. Add date sent to the end of the Excel data file name (e.g., sent mm-dd-yy)

   b. Move (or copy) data file to the \SENT folder in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\Consent Resends\DanaFarber 2010 ff\SENT.**

   c. We do NOT need to save the electronic merged letters or HIPAA forms.

Processing returned HIPAAs

When we receive the properly signed MR (parent or LAR authorized to sign for minors and for deceased)

1. Date-stamp and initial in the upper right corner.
2. Photocopy the signed MR and file in the *DF HIPAA Photocopies* folder (where it will be held until being mailed to the data manager)
3. Record in the database
   a. Baseline tab:
      i. Change **MR Status** to 1 (complete)
      ii. Record the signature date in **Date MR Signed**.
      iii. Annotate in **Tracking Comments** (mm/dd/yy: received MR signed by participant/parent/LAR [inits]).
   b. If the person completed the contact update information sheet, update accordingly in the database

4. Retrieve the copy of the request letter from the DanaFarber standing desk file. Shred the letter.
5. File the original signed HIPAA in the *Signed HIPAA* file drawer

Revision Record Printed 5/14/2013 10:50 AM

(63) Current Filename:		Obtaining Signed HIPAA for Dana Farber-Batch ver1_4.doc	
Revision No.	Date	Responsible Author	Change Description
1	7/27/11	J.Bates	Initial Development
1.1	7/28/11	J.Bates	New field available for letter date
1.2	8/30/12	J.Bates	File location for query data file; differentiate from one-by-one procedure; rename
1.3	3/7/13	J.Bates	Resending
1.4	5/14/13	J.Bates	Participant copy is separate merge document; update file reference names

Obtaining Signed HIPAA from Dana Farber-Age of Majority

Background

We must obtain a signed LTFU medical release (HIPAA) from every Dana Farber (inst code 05) study participant before Dana Farber will release medical records to us. If the survivor has attained the age of majority before we obtain a signed medical release, we also re-consent the survivor while obtaining the medical release. To do this, we use a modification of the Age of Majority informed consent letter (originally designed as the cover letter for the expansion followup survey) to send the HIPAA form. While reconsent can be provided verbally (by phone), or by returning the signed medical release, HIPAA medical release can only be provided by returning the signed form. Refusing to sign the LTFU medical release does NOT constitute a refusal to participate in the study. This procedure outlines document production and database tracking.

Procedures

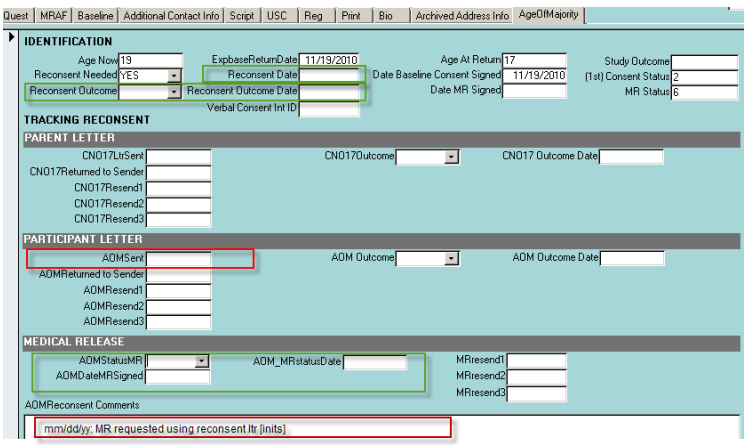
This procedure refers to documents located in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\Consent Resends\DanaFarber 2010 ff\MERGEdocuments\DFCI MR only**.

Generate a list of Dana Farber cases needing the signed medical release who ALSO need to be reconsented (qry_JB_Need_MR_DFCI), saving the file in the above location. For those needing to be reconsented (identified in the "Need Reconsent" column):

1. Mail merge and print the following
   a. ReconsentLtrToSubjectNowatAgeofMaority-Merge Fields, filtering for cases where NeedReconsent = "YES".
   b. LTFU HIPAA Living-MergeFields with Contact InfoSheet (staple the 2 pages together)
   c. EnvelopeOnly-MergeFields.
2. Print LTFU HIPAA Living-ParticipantCopy.pdf

3. Assemble the package with the letter, the HIPAA with Contact Sheet, a #9 return envelope with the MailStop 735 sticker, and participant copy. Insert into the addressed envelope.

4. After setting materials out for mail pickup, record the event in the Expansion Tracking database:
   a. On **Baseline** tab,
      i. Record mailing date in MR Letter Date *if this field is blank.*
      ii. Record note in Tracking comments: "mm/dd/yy: MR requested using the reconsent letter [inits]"
   b. On the **AgeOfMajority** tab,
      i. In the AOMSent field, record the letter mailing date
      ii. In AOM Reconsent Comments, record note: "**mm/dd/yy: MR requested using the reconsent letter prior to survey mailing [inits]**"



5. When the AOM Medical Release outcome is obtained (form returned in the mail)
   a. Date stamp the document in the upper right corner
   b. Use any information provided on the contact update sheet to update the contact information (as per usual procedure)
   c. On the **AgeOfMajority** tab
      i. In the **IDENTIFICATION** section,
         1. In ReconsentDate, enter the date the respondent provided on the signed MR
         2. In ReconsentOutcome, select 1 (Consented) if the survivor signed, or 2 (LAR consented) if the parent or LAR signed the MR. (If participant notified us of refusal, select 7 Participant refused)
         3. In Reconsent Outcome Date, enter the date the document was received

      ii. In the **MEDICAL RELEASE** section,
         1. In AOMStatusMR, select '1' for a signed medical release or '7' for a refused medical release
         2. Enter the date received in AOM_MRstatusDate
         3. IF participant did not refuse, then in AOMDateMRSigned, enter the date the individual wrote on the MR. (If no date was provided, date-stamp the form with the current date and enter the current date in AOMDateMRSigned)

   d. Initial the top of the signed MR with your initials.
   e. File a color photocopy of the signed release in the Dana Farber data manager pending folder, and log the CCSSID in the **!DanaFarber-register of CCSSIDs sent to datamanager.xls** (**z:\sjshare\SJcommon\ECC\CCSS\Jerry\DanaFarber-HIPAA authorization**)
   f. File the original signed HIPAA in the *Signed HIPAA* file drawer.

Revision Record Printed 2/19/2013 2:18 PM

(230) Current Filename:		Obtaining Signed HIPAA for Dana Farber Age of Majority ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/19/13	J.Bates	Initial Development

Online Registration of Verbal HIPAA Authorizations

Background

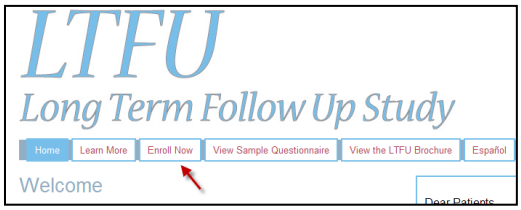
This procedure describes the online registration of a verbal HIPAA authorization obtained during Expansion Cohort recruitment and outlines what to do if the recruitment website times out before the online data entry process is completed. The process for obtaining a verbal HIPAA and its subsequent database data entry is covered in the SOP titled **Expansion Recruitment Process for Survey Interviewers**.

IMPORTANT: Verbal HIPAAs obtained with participants from Riley Hospital (institution 24) should NOT be registered online. Instead, see the SOP titled **Verbal HIPAA Authorization Process for Riley (institution 24).**

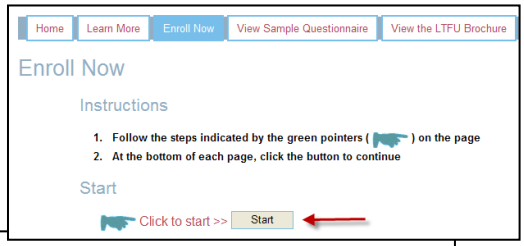
Procedures

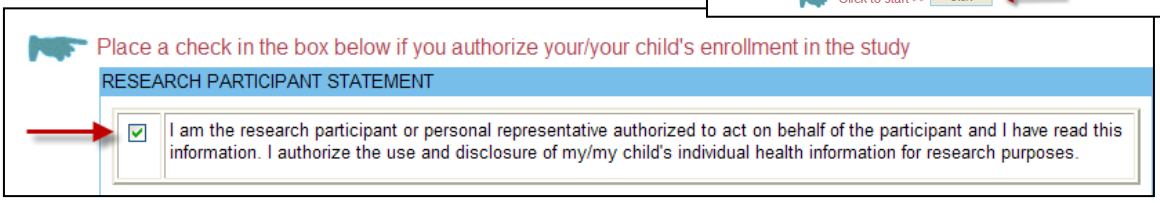
ONLINE HIPAA:

NOTE: Skip this step for Riley (institution 24) cases. Instead, see the SOP titled **Verbal HIPAA Authorization Process for Riley (institution 24)**.



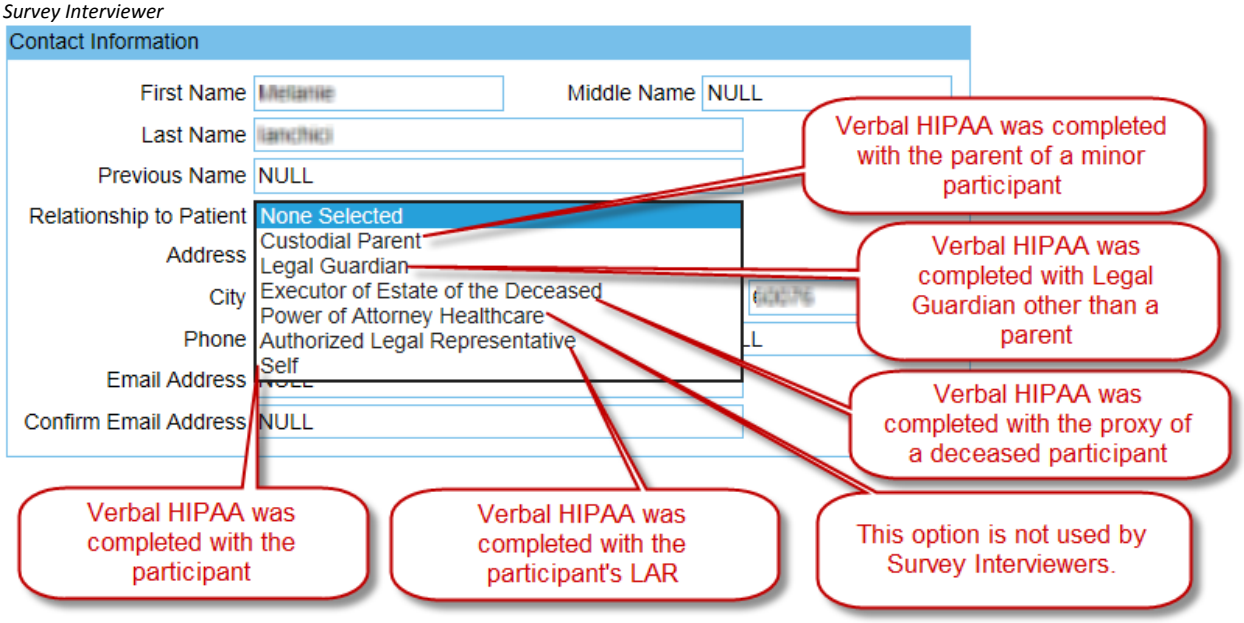
1. Read approved script and verbal HIPAA.
2. If the participant agrees to participate, do one of the following, as appropriate:
   A. Proceed to the questionnaire site to complete the questionnaire with the participant or, if appropriate, transfer the caller to another Survey Interviewer (SI) to complete the questionnaire.
   B. Set-up an appointment to complete the telephone survey.
   C. Remind the participant that they can complete the questionnaire using the booklet they will receive.
   D. Offer to email the link so that the participant can complete the baseline survey online.
3. Go to www.longtermfollowup.org.
4. Login as the participant.
5. Click the **Enroll Now** button, then click the **Start** button.
6. Scroll to the bottom of the HIPAA page.
7. Mark the checkbox beside the **I am the research participant …** statement, and then click **Continue**.





8. Enter the name and contact information for *the person who is providing the HIPAA authorization*, and then click the **Continue** button [Step 2 of 4 on the online HIPAA form].

Survey Interviewer



9. Review the information, and then click the **Continue** button. 

Online HIPAA: Time-Out During the Verbal HIPAA Data Entry Process

NOTE: Skip this step for Riley (institution 24) cases. Instead, see the SOP titled **Verbal HIPAA Authorization Process for Riley (institution 24)**.

If the recruitment website time-outs before the data entry is completed (e.g., The SI is interrupted during the online data entry process, the system exits, and upon re-entry the SI is directed to the baseline survey website.), do the following:

1. Ensure that all the information that was confirmed with the participant while on the phone is entered in the CCSS Recruitment database. See the SOP titled **Expansion Recruitment Process for Survey Interviewers** for details.

2. In the **Comments** field of the Recruitment database's Quest tab, add a dated message with your SI ID. For example: *"6/24/2015: Gained verbal HIPAA with participant. Recruitment website timed out during data entry. Unable to key in… [New address, telephone, name change, etc.]. [162]."*

3. The following day after 10am, check the Expansion Tracking database to see if the participant rolled over from the Recruitment database.
   A. If the Participant did not roll over into Expansion Tracking, send an email to the CRAs and copy the Call Center Coordinator and LSI team. Indicate the CCSSID number in the Subject bar and in the body of the email, explain what happened, and include the data that was not entered due to the website time-out.
   B. If the Participant DID roll over into Expansion Tracking:

i. Review the data on the Quest tab to determine what information needs to be updated.
ii. Send an email to the CRAs and copy the Call Center Coordinator and LSI team. Indicate the CCSSID number in the Subject bar and body of the email, explain what happened, include the data that was not updated due to the website time-out, and advise that the participant DID roll over.

Revision Record Printed: 10/31/2016 9:01 AM

Current Filename:		Online Registration of Verbal HIPAA Authorizations ver 2_6.docx	
Revision No.	Date	Responsible Author	Change Description
1	9/10/10	A. McDonald	Initial Development
1.1	1/4/11	J.Bates	Clarify resend request; document preparation
1.2	6/28/11	J.Bates	Remove 3-verbal HIPAA INST MR source
1.3	9/15/11	D. Rinehart	Modify Steps 4 and 5
1.4	11/30/11	D. Rinehart	Added Step 7
1.5	4/30/12	A. McDonald	Added Background section
2.0	5/4/12	J.Bates	Removed sending Participant Copy SOP to separate doc
2.1	7/11/12	M. Jackson/B. Carson	Revised Background for institution 24 (Riley)
2.2	8/17/12	Procedure Team	Procedures for incomplete online data entry added
2.3	7/31/13	R. Massey	Content Update
2.4	2/27/14	R. Massey	No online option for Spanish surveys, content & format update
2.5	7/10/15	R. Massey	Updated title, removed procedures outlined in separate SOP
2.6	10/26/2016	A. Cobble	Content update, added Contact Information screen shot

Ordering CCSS Call Center Appointment Calendars

Background

All Call Center appointments with CCSS participants are logged and tracked on large appointment calendars posted in the Call Center. These calendars are posted for 2 months at a time: the current month and the month following the current month. Used calendars are rolled tightly and stored in file cabinet 1.

The Call Center appointment calendars are ordered 3 times per year. A Lead Survey Interviewer (LSI) places the order when the last month in stock is posted.

Procedures

1. The LSI will add a reminder to his/her Outlook calendar to place the order in the first week of the month when only one calendar will be left in stock. Currently the orders are placed in the following months:

    - First week of December for the following calendars:
      January, February, March, April

    - First week of April for the following calendars:
      May, June, July, August

    - First week of August for the following calendars:
      September, October, November, December

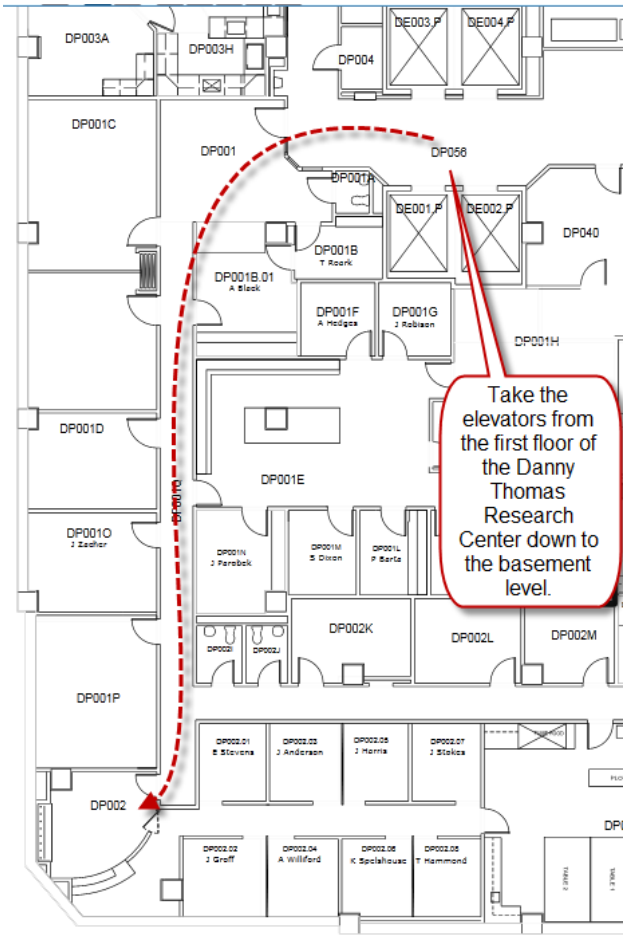
2. When the last calendar in stock has been posted, the LSI will email an order for the next four months to the Graphic Arts Coordinator in Biomedical Communications (BMC). The order should be charged to Cost Center 0400.

3. When the order is complete, BMC will notify the LSI via email that the calendars are ready to be retrieved.

4. The LSI will notify the Call Center Coordinator that they are leaving the Call Center to retrieve the calendars.

5. The calendars can be retrieved in room DP002 in the Danny Thomas Research Center.

6. The LSI will store the rolled calendars in the overhead storage at his/her workstation, posting the current and subsequent months and filing the expired month in cabinet 1.



Revision Record

Printed 12/23/2014 11:28 AM

[ ] Current Filename:		Ordering CCSS Call Center Appointment Calendars v1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	7/9/13	D. Rinehart, B. Carson, R. Massey	Initial Development
1.1	12/19/14	R. Massey, A. Oyuela	

Outcome and Tracing Code Guidelines

Background

Outcome and tracing codes are used in the participant tracking databases to note (a) the outcome associated with a questionnaire; (b) the outcome associated with the overall study; and (c) tracing (address and phone number) status. Although the use of the codes is often situation-specific, general guidelines are provided here to enhance consistency. This document presents guidelines and illustrates where codes may be located on various forms.

Tracing Codes

- Used when a participant has a "bad" or unknown address and/or phone number
- Denotes what information is needed or when a survey can be resent.
- Usually located on the main participant page in the database. This field is often "linked" to a tracing field on a questionnaire-specific page in the database. Thus if you update one of the fields, the other one will be updated too.
- Tracing codes are also called address codes.
- Example Tracing codes:
    - 13 – Needs tracing
    - 18 – Search new address
    - 19 – Disconnect (no phone number)
    - 82 – Resend survey
    - 83 – Resend newsletter
    - 84 – Temporarily away

Outcome Codes

- Two types of outcome codes. These are used indicate the "status" of a participant with regard to completing (a) a specific questionnaire or (b) the study.
- The Outcome code for a questionnaire is located on the database form associated with that questionnaire.
- Common Questionnaire Outcome codes are:
    - 7: Refused
    - 10: Ineligible
    - 11: Parental refusal
    - 25: Unavailable
    - 31: Language
    - 38: Deceased
    - 41: 2nd party completion
- The Outcome code associated with the overall study is in different locations depending on the database and participant.
- Common Study (Final) Outcome codes are:
    - 10: Ineligible
    - 31: Language
    - 37: Refused all else
    - 38: Deceased
    - 40: Wants newsletters but no surveys

Examples

The post office returns a MHQ as undeliverable:

- Enter tracing code 18 (Search new addr)

What if there is already a tracing code such as 19 (disconnect)?

- Change to a 13 (Needs Tracing)

A blank FU07 is returned with a note – my son (the participant) died …..

- Update Alive/Dead status
- Enter a 38 in both Outcome fields

A blank MHQ returned with a note – I don't want to do this one

- 7 (Refused) in MHQ Outcome
- Leave Study Outcome blank

A completed Sib FU07 is returned with a note – I don't want to do this anymore

- Leave Sib FU07 Outcome blank (because questionnaire was completed)
- 37 (Refused all else) in Study Outcome

A blank FU07 is returned with a note – take me off this study

- 7 (Refused) in FU07 Outcome
- 37 (Refused all else) in Study Outcome

If we find out a participant has expired during the Expansion Baseline Questionnaire period, typically do not initially enter a "38" in the Baseline or Study Outcome fields because we contact the parents for an interview

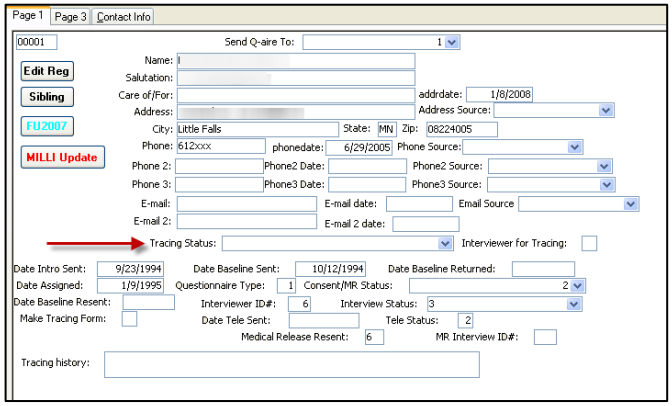
- Do update Alive/Dead status
- 38's will be entered in outcome fields after questionnaire completion/refusal

You get a call or receive an email from an Expansion participant's parent saying their child has died, and therefore, do not need to do the survey

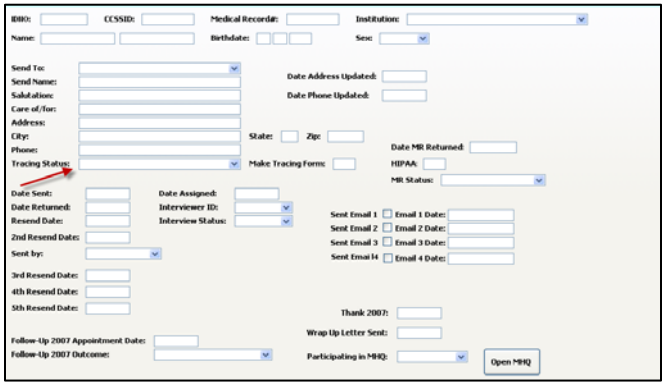
- Open death data form; Code alive/dead status as 2; Enter date of death and other pertinent information
- Do <u>not</u> code 38 in Baseline or Study Outcome fields (the interviewers will call the participant's parents to try to do a brief phone survey)

Tracing and Outcome Code Locations

Registration Database (Original Cohort) "Case" Tracing Codes: *Quest Tab*

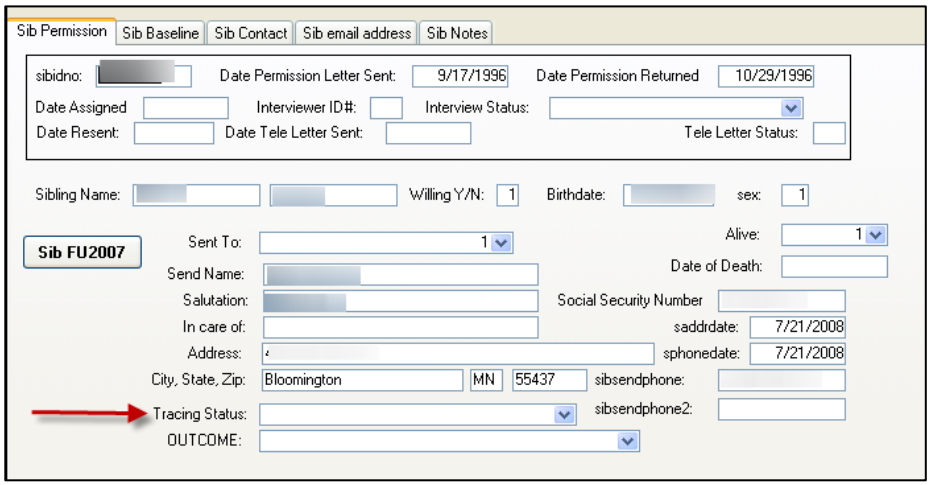


FU2007 Form

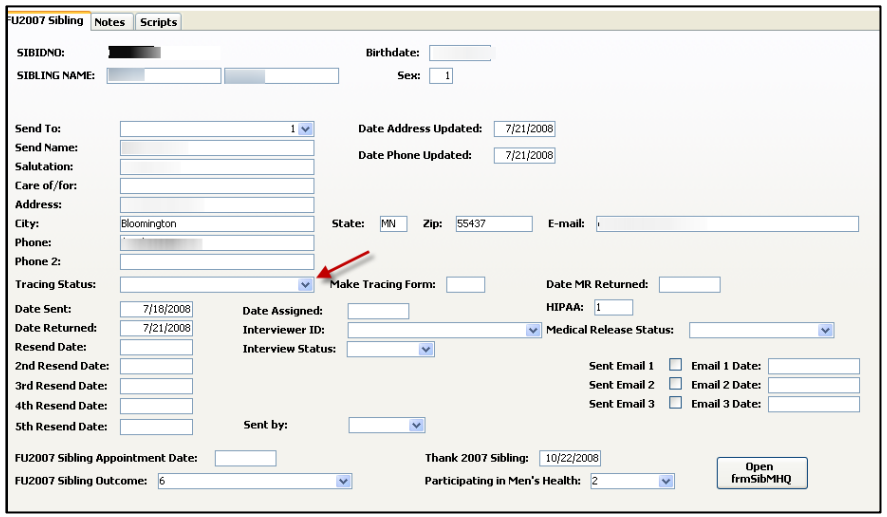


Registration Database (Original Cohort) "Sibling" Tracing Codes

Sib Permission Tab (Main Page)



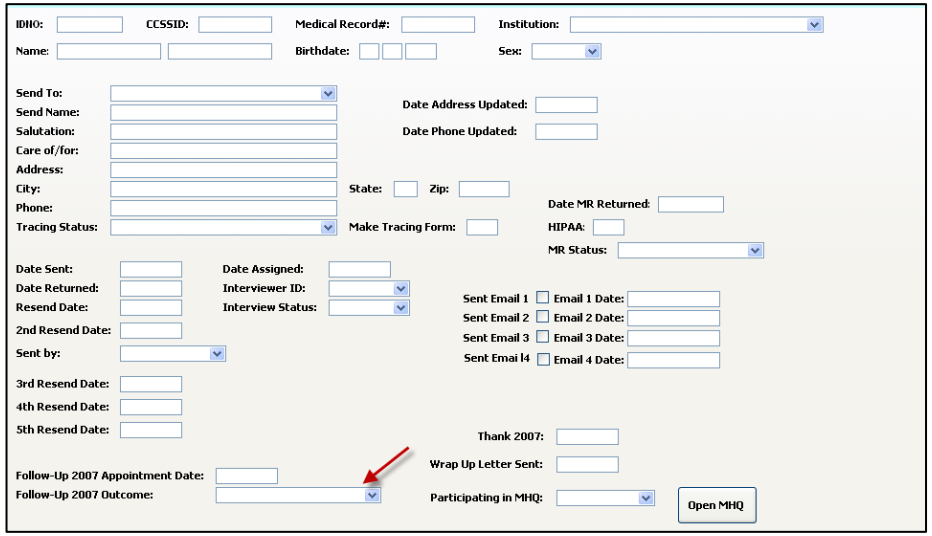
Sib FU2007



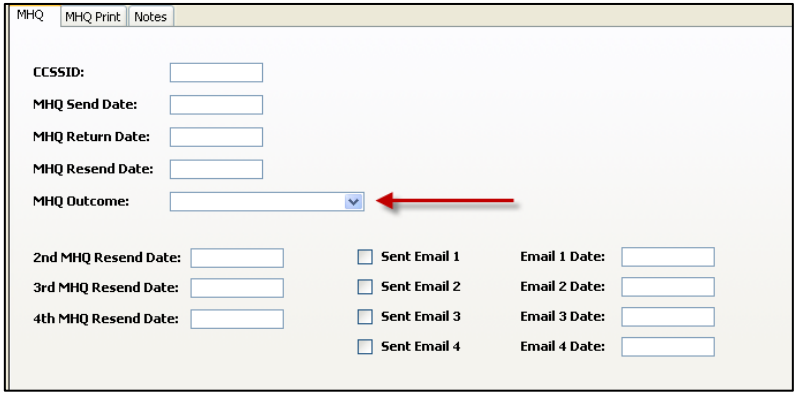
Registration Database Questionnaire Outcome Codes

(Case is shown; Sibling is Similar)

FU07 Form

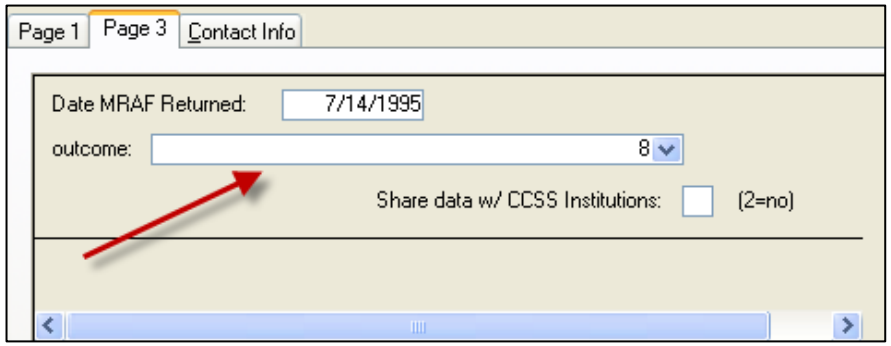


MHQ Form



Registration Database "Case" Study Outcome Code

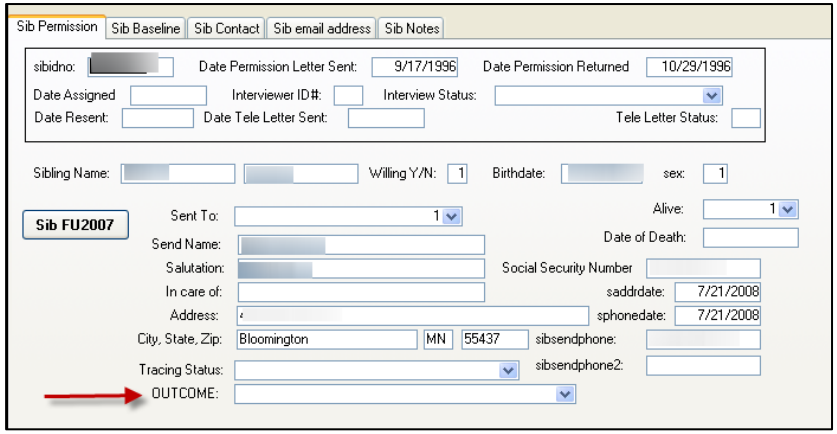
Page 3 of Quest Tab



[space intentionally blank]

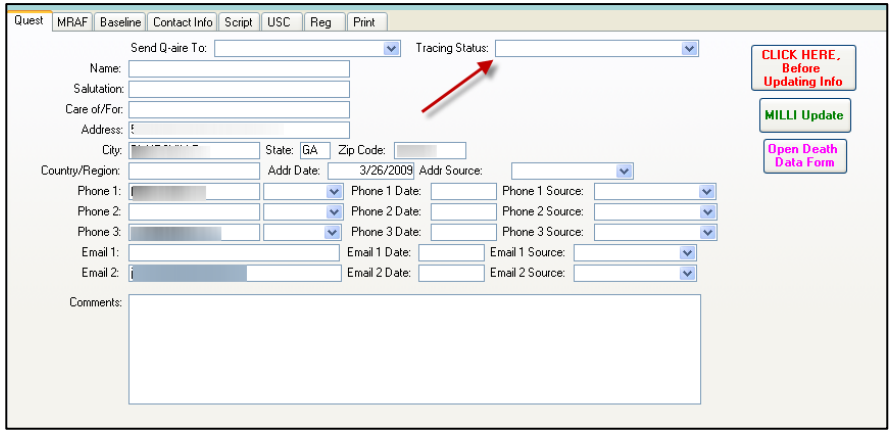
Registration Database "Sibling" Study Outcome Code

Sib Permission Tab



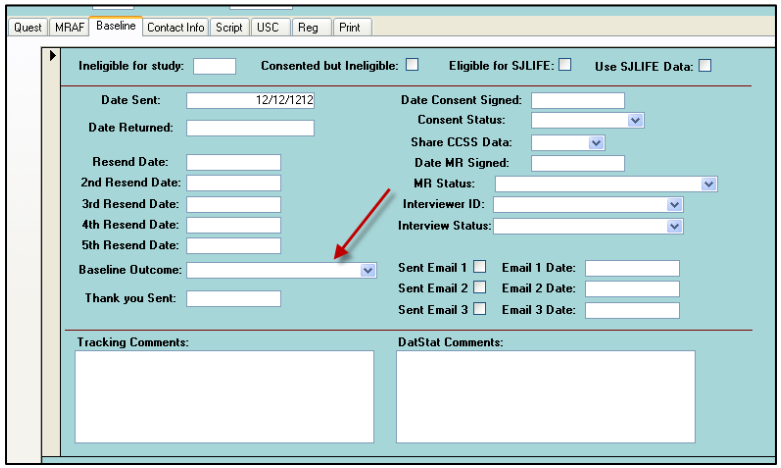
Expansion Database "Case" Tracing Code

Quest Tab



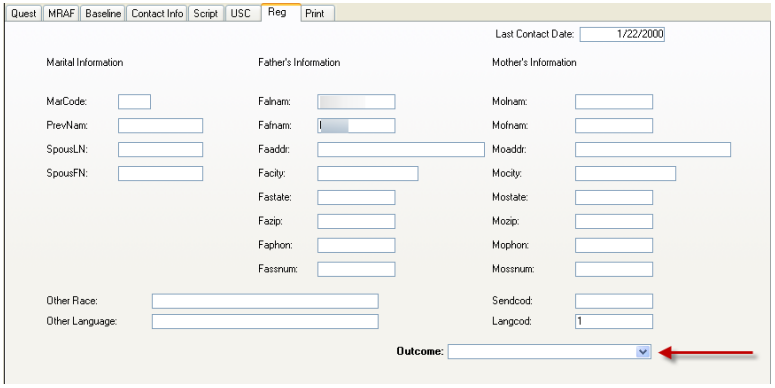
Expansion Database "Case" Questionnaire Outcome Code

Baseline Tab



Expansion Database "Case" Study Outcome Code

Reg Tab



EXPANSION DATABASE

Expansion Outcome Codes
(Reg tab)

7	refused
8	Lost to follow up at baseline
10	Ineligible
11	Parental Refusal
25	unavailable
31	Language
37	Refused all else
38	Deceased
40	Wants newsletters but no surveys

Expansion Baseline Outcome Codes (Baseline tab)

2	Died Before Baseline
6	Passive Refusal
7	Refused
8	Lost to follow up at Baseline
10	Ineligible
11	Parental Refusal
18	Lost since Baseline, traced
25	Unavailable
31	Language
37	Refused All Else
38	Deceased
39	Survey Pending or in Tracing
40	Wants news letters but no surveys

Expansion Tracing Codes (Tracing Status) (Quest tab)

13	Needs tracing
18	Search new addr
19	Disconnect
20	Survey returned w/o new addr
21	Needs telephone letter
81	Newsletter returned w/o new addr
82	Resend survey
83	Resend newslwtter
84	Temporarily away
85	Resend survey & newsletter

Expansion Script Outcome Codes
(Script Tab)

7	Refused
10	Incomplete
12	Complete
19	Disconnect
25	Unavailable
38	Deceased

REGISTRATION DATABASE

Registration Database Outcome Codes

2	died before baseline
6	passive refusal
7	refused
8	Lost to follow up at baseline
9	Eligible, but not sending out q'air
10	Ineligible
11	Parental Refusal
12	Completed baseline, refused all els
13	Completed baseline, moved out of country
14	Died after completing baseline
16	Did baseline, no one left to contac
18	Lost since baseline, traced
19	Died after followup questionnaire
21	Refused all else after followup
25	unavailable
26	didn't do FU; in tracing
29	died after FU2
30	old LTFU trying new address
31	Language
32	Refused all else after FU2
33	Refused all else after FU3
34	Died after FU3
35	didn't do FU2;in tracing
36	didn't do FU3 pending or in tracing
37	Refused all else
38	Deceased
39	Survey pending or in tracing
40	Wants newsletters but no surveys
41	2nd party completion
82	Resend

Registration FU2007 Outcome Codes

6	passive refusal
7	refused
25	unavailable
38	Deceased
39	Survey pending or in tracing

Registration FU2007 *Tracing Codes*

13	Needs Tracing
14	2001 Newsletter bad address
15	Moved after baseline completed
17	FollowUp Questionnaire Returned
18	Search new addr
19	Disconnect
20	Survey returned w/o new addr
21	Needs Telephone Letter
81	Newsletter returned w/o new addr
82	Resend survey
83	Resend newsletter

Registration *Tracing Codes* (Page 1)

13	Needs Tracing
18	Search new addr
19	Disconnect
20	Survey returned w/o new addr
21	Needs Telephone Letter
81	Newsletter returned w/o new addr
82	Resend survey
83	Resend newsletter
84	Temporarily away
85	Resend survey & newsletter
84	Temporarily away
85	Resend survey & newsletter

2007 Script Outcome

7	Refused
10	Incomplete
12	Complete
19	Disconnect
25	Unavailable
38	Deceased

Sibling…

Sibling Outcome Code

2	died before baseline
6	passive refusal
7	refused
8	Lost to follow up at baseline
9	Eligible, but not sending out q'air
10	Ineligible
11	Parental Refusal
12	Completed baseline, refused all els
13	Completed baseline, moved out of country
14	Died after completing baseline
16	Did baseline, no one left to contac
18	Lost since baseline, traced
19	Died after followup questionnaire
21	Refused all else after followup
25	unavailable
26	didn't do FU; in tracing
29	died after FU2
30	old LTFU trying new address
31	Language
32	Refused all else after FU2
33	Refused all else after FU3
34	Died after FU3
35	didn't do FU2;in tracing
36	didn't do FU3 pending or in tracing
37	Refused all else
38	Deceased
39	Survey pending or in tracing
40	Wants newsletters but no surveys
41	2nd party completion
82	Resend

Sibling FU2007 Outcome Codes

6	passive refusal
7	refused
25	unavailable
37	Refused all else
38	Deceased
39	Survey pending or in tracing
40	Wants newsletters but no surveys

Sibling Tracing Codes (Sib Permission Tab)

13	Needs Tracing
14	2001 Newsletter bad address
15	Moved after baseline completed
17	FollowUp Questionnaire Returned
18	Search new addr
19	Disconnect
20	Survey returned w/o new addr
21	Needs Telephone Letter
81	Newsletter returned w/o new addr
82	Resend survey
83	Resend newsletter
84	Temporarily away
85	Resend survey & newsletter

Sibling FU2007 Tracing Codes

13	Needs Tracing
19	Disconnect
20	Survey returned w/o new addr
21	Needs Telephone Letter
81	Newsletter returned w/o new addr
82	Resend survey
83	Resend newsletter
84	Temporarily away
85	Resend survey & newsletter

Sibling Tracing Codes (Sib Baseline Tab)

13	Needs Tracing
14	2001 Newsletter bad address
15	Moved after baseline completed
17	FollowUp Questionnaire Returned
18	Search new addr
19	Disconnect
20	Survey returned w/o new addr
21	Needs Telephone Letter
81	Newsletter returned w/o new addr
82	Resend survey
83	Resend newsletter
84	Temporarily away
85	Resend survey & newsletter

Revision Record

Printed 7/9/2012 3:06 PM

Current filename:		Outcome and Tracing Code Guidelines ver 1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/29/09	A. McDonald	Initial Development
1.1	10/23/09	J. Bates	Add code lists/ screens
1.2	9/23/10	J.Bates	formatting

PAQOL: Scanning, Verifying and Data Review

Background

We assist the PAQOL study by scanning, correcting and verifying four (4) assessment logs and scanning and correcting data for five (5) of their study instruments.

The 4 assessment logs that are scanned and verified include: (1) **PAQOL New Weekly Exercise Log**; (2) **PAQOL Weekly Exercise Log Control**; (3) **PAQOL-PT Session Log**; (4) **PAQOL-PT Session Log Control.**

The 5 instruments that are scanned and the data corrected are also referred to as the T3 documents and are titled: (1) **PAQOL CHQ-CF44**; (2) **PAQOL CHQ-PF50**; (3) **PAQOL-CRF**; (4) **PAQOL BREQ-2 Child**; and (5) **PAQOL BREQ-2 Parent**.

For all instruments, the PAQOL study coordinator cleans them and delivers them to the designated CRA 2. The PAQOL study coordinator will deliver the surveys to the CRA 2 as they arrive via mail. The CRA 2 logs them into a tracking database, assigns the tasks to a team member, and enters a target completion date. During these processes, instruments are housed in a designated file cabinet on the 5th floor. The CRA 2 returns them to the PAQOL study coordinator when tasks are completed.

Procedures

Obtaining/Scheduling/Returning

1. The PAQOL study coordinator delivers the surveys to the CRA 2 assisting with the study.
2. The CRA 2 logs each instrument into the Excel spreadsheet PAQOL Scanning, Correcting and Verifying Tasks Assignments Log.xlsx located on the server at the following location: Z:\SJShare\SJCOMMON\ECC\CCSS\PAQOL
3. The CRA 2 notes the team member responsible for the tasks and includes the date of receipt and the target date the work is to be finished.
4. The CRA 2 puts the instrument(s) in the project's hanging folder in the designated file cabinet..
5. The assigned team member conducts the required processes and updates the Assignments Log spreadsheet as the tasks are completed.
6. When all processes are complete and the spreadsheet updated, the team member (s) will notify the CRA 2.
7. The CRA 2 will review and return to the PAQOL study coordinator.

Scanning, Verifying and Committing for 4 Assessment Logs

Scanning

1. Select an assessment for scanning (usually 3 pages at a time – front and back).
2. Open Teleform *Scan Station, Reader, and* Verifier. All 3 must be open.
3. In Scan Station window, select the appropriate survey type from the drop down menu:
   a. PAQOL – New Weekly Exercise Log
   b. PAQOL – Weekly Exercise Log Control
   c. PAQOL – PT Session Log
   d. PAQOL – PT Session Log Control

4. Once the questionnaire type is selected, go to File and select New Batch.
5. Place the surveys face up in the scanner, and click Start in the Scan Station window.
6. When all pages are scanned, click Accept. The Reader program will read the pages. When the status displays "Ready for Classification QC" click Process.
7. After the forms load, make sure the pages are displayed correctly. See the CCSS procedure **Scanning Expansion Baseline Questionnaires** in the SOP library for instructions on any corrections that need to be made (pages out of order, etc.)
8. Add a sticky note to the batch with the batch number.
9. Initial, date and mark "scanned" on the survey in the bottom left corner of the questionnaire.
10. It is preferable to verify surveys immediately after scanning, but if you cannot, place the scanned questionnaires in the appropriate project folder in the file cabinet.

Verifying and Committing

1. Open Teleform *Verifier* and *Reader*
2. From the Utilities menu, select Batch Management Dialog.
3. Locate the questionnaire batch number in *Verifier*. The status of the survey should read: "Ready for Correction." Click the Process button.
4. Verify using standard CCSS procedures ensuring that the answers on the questionnaire are marked correctly in Teleform *Verifier*.
5. When verifying PAQOL logs, it may be difficult to read the physical therapists' writing. When this occurs, use "illegible" to replace the written text. Flag these surveys with a post it so the PAQOL study coordinator can follow up with the physical therapist if necessary.
6. Use the **PAQOL Scanning and Verifying Discrepancy Log** when you find responses on the questionnaire that are not clear (e.g. more than one response selected). The log is found: Z:\SJShare\SJCOMMON\ECC\CCSS\PAQOL. Flag the discrepancy on the survey and in the log enter the participant i.d. #, the assessment type, the problem, the page and question number and the resolution (response chosen). Save the log after each entry.
7. When you reach the end of the survey, the Verifier prompt "Save corrections to the results file?" will appear. Click OK.
8. The status of the survey will now read "Ready for Data Review."
9. The teleform verifier will move through the verification process, and will stop on the fields that need to be verified.
10. Check the values to be sure they have been scanned correctly and make corrections when necessary.
11. After the verification process is complete, you will commit the batch. Initial and date the survey in the bottom left corner of the questionnaire and write "Verified."
12. Send an email to the CRA 2 that the data is complete and put the finished surveys in the designated project folder.
13. Update then PAQOL Scanning and Verifying Assignments Log.xlsx with the date the assignment was completed.

Scanning and Data Correction for 5 Study Instruments

Scanning The same Scanning steps listed above are followed for the 5 study instruments except in:

3. In Scan Station window, select the appropriate survey type from the drop down menu:
   a. PAQOL CHQ-CF44
   b. PAQOL CHQ-PF50
   c. PAQOL CRF
   d. PAQOL BREQ-2 Child
   e. PAQOL BREQ-2 Parent

Data Correction

1. Open Teleform *Verifier* and *Reader*
2. From the Utilities menu, select Batch Management Dialog.
3. Locate the questionnaire batch number in *Verifier*. The status of the survey should read: "Ready for Correction." Click the Process button.
4. Verify using standard CCSS procedures ensuring that the answers on the questionnaire are marked correctly in Teleform *Verifier*.
5. When verifying PAQOL logs, it may be difficult to read the physical therapists' writing. When this occurs, use "illegible" to replace the written text. Flag these surveys with a post it so the PAQOL study coordinator can follow up with the physical therapist if necessary.
6. Use the **PAQOL Scanning and Verifying Discrepancy Log** when you find responses on the questionnaire that are not clear (e.g. more than one response selected). The log is found: Z:\SJShare\SJCOMMON\ECC\CCSS\PAQOL. Flag the discrepancy on the survey and in the log enter the participant i.d. #, the assessment type, the problem, the page and question number and the resolution (response chosen). Save the log after each entry.
7. When you reach the end of the survey, the Verifier prompt "Save corrections to the results file?" will appear. Click OK.
8. The status of the survey will now read "Ready for Data Review."

Data Review and Committing these instruments will be conducted by the PAQOL Study Coordinator.

Completing

1. Send an email to the CRA 2 that the process has been completed and put the finished surveys in the designated project folder.
2. Update then PAQOL Scanning, Verifying and Data Review Assignments Log.xlsx with the date the assignment was completed.

[271] Current Filename:		PAQOL Scanning, Verifying and Data Review ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
	4/30/12	Harrison/Williams	Initial Development

Participant Status and Call Tracking Across Projects

Background

A participant can be in multiple CCSS-related studies (i.e., ancillary, saliva collection, etc.) at the same time. We do not yet have a single database that tracks study participation/contact at the individual participant level. There are two important interim measures that we use to make sure we do not call a person who should not be contacted and to also see prior call information.

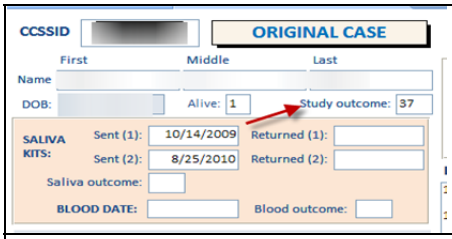
Procedure

Before calling a participant, it is important that you check the **overall CCSS study status** field as well as the **prior call history**. There are several other pre-call checklist items to review, but these two items are specifically aimed at reducing participant burden.

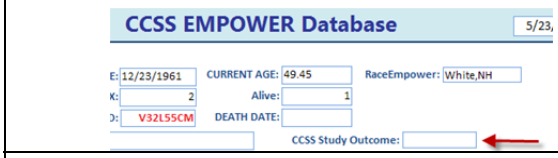
Overall CCSS Study Status: Outcome codes

1. Each primary CCSS database (i.e., Reg, Expansion Tracking) has an outcome field to show ***overall study participation status***. ALWAYS check the overall study outcome to see (a) if the participant has refused (overall) participation or (b) if there is another reason the person should not be contacted (see the comprehensive document **Outcome and Tracing Code Guidelines** for more information).
2. Ancillary study databases DO display "overall" study outcome from the Reg or Expansion
3. Ancillary study tracking databases.
   a. When the overall study outcome is CHANGED in the primary database, the change will automatically display in the Ancillary Study database.
   b. BUT! Changing the overall study outcome in the primary database does NOT update the outcome code for each ancillary study.
4. Keep in mind that someone can refuse participation in ancillary study, but still continue in the overall LTFU study (as well as other ancillary studies).
5. Look at BOTH the overall study outcome AND the individual ancillary study outcome codes before contacting a person. (Sample screen shots from selected ancillary studies illustrate where the overall study outcome is located.
6. In general, if the overall study outcome is NOT BLANK, then you need to investigate what the outcome code means before contacting someone.

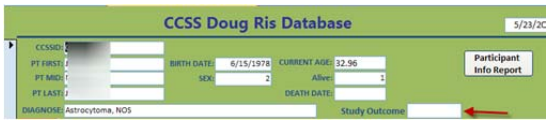
Saliva Calls Database



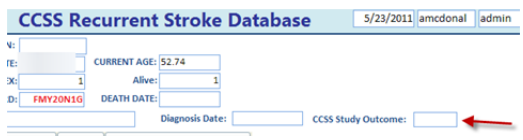
EMPOWER



Low Grade Brain Tumor Study



Recurrent Stroke



Phone logs

1. We use a master call log for EACH CCSS participant to track ALL phone calls made AFTER they have been recruited to the LTFU study. (Expansion RECRUITMENT calls are logged using the Recruitment database's built-in call logs.)

   a. This prevents us from calling bad numbers, calling a person too many times, and calling a person who is "on-hold" or has refused further participation in CCSS. You should check this log before calling a CCSS participant.

   b. If you cannot locate a log, then you may need to create one (check with Bryan, Melanie, or Dayton in this case; also see the procedure called XXX).

   c. Remember that expansion **recruitment** calls are NOT entered in these logs because (a) the Recruitment Database has built-in call logs and (b) the people we are recruiting are not yet participants!

   d. All other calls should be logged using the master call logs. The call logs are here:
      - **Z:\SJShare\SJCOMMON\ECC\Interviewers\Original Cohort Call Logs - Reg db**
      - **Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Participant call logs**

***Note about St. Jude Life**

- Former St. Jude patients (institution 15) may also be in the St. Jude Life study.
- You should also check the SJL database to see if a CCSS participant is in the database. If so, there may be updated contact information and/or relevant notes for review.

Revision Record Printed 7/10/2012 2:37 PM

Current Filename:		Participant Tracking Across Projects ver1_2.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development
1.1	4/30/12	A. McDonald	Content clarification and formatting

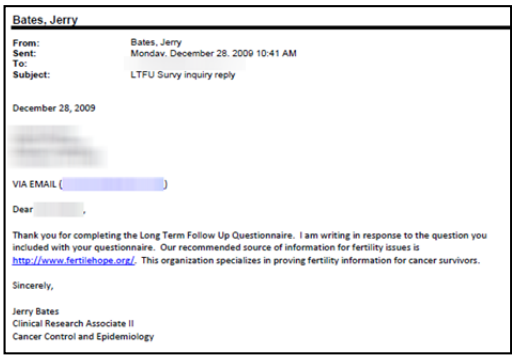
Patient Request Documents

Background

When participants request information on a survey or through the online system, the CRA2 reviews the request to determine whether information may be sent.

Procedure

1. If warranted, reply to the request.
2. Store a copy of the correspondence, identified by CCSSID, on the server, …\ECC\CCSS\Patient Request Documents
   a. If response is by email, consider printing the email to Adobe pdf, or composing in Word and saving the Word document.
   b. Include CCSSID in the filename.
   c. Sample list/letter:



Bates, Jerry

From: Bates, Jerry
Sent: Monday, December 28, 2009 10:41 AM
To:
Subject: LTFU Survy inquiry reply

December 28, 2009

[redacted]

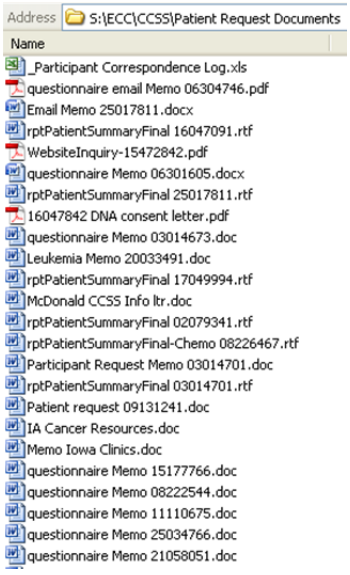
VIA EMAIL ([redacted])

Dear [redacted],

Thank you for completing the Long Term Follow Up Questionnaire. I am writing in response to the question you included with your questionnaire. Our recommended source of information for fertility issues is http://www.fertilehope.org/. This organization specializes in proving fertility information for cancer survivors.

Sincerely,

Jerry Bates
Clinical Research Associate II
Cancer Control and Epidemiology



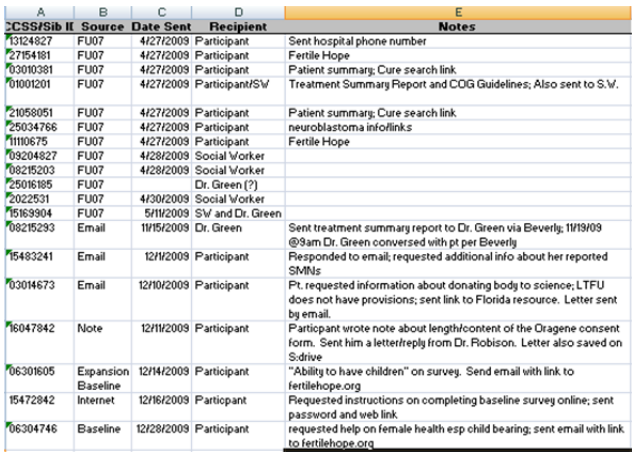
Address S:\ECC\CCSS\Patient Request Documents

Name

_Participant Correspondence Log.xls
questionnaire email Memo 06304746.pdf
Email Memo 25017811.docx
rptPatientSummaryFinal 16047091.rtf
WebsiteInquiry-15472842.pdf
questionnaire Memo 06301605.docx
rptPatientSummaryFinal 25017811.rtf
16047842 DNA consent letter.pdf
questionnaire Memo 03014673.doc
Leukemia Memo 20033491.doc
rptPatientSummaryFinal 17049994.rtf
McDonald CCSS Info ltr.doc
rptPatientSummaryFinal 02079341.rtf
rptPatientSummaryFinal-Chemo 08226467.rtf
Participant Request Memo 03014701.doc
rptPatientSummaryFinal 03014701.rtf
Patient request 09131241.doc
IA Cancer Resources.doc
Memo Iowa Clinics.doc
questionnaire Memo 15177766.doc
questionnaire Memo 08222544.doc
questionnaire Memo 11110675.doc
questionnaire Memo 25034766.doc
questionnaire Memo 21058051.doc

3. Update the "**_Participant Correspondence Log**" (same folder).
   a. Record CCSSID, source of inquiry, date response sent, individual to whom response was sent, and a brief note on what was sent.
   b. Sample:

   NOTE: Use this log to record referral actions (See Dr. Green example).



	A	B	C	D	E
	CCSS#/Sib ID	Source	Date Sent	Recipient	Notes
1	13124827	FU07	4/27/2009	Participant	Sent hospital phone number
2	27154181	FU07	4/27/2009	Participant	Fertile Hope
3	03010381	FU07	4/27/2009	Participant	Patient summary; Cure search link
4	01001201	FU07	4/27/2009	Participant/SW	Treatment Summary Report and COG Guidelines; Also sent to S.W.
5	21058051	FU07	4/27/2009	Participant	Patient summary; Cure search link
6	25034766	FU07	4/27/2009	Participant	neuroblastoma info/links
7	11110675	FU07	4/27/2009	Participant	Fertile Hope
8	09204827	FU07	4/28/2009	Social Worker	
9	08215203	FU07	4/28/2009	Social Worker	
10	25016185	FU07		Dr. Green (?)	
11	2022531	FU07	4/30/2009	Social Worker	
12	15169904	FU07	5/11/2009	SW and Dr. Green	
13	08215293	Email	11/15/2009	Dr. Green	Sent treatment summary report to Dr. Green via Beverly; 11/19/09 @9am Dr. Green conversed with pt per Beverly
14	15483241	Email	12/1/2009	Participant	Responded to email; requested additional info about her reported SMNs
15	03014673	Email	12/10/2009	Participant	Pt. requested information about donating body to science; LTFU does not have provisions; sent link to Florida resource. Letter sent by email.
16	16047842	Note	12/11/2009	Participant	Participant wrote note about length/content of the Oragene consent form. Sent him a letter/reply from Dr. Robison. Letter also saved on S:drive
17	06301605	Expansion Baseline	12/14/2009	Participant	"Ability to have children" on survey. Send email with link to fertilehope.org
18	15472842	Internet	12/16/2009	Participant	Requested instructions on completing baseline survey online; sent password and web link
19	06304746	Baseline	12/28/2009	Participant	requested help on female health esp child bearing; sent email with link to fertilehope.org

Revision Record

Printed 7/10/2012 1:23 PM

Current Filename:		Patient Request Documents ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/28/09	J.Bates	Initial Development

Posting Expansion Baseline Surveys Using Posting Database

Background

After Expansion Baseline surveys for cases are put in the mail, we post the mailing date and clear any resend codes that are on file. A special "posting" database has been created to facilitate this process. It archives the individual posting tables which provides an archive of the mailing lists, without leaving temporary posting tables in the main expansion tracking database. This procedure outlines posting the surveys using the special posting database.

Procedures

1. Use the excel file that lists all the expansion baseline surveys that are in the production run. (qry_JB_IdentifyResendCases).
2. Copy the CCSSID column onto a new sheet. Name the new sheet "_TEMP_ResendList"
3. Save and close the excel file.
4. Open the JB_Posting Tables_ExpansionTracking Resend Tables database (located on the server at **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\LOCAL COPY-DATABASES\!!JB-POSTING TABLES_ExpansionTracking Resend Tables.mdb**)
5. Import the "_TEMP_ResendList" sheet from your excel production file into a new table. If prompted, you DO want to replace the existing table.
6. From the list of Queries, locate and run **qry_Post_TEMP_ResendList**
7. This should list all the cases in the production run.
8. Review the list to identify which CCSSID *has had the most resends*. This tells you the "highest" number of resends that have been made for this group to date.
9. Change to the query's design view.
10. Modify the criteria for the query, such that ExpbaseDate, and each of the resend fields (expbaseresend, expbase2ndresend, expbase3rdresend, etc) up to and including the HIGHEST resend field used so far is set to **IS NOT NULL**
11. Set the criteria for the NEXT resend field to **IS NULL** (E.g., if the highest sent to date was 5thresend, you will set 6thresend to IS NULL).
12. View the query to be sure you set the criteria appropriately.
13. Change the query to an UPDATE query.
14. In the Update To row, set the UPDATE TO value to the mailing date, for the smallest field with the criteria IS NULL. Run the query. Note on your production schedule the number of cases that were at that resend level.
15. Clear the Update To value and change back to a Select query
16. Modify Criteria by changing criteria for next smaller resend date field from IS NOT NULL to IS NULL.
    a. Run the query and note the numbers.
    b. Change to an update query, and for that next smaller resend field (IS NULL), update it to the mailing date.
17. Continue to work backward toward the ExpbaseDate field, posting and noting the number being mailed at that resend level.
18. Return the query to a select query
    a. Clear all criteria
    b. View results to make sure each record has the current mailing date on its "highest" resend value.
19. Change the query one last time to an update query, setting the criteria for Addresscode = 82.
    a. For those records, update addresscode to NULL and the TracingDate field to NULL

b. Run the query
c. Change back to select query
d. Close the query without saving the changes.

20. In the list of tables, COPY the _TEMP_ResendList table. In the copy, add the date (mm-dd-yy format) to the end of the table name.

Revision Record Printed 7/2/2013 1:17 PM

[251] Current Filename:		Posting Expansion Baseline Surveys in Posting Database ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	7/2/13	J.Bates	Initial Development

Posting Incentive Transactions

Background

The incentive tracking database is designed to record the distribution and return of incentives (gift cards) and to maintain the inventory status for each card in an individual project. The project manager is responsible for posting transactions and maintaining the inventory in this database. A TRANSACTION is one of two types of activities for a card: Mailing it (distribution transaction), or recording that it was returned to us (return transaction). There can be multiple transactions for a single card over time (e.g., a given card could be mailed out the first time, then returned to sender, and later sent to a different person (and potentially returned to sender, and so on.)) The two-part New Transaction form is used both to post the transaction and to update the inventory record. Note that certain initial database set-up procedures are outlined fully in the Technical Reference for Incentive Gift Card Tracking, which is cross-referenced in this procedure.

Procedures

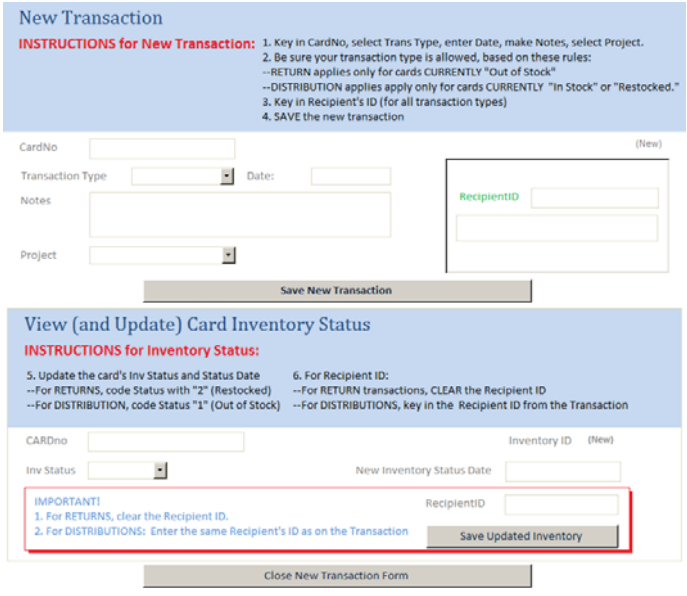
ABOUT DISTRIBUTIONS: When a large number of cards is distributed at the same time, it makes more sense to use update queries to add those transactions and update the inventory in a batch. (See **Technical Reference for Incentive Gift Card Tracking**.) But when only a few cards are going out at a time, it is easier to post the transactions on a one-by-one basis, using the New Transaction form interface. *NOTE: exception distributions (such as sending a second card via FedEx signature required) should ALWAYS be posted singly so you can document the situation fully. Batch posting does not accommodate adding transaction notes.*

ABOUT RETURNS: all returns need to be handled on a one-by-one basis, using the New Transaction form interface.

The NEW TRANSACTION FORM is divided into 2 sections. The first section (on top) deals with the individual transaction. The second section (on bottom) deals with updating the inventory status of the card specified in the transaction at the top of the form.

Posting a New Transaction

- Click **Post New Transaction** button from main menu.
- When using New Transaction form, you must know what type of transaction you are posting: distribution or return.
- After entering one transaction, you can enter another, by going to the next record. (Subsequent transactions can be a different transaction type.)
- When you finish posting transactions, click the Close New Transaction Form button.



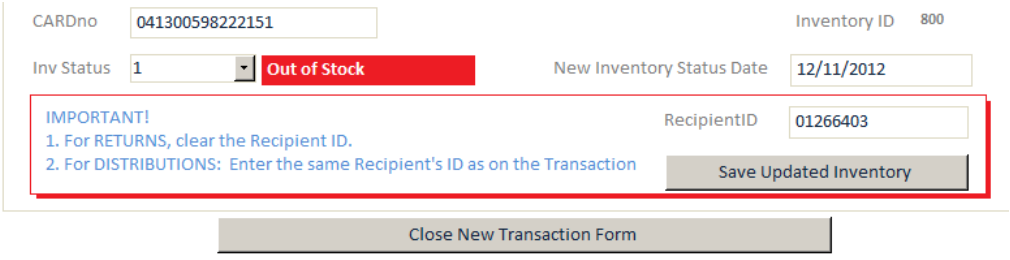
Lead CRA

Posting a DISTRIBUTION Transaction (Sending out a card)

1. STEP 1: In the TOP of the form:
    a. Key in the **CardNo** (from the face of the card)
        i. **Inv Status** for this card will display at the bottom of the form. *If it does not, then check your typing! You may have made a typo in entering the CardNo.*
        ii. Check the Inventory status of this card in the bottom of the form. At this point, the inventory status for this new DISTRIBUTION transaction should be either In Stock (0) or Restocked (2). (Cards that are Restocked are cards that have been sent out before, but then were returned to sender. Important to remember that you could not distribute a card that is Out of Stock!)

    b. Select the **Transaction Type 1 (Distribution)** from the dropdown box
    c. Key in the current date for (transaction) **Date**
    d. Enter any **Notes** needed
    e. Select the **Project** from the drop down.
    f. Key in the **RecipientID** (CCSSID). When you key in the CCSSID, the name will be displayed underneath. If no name appears or it is the wrong person, check for typos.
    g. Click the **Save New Transaction** button

2. STEP 2: In the BOTTOM of the form:
    a. Change **Inv Status** to **1 (Out of Stock)**



    b. Enter the return date in **New Inventory Status Date**
    c. Copy and Paste the Recipient ID from the TOP of the form into the **Recipient ID** in the bottom of the form.
    d. Click the **Save Updated Inventory** button

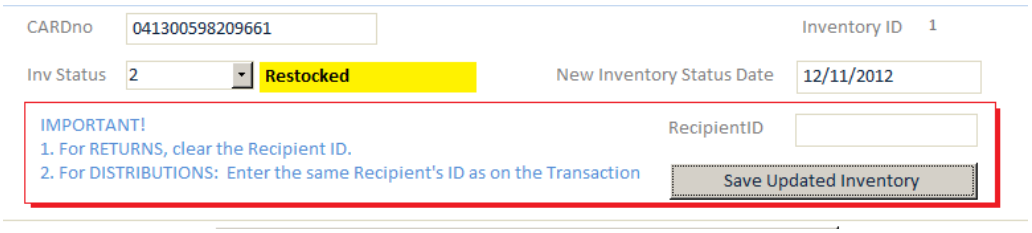
Lead CRA

Posting a RETURN Transaction (recording a card returned to sender)

1. STEP 1: In the TOP of the form
    a. Key in the **CardNo** (from the face of the card).
        i. The **Inv Status** will display at the bottom of the form. *If it does not, then check your typing! You may have made a typo entering the CardNo.*
        ii. ***At this point***, the inventory status for this new Return transaction should still be **1 (Out of Stock)** (A card that is in stock or restocked cannot be returned!)

    b. Select **Transaction Type 2 (Return)**
    c. Key in the return date in **Date**
    d. Add **Notes** (very important to document how it came back; e.g., returned to sender….)
    e. Select the **Project** from the dropdown
    f. Key in the **RecipientID** (CCSSID). You SHOULD be able to get this from the mailing label of the returned item. The system does NOT look up the CCSSID last associated with this card. (If you need to do that, you can do so manually, with care.) When you key in the CCSSID, the name will be displayed underneath.
    g. Click the **Save New Transaction** button

2. STEP 2: In the BOTTOM of the form
    a. Change **Inv Status** to 2 (Restocked)



    b. Enter the return date in **New Inventory Status Date**
    c. CLEAR the **RecipientID** from the *BOTTOM* of the form (Do NOT clear it from the top of the form!)
    d. Click the **Save Updated Inventory** button

ADDITIONAL NOTES

1. In order to post the distribution and return of the gift card incentives, the incentive tracking database needs to have been pre-loaded with the gift card numbers. The procedures for loading the gift cards is described in the **Technical Reference for Incentive Gift Card Tracking** as part of setting up a new incentive tracking database for a project.

2. If ADDITIONAL gift cards are procured for the project, they will also need to be added to the database. See **Adding New Cards to Inventory** in the **Technical Reference**.

3. Initially setting up the database for a project includes building a name table to provide a comprehensive list of the potential RecipientIDs and names from the master tracking databases.
    a. As new cases/siblings are added to the master tracking databases, you may need to rebuild the name table in the incentive tracking database. To do so, see **Rebuild Name Table** in the **Technical Reference**.
    b. Similarly, if there may have been participant name updates, the same procedure may be used to rebuild the name table.

4. At the close of each month, the project manager sends an auditor report to the accounting manager. The MONTHLY AUDITOR LIST button: **Distributions and Returns-Monthly Auditor List** can be used for this purpose.

Revision Record Printed 6/26/2013 1:37 PM

(227) Current Filename:		Posting Incentive Transactions ver 1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/13/12	J.Bates	Initial Development
1.1	1/4/13	J.Bates	typos
1.2	2/12/13	J.Bates	Additional notes; adding new cards; rebuild table
1.3	6/26/13	J.Bates	Advice on single-transaction posting for FedEx resends “Exception transactions”

Posting Riley Verbal HIPAAs after SI E-mail

Background

When the survey interviewer obtains a verbal HIPAA from a Riley participant (CCSSID starting with 24), the SI annotates the fact in the RecruitNotes, enters the interviewer ID on the Tracking tab, completes a paper information sheet, updates contact information, and notifies designated people by email to indicate the verbal HIPAA has been obtained. The email is to be sent on the same day the vHIPAA is obtained. When the CRA2 receives the Riley email notice of verbal HIPAA, the following procedure is used to post to the recruitment database.

Procedure

1. Locate the record in the Recruitment database. Verify that the contact information is updated and the verbal HIPAA is properly documented.
2. On the Tracking tab
    a. Select **1-Recruited** for OutcomeCode
    b. Enter the **CURRENT DATE** in OutcomeDate. This is necessary to maintain accurate weekly tracking of recruiting outcomes. (Queries for weekly status reports and counts of weekly verbal HIPAAs all hinge on the date in outcome date. They do NOT reference the DateInstMRsigned value.)
    c. In InstMRStatus, select **1-Complete**.
    d. In DateInstMRsigned, use ***the date the verbal HIPAA was obtained***. If the SI's email was sent the same day as the HIPAA was obtained, the email date may be used. Otherwise, you will need to read the documentation to determine the date the HIPAA was obtained.
    e. Select **1-Online** for InstMRsource. (Note: do not use 3-Verbal)
3. Move to the next record
4. Perform the Rollover procedure
5. Reply to the SI email indicating the record has rolled over

Note:

- This procedure can result in InstMR signature dates pre-dating the outcome date. In so doing, it retains the true Inst MR signature date, while making it possible to keep accurate weekly accounting for the recruitment outcomes.
    - Emails for Riley verbal HIPAAs obtained over the weekend cannot be processed until Mondays. Use the current date for Outcome date, and the actual HIPAA obtained date in DateInstMRsigned.
- Weekend online recruits (whether via Interviewer or by self) also exhibit different dates in date instmrsigned (date/time stamp when actually submitted) and outcome date (posted by macro, with the current date). Similarly, paper HIPAAs will have the current date in the outcome date, while the actual signature date is keyed into DateInstMRsigned.

Current Filename:		Posting Riley verbal HIPAAs after SI notice ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	12/5/11	J.Bates	Initial Development

Posting Sibling Permission Letter Mailings

Background

When we post the mailing of a Sibling permission letter, we must update the database to indicate when the permission letter was mailed as well as the type of letter and form we used. We also update the Send_to code to indicate whether sent to case (1) or parents (2). If sent to parents, we update Send_Permission_To so that it starts with "The Parents of " followed by the case name. Posting permission resends uses a similar process and also clears any resend request code.

Procedures

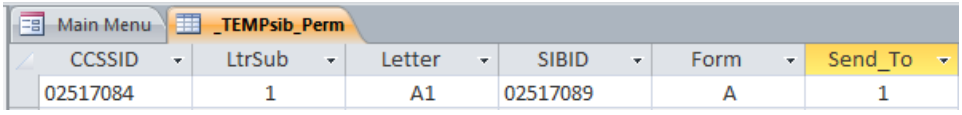
First Time Mailings

1. *** IMPORTANT *** Process CASE and PARENT permission letters in separate posting jobs.
2. Build the tab "**_TEMPsib_Perm**" in the production data file.
    a. Copy/paste columns from production team tabs: **CCSSID**, **LtrSub**, **Letter**, **SIBID**, **Form**.
    b. ADD a new column "**Send_To**" and fill the column with the appropriate code (1 or 2), depending on the letter type
        i. For Letters A1 and A2, use 1 (case)
        ii. For ALL OTHER LETTERS, use 2 (Parents)

LtrSub	CCSSID	SIBID	Letter	Form	Send_To

    c. Save and close the excel file (The order of the fields is NOT important)

3. Import the _TEMPsib_Perm tab into a new table in the tracking or posting database. You will be replacing the table that is already there.



4. Open the appropriate posting query
    a. Posting Permissions sent to CASE: **qry_PostSibPermission_1**
    b. Posting Permissions sent to PARENTS: **qry_PostSibPermission_2**
5. Double-check the query to see if ANY of the recipients have ALREADY RECEIVED the initial permission mailing. (If Date_Sent_Permission is NOT blank, then a letter has already been sent, and you will need to use the **Permission Resends** (below) procedure instead.)
6. MODIFY the query as follows:
    a. Set the criteria for Date_Sent_Permission and each of the 5 Resend#_date_Permission fields to IS NULL (to be sure to exclude those who are NOT first-time mailouts).
    b. Run the select query to double-check
    c. Change query to an update query
    d. Set the update values for tblSibPermission to the values specified in the documentation of ***Sibling Permission Posting Queries***.
7. Run the Update query
8. Change the query to a SELECT query
9. Run the Select query. If any records have Tracing_Status_Permission of 82, clear the Tracing_Status and the Tracing_Date.

10. Save and Close the query.
11. When you are finished, make a COPY of the table (_TEMPsib_Perm), and in the copy, add the posting date to the end of the table name (e.g., _TEMPsib_Perm copied and the copy renamed as _TEMPsib_Perm_Posted 03-28-13). This becomes an archive reference. If you store this _Posted mm-dd-yy table in the POSTING TABLES database (see below), you may delete it from the production database. However, be sure to leave the generic table _TEMPsib_Perm so the posting queries will not lose their reference.

Permission Resends

1. *** IMPORTANT *** Process CASE and PARENT permission letters in separate posting jobs.
2. As with initial mailings, build the sheet in the data file that you will import into the database (sheet name _TEMPsib_Perm) and import it into the database, replacing the table that is already there.
3. Open the appropriate RESEND posting query. NOTE: These are SELECT queries at this point. Never save the query as an update query!
    a. Posting Permissions resent to CASE: **qry_PostSibPermission_RESEND_1**
    b. Posting Permissions resent to PARENTS: **qry_PostSibPermission_RESEND_2**
4. Run the query to compare the values in LetterType to Letter and in FormType to Form. For instances where they differ, go to the data entry screen for that recipient, and document what the previous mailout used. E.g., "m/d/y: previous permission mailed Ltr xxx, form yyy [inits]"
5. MODIFY the query as follows:
    a. As a select query, in an iterative fashion, set the select criteria for Date_Sent_Permission and each of the 5 Resend#_date_Permission fields as indicated the query documentation
    b. After setting the criteria for a specific iteration, switch to an Update query. Fix the Update to values for tblSibPermission to the values specified in the documentation. Run the Update Query, then switch back to a select query to set the criteria for the next iteration.
6. After all necessary update iterations, review the query as a select query, for records where Tracing_Status_Permission was an 82. Clear the Tracing_Status and the Tracing_Date.
7. Save the query as a SELECT query.
8. When you are finished, make a COPY of the table (_TEMPsib_Perm), and in the copy, add the posting date to the end of the table name (e.g., _TEMPsib_Perm copied and the copy renamed as _TEMPsib_Perm_Posted 03-28-13). This becomes an archive reference. If you store this _Posted mm-dd-yy table in the POSTING TABLES database (see below), you may delete it from the production database. However, be sure to leave the generic table _TEMPsib_Perm so the posting queries will not lose their reference.

Storing the "TEMP" archive reference tables

To avoid unnecessary clutter in the database, you may put a copy of the TEMP archive reference tables in the POSTING TABLES version of the Expansion Database (stored in **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\LOCAL COPY-DATABASES**)

Revision Record Printed 6/6/2013 8:02 AM

[235] Current Filename:		Posting Sibling Permission Letter Mailings ver 1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	5/8/13	J.Bates	Initial Development
1.1	6/6/13	J.Bates	Corrections for B letters

Preparing and Sending Subsequent Neoplasm Final Reviews to Biostatisticians

Background

After the Subsequent Neoplasm (SN) project final reviews are coded and documented in the SNT database, the final review adjudications and codes must be sent to the biostatistics team at Fred Hutchinson Cancer Research Center in Seattle to be analyzed and added to the "frozen" dataset of SN conditions. The "frozen" dataset is the resource used by researchers.

This procedure describes the process for preparing the data for the biostatisticians and sending the data to the Seattle team. For information about coding and documenting the final reviews, see the SOP titled **Retrieving and Documenting Subsequent Neoplasm Final Reviews**, which precedes this procedure.

Procedures

1. Open the Excel workbook titled **Seattle Submission Tracking**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\Seattle*.
2. Review the **New SN Conditions** section of the workbook. This will provide the names of all DatStat download Excel workbooks that are ready for submission to Seattle, their location on the network, the date they became ready for submission, and, when applicable, the date the information was sent to the biostatistics team.
3. For any DatStat download workbook in the **New SN Conditions** section without a **Date Sent** in **Seattle Submission Tracking**, create a copy of the sheet at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\Seattle\Final Reviews*. Name the copy **Completed SN Final Review – [SurveyType] Batches Month YYYY-Biostats** (e.g. **Completed SN Final Review, FU6 Batches Jan 2019-Biostats**).
4. In the "Biostats" copy:
    a. *IMPORTANT*: Remove ALL suffixes from CCSSIDs (e.g. CCSSID 01234567A should be changed to 01234567).
    b. Delete all blacked-out rows flagged for deletion.
    c. Remove any/all data filters from the worksheet.
    d. Remove any/all internally added columns such as flags that the condition's information has been entered into the database, coder notes, duplicated columns, etc. NOTE: The Dx Code and Site Code columns are exceptions; these should not be removed.
    e. Remove any columns that only provide data about the DatStat login session and are not relevant to the SN condition.
    f. Remove any color coding not applicable to the biostatistics team.
    g. Ensure there are *NO* duplicate columns in the sheet.
5. Obtain a copy of the data dictionary related to each sheet, which may be different over time, and include it with the sheet when sending to the biostatistics team.

6. Ensure that *every* variable in the "Biostats" copy is listed in the data dictionary. NOTE: The Dx Code and Site Code columns are exceptions. They will not be in the data dictionary but should not be removed.
7. When the sheet is ready to be submitted to the Seattle biostatisticians, populate the **Prepared for Seattle** cell in the Excel workbook titled **Seattle Submission Tracking**, located at *Z:\Research Home\Departments\EpidemiologyCancerControl\common\CCSS\SMN\Seattle*.
8. Send the final review workbooks to the biostatistics team at Fred Hutchinson Cancer Research Center in Seattle. If the files total less than 5MB of data, send them via an encrypted email. If the files total more than 5MB of data, send them via St. Jude File Transfer Application (FTA).
    a. Include the applicable data dictionary/dictionaries. Alert the biostatisticians if the variables will not be the same across all submitted workbooks.
    b. Alert the biostatisticians if both cases and siblings/controls are included.
    c. Remind the biostatisticians that the Dx Code and Site Code fields will not be in the data dictionary.
    d. Alert the biostatisticians if the workbooks contain mixed sources and how to tell what source is related to what condition.
    e. Alert the biostatisticians if rejected conditions are included in the workbooks and whether they might be coded.
    f. Alert the biostatisticians that there is one row per condition, so a single CCSSID may appear multiple times.
    g. Remind the biostatisticians that in-situ cancers (with .2 diagnosis code suffixes) are generally accepted and coded but should be handled appropriately in analysis.
    h. Include any other applicable reminders.
9. When the cleaned sheet has been sent to the biostatistics team in Seattle:
    a. Move the Excel workbook from *Z:\ResearchHome\Departments\EpidemiologyCancer Control\common\CCSS\SMN\Seattle\Final Reviews* to *Z:\ResearchHome\Departments \EpidemiologyCancerControl\common\CCSS\SMN\Seattle\Final Reviews\Sent*.
    b. Move the corresponding sheet from the survey folder's –Coding subfolder to the Sent to Seattle Biostats folder.
    c. Document the **Date Sent** in the Excel workbook titled **Seattle Submission Tracking**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS \SMN\Seattle*.
    d. Document the **Date Sent to Seattle** in the **SN Batch Tracking** workbook, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN*.
    e. Populate the **Date Sent to Seattle** field in the confirmation record. It may be possible to create a Select query to identify all conditions with populated confirmation record fields, a blank **Date Sent to Seattle** field, and a final review date within a specified range, then change the query to an update query to populate the **Date to Seattle** field. Take note of those conditions which may have been sent for "further review" rather than "2nd review."

Revision Record Printed 3/2/2020 12:15 PM

Current Filename:		Preparing and Sending SN Final Reviews to Biostatisticians ver1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	11/21/17	R. Massey	Initial Development
1.1	8/26/19	R. Massey	Update network paths, add directive to remove CCSSID suffixes
1.2	3/2/20	R. Massey	Added directive to remove rows flagged for deletion.

Preparing Dana Farber Initial Production Files

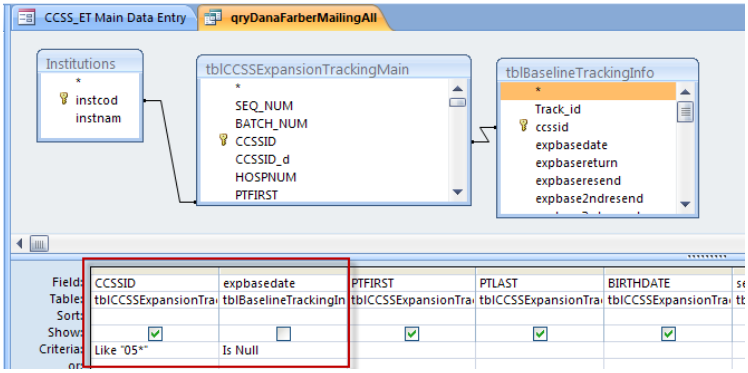
Background

Dana Farber "recruits" its own cases to the LTFU study. The data manager uploads the list of new recruits to the St Jude Share site and then notifies the IT team. Our IT team processes the data file, places an excel file on the server in **z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Expansion Tracking\Dana Farber Updates** and uploads the records to the Expansion Tracking database. IT emails us when new Dana Farber cases are ready for the baseline survey. The email indicates how many adults, minors, and deceased cases there are. We prepare survey booklets for adults and minors as well as a consent form booklet for family of deceased individuals. In preparing production data files, we refer to the most recent Dana Farber Updates file as a cross-check to be sure our queries pick up the correct cases. See *Expansion Baseline-Generating Survey Production List.* For special production procedures for these cases, see *Expansion Baseline Survey Mailing for Dana Farber*.

Procedure

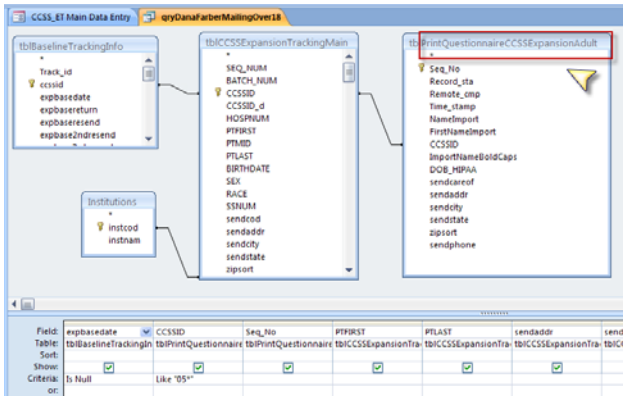
Use the ExpansionTracking database to generate data files to distribute to the production team who then print the booklets and generate the cover letters and labels. The following 4 queries address this process:

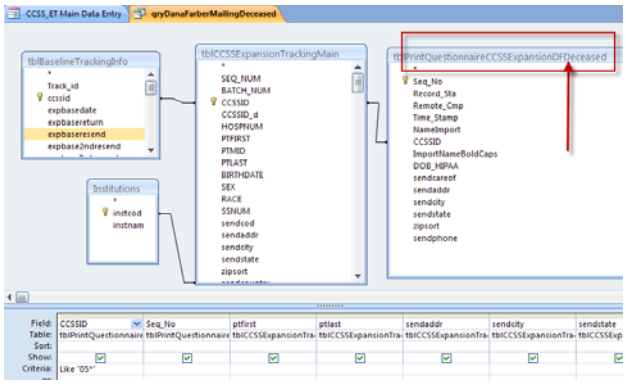
1. **qryDanaFarberMailingAll.** Shows whether there are any DanaFarber cases that have NOT been sent a survey yet. This should match information that the IT department provides. Export this query to excel, so you can use it as a reference for updating the expbasedate after the surveys are mailed. If the list does NOT match the xls file, investigate each case in Expansion Tracking's baseline tab searching by CCSSID.

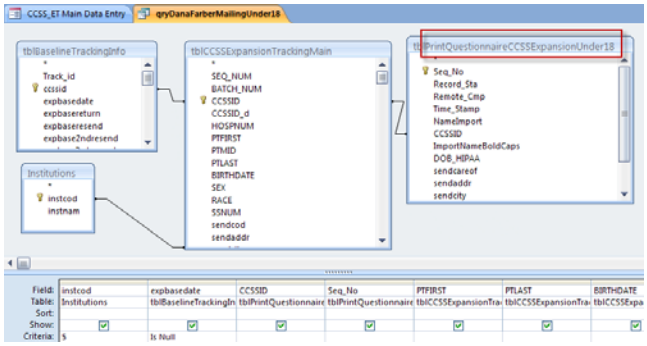


2. To produce data tables for the production team, run each of the following 3 queries. Each links to its respective print table (giving seq_no). When the query lists some records, export the query to excel; provide to the production team. When the query lists NO records, no need to output the file. The sum of records in all 3 of the queries should equal those shown in the "All" query (above).

    a. **qryDanaFarberMailingDeceased**
    b. **qryDanaFarberMailingOver18**
    c. **qryDanaFarberMailingUnder18.**







Revision Record

Printed 7/6/2012 11:14 AM

Current Filename:		Preparing Dana Farber Initial Production Files ver 2_1.doc (Formerly DanaFarber DataFile Queries)	
Revision No.	Date	Responsible Author	Change Description
1	11/22/10	J.Bates	Initial Development
2	7/7/11	J.Bates	Saving “all” query for updating use
2.1	3/8/12	J.Bates	Data file location; cross references

Pre-Post Call Checklist – ASK Study Calls

Background

This procedure lists the key steps that should occur before and after ASK telephone calls. See the SOP titled **ASK Study Calls** for more detailed information on making ASK calls.

Procedures

BEFORE THE CALL: Review all available data.

- CCSS SI Assignments database
  - Assignments list
  - Determine # of studies for each participant
  - Determine type of call needed
- CCSS LTFU Participants database
  - Header
    - ✓ Name (including pronunciation)
    - ✓ **Spanish Status**
    - ✓ DOB/**Current Age** (>18)
    - ✓ Gender
    - ✓ Alive status – No calls to deceased pts.
    - ✓ Diagnosis and Diagnosis Date
    - ✓ LAR status
    - ✓ **CCSS Study Outcome** and date
    - ✓ Hold status and date
    - ✓ **Contact Log History**
    - ✓ **Trace History**
  - Participant tab
    - ✓ Address/Phone/Email Date and Source
    - ✓ **Notes**
    - ✓ **Tracing Code** and date
    - ✓ Time zone
    - ✓ **Date Last Phone Call**
    - ✓ Preferred name and contact time
  - FU5 Tracking – Reconsent needed?
  - Associates tab – All associates and the contact status
- MS Word **Phone Contact Log** (if available)
- ASK .NET database
  - Case tab – Missing info?
  - Tracking tab
    - ✓ **Study Group ID**
    - ✓ **Skin Cancer Study Outcome** and date
    - ✓ Baseline survey information
    - ✓ 12-Month and 18-Month survey information
    - ✓ Preferred contact info/time
    - ✓ **Notes**
    - ✓ Resend dates and materials
  - HIPAA tab

AFTER THE CALL:

- Send survey or HIPAA email, if requested
- CCSS LTFU Participants database
  - Contact log or trace log
    - ✓ Call documentation
    - ✓ Email documentation
    - ✓ **DB Change**
  - Contact information – participant and associate
  - **Tracing Code** and date, if applicable
  - Refused all else documentation, if applicable
- ASK .NET database
  - Case tab – Enter missing information obtained
  - Tracking tab
    - ✓ Resend requests
    - ✓ **Interviewer ID** – completed surveys only
    - ✓ **Notes**
    - ✓ **Reason for Refusal**, if applicable
- Email project coordinator and Research Scientist for refusals, missing information obtained, deceased outcomes, and surveys begun by participant then completed with SI
- File ASK consent form in cabinet A, if applicable
- File **Expired Participant Info Sheet** in cabinet A, if applicable

Revision Record

Printed 4/20/2015 3:53 PM

[293] Current Filename:		Pre-Post Call Checklist - ASK Study Calls ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	4/17/2015	R. Massey	Initial Development

Pre-Post Call Checklist - Blood/Tissue Consent Form

Background

This procedure lists the key steps that should occur before and after Blood/Tissue consent form calls. See the procedures: **Interviewer Follow-up with Blood and Tissue Participants** (located in the SOP library) and **INTERVIEWER SCRIPT- SMN - Blood and Tissue_v1** (located in *Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue*) for detailed information concerning Blood and Tissue calls.

Procedures

BEFORE THE CALL - Review all available data:

- **the Expanded Cohort Blood and Tissue Workbook mm-dd-yyyy** workbook located in *Z:\SJShare\SJCOMMON\ECC\Interviewers\SMN and Blood and Tissue\Blood and Tissue\Expanded Cohort*.
  - CCSSID
  - Name
  - Last Call
- Expansion Tracking database - frmSMNTracking
  - **Date Consent Sent**
  - **Date Resent Returned**
  - **Interviewer's Section**
- Expansion Tracking database – Main Data Entry
  - **Date of Birth** (Adult or minor?)
  - **Gender**
  - **Survival Status**
  - **Spanish Status**
  - All contact information
  - **Care of** field (Should you speak to the participant, parent, or LAR?)
  - **Time Zone**
  - **Tracing Code**
  - **Comments**
- MS Word **Phone Contact Log** - Review all call information for the participant (tip: search for the call log by CCSSID)

AFTER THE CALL:

- Update all data concisely and completely in:
  - Interviewer's Section of the form frmSMNTracking
    - **Outcome**
    - **Outcome Date**
    - **Int. Notes**
    - **Resent Date #**
  - Expansion Tracking database – all contact information for case, parents, and additional contacts
  - MS Word **Phone Contact Log**
  - **the Expanded Cohort Blood and Tissue Workbook mm-dd-yyyy**
  - **Call Outcomes Log**, if applicable
- Resend consent via email, if applicable
- File **Expired Participant Information Sheet**, if applicable
- Email the lead CRA with refusals or anything out of the ordinary

Revision Record — Printed 11/13/2013 8:09 AM

Current Filename:		Pre-Post Checklist – Blood Tissue Consent Calls ver1_2	
Revision No.	Date	Responsible Author	Change Description
1	10/21/10	D. Rinehart	Initial Development
1.1	5/31/12	Procedure Team	Content and formatting revisions
1.2	10/28/2013	R. Massey, D. Rinehart, B. Lewis, E. Moore	Content Revision

Pre-Post Call Checklist - EASE Study

Background

This procedure lists the key items that should be reviewed before and after EASE telephone calls. See the document titled **EASE Study Follow-Up Calls** for detailed information about making these calls and for the location of referenced files.

Procedures

BEFORE YOU CALL: Review all available data.

- CCSS Survey Interviewer Call Assignments database
- CCSS LTFU Participants database
  - ✓ **CCSSID**
  - ✓ Name and **Preferred Name**
  - ✓ **Alive** status
  - ✓ **CCSS Study Outcome** and **Date**
  - ✓ **CCSS Hold** and **Hold Date**
  - ✓ **Current Age**
  - ✓ **Spanish Status**
  - ✓ **LAR/Proxy** checkbox and date (Pt. is Ineligible if LAR/Proxy status is confirmed)
  - ✓ Gender
  - ✓ Contact and trace history
  - ✓ **Preferred Contact info/time**
  - ✓ **Tracing Code** and **Date**
  - ✓ **Notes**
  - ✓ Associate names and contact status
  - ✓ Reconsent needed?
- **EASE** database
  - ✓ **Eureka App Outcome-** Do not call if field is populated with Code 2, 3 or 4
  - ✓ **EASE Outcome Code** – Do not call if populated
  - ✓ **Date EASE Invite Sent**
  - ✓ **Date Consented** – Do not call if populated
  - ✓ **Date Baseline Completed**- Do not call if populated

AFTER YOU CALL: Update all appropriate fields.

CCSS LTFU Participants Database

- ✓ Contact or trace log
  - Call documentation
  - **DB Change**
- ✓ Contact information – participant and associate

- **EASE** database
  - ✓ **Resend Request**
  - ✓ **Notes**
  - ✓ **Opened Invite Email Y/N**
  - ✓ **Clicked App Link Y/N**
- If applicable, file **Expired Participant Information Sheet**
- If applicable, send **Eureka App Technical Issue Email** and/or **EASE Enrollment Email**

Revision Record
Printed 11/6/2018 4:20 PM

Current Filename:		Pre-Post Checklist - EASE Calls ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/7/2018	P. Davis	Initial Development
2	9/10/2018	D. Rinehart; P. Davis; A.Cobble	Content Revision

Pre-Post Call Checklist - ECHOS Study

Background

This procedure lists the key steps that should occur before and after the ECHOS Study calls. See the procedure called *ECHOS SOP 1_1* document, located: **Z…Interviewers\ECHOS** for more detailed information about making the calls.

Procedures

BEFORE THE CALL: Review all available data

1. Open all five relevant databases and workbooks
   a. The CCSS REG Database: to search for alternate or more current contact information
   b. The Original Cohort Call Logs: where contact data from each call is stored
   c. New ECHOS Workbook: where call assignments are kept and contact data is updated
   d. The SRCInterviewer ECHOS Database: where each case is worked, call notes, study status, and call times are updated
   e. The New Tracing Workbook: where tracing cases are sent and updated contact information is stored for use by the Survey Interviewers
2. Review the New Tracing Workbook, to first work your cases that have been traced
   a. Enter START TIME in Assignments Workbook
   b. Update address and phone number information in the Database and Call Log
3. In The New ECHOS Workbook, enter START TIME for the next participant to call, begin review of all data in all databases, Call Log entries, and Call Notes
   a. Review name, address, phone, birth date, gender, date packet sent, Study Status, Two Month Hold, Date off 2 Month Hold, and SRC Interviewer Call Notes to determine previous call outcome history.
   b. Read notes to become knowledgeable of any important information that you need to be aware of prior to making your call.
   c. Review notes in the Nurse Notes section of the database

AFTER YOU CALL: Enter all data completely, concisely and completely in the Database, Participants Call Log and the ECHOS Assignments Workbook

1. Update the Database, Call Log, and Assignments Workbook
   a. ECHOS Database:
      i. Always include the date, time, and your initials when entering notes from your call.
      ii. Update notes accordingly per conversation. Please be sure to archive contact information prior to updating an address or phone number.
      iii. Include updated addresses and phone numbers in notes.
      iv. Update Study Status: enter the current study status code and date
      v. Enter or update the Total # of Calls: *weekdays/weekends*
      vi. Two Month Hold: Click box to indicate participant has been placed on hold and enter the date the hold is expected to be released
   b. Call Log:
      i. Update the Original Cohort Call Log for the participant
   c. Assignments Workbook
      i. Enter the "First, Second, Etc., Call Date" and ATTEMPTS code from the legend
2. Enter the "*END TIME*" when completing call attempts for each case

Revision Record

Printed 7/13/2012 11:39 AM

Current Filename:		Pre-Post Checklist - ECHOS Calls ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/11/10	D. Rinehart	Initial Development
1.1	5/31/12	Procedure Team	Content and format revisions

Pre-Post Call Checklist - EMPOWER Study

Background

This procedure lists the key steps that should occur before and after EMPOWER recruitment and survey interview phone calls. See the SOP titled **EMPOWER Study Calls** for more detailed information.

Procedures

BEFORE THE CALL: Review all available data.

- CCSS SI Assignments database – Locate assignments.
- CCSS LTFU Participants database
  - Header
    - ✓ Name (including pronunciation)
    - ✓ **Spanish Status**
    - ✓ DOB/**Current Age** - *Anyone over 49 years old is Ineligible for recruitment.* If they joined the study and then turned 50, then they can still participate
    - ✓ Gender
    - ✓ Alive status – No calls to deceased pts.
    - ✓ Diagnosis and Diagnosis Date
    - ✓ LAR status
    - ✓ **CCSS Study Outcome** and date
    - ✓ Hold status and date
    - ✓ **Contact Log History**
    - ✓ **Trace History**
  - Participant tab
    - ✓ Address/Phone/Email Date and Source
    - ✓ **Notes**
    - ✓ **Tracing Code** and date
    - ✓ Time zone
    - ✓ **Date Last Phone Call**
    - ✓ Preferred name and contact time
  - Associates tab – All associates and their contact status.
- MS Word **Phone Contact Log** (if available)
- CCSS EMPOWER Database
  - Quest Tab
    - ✓ **Comments**
    - ✓ Review call logs
  - TRACKING TAB
    - ✓ **Recruit Notes**
    - ✓ **HIPAA** and **Consent Status**
    - ✓ **Outcome Code**
    - ✓ **Ineligible Reason**
    - ✓ **Treatment** or **Control Group**
    - ✓ Date packets sent
    - ✓ Survey(s) returned
    - ✓ Resend requests and dates
    - ✓ **Interview Preferences**

AFTER THE CALL:

- LTFU Participants database
  - Contact log or trace log, as appropriate
  - Tracing code and date, if applicable
  - Update or confirm contact information
- EMPOWER database
  - **Date Eligibility Received**
  - **Eligibility Checklist Source and Interviewer ID**
  - **Consent Status** and date
  - **Outcome Code** and date
  - **Ineligible Reason (Outcome Code=2)**
  - **Comments** and/or **Recruit Notes**
  - **Date Baseline Q'naire Returned** and Source
  - **Baseline Interviewer ID**
  - **2-Week Control Interviewer ID**
  - **Date 2-week Interview Complete**
  - **Date 12-month Q'naire Returned** and Source
  - **12-month Interviewer ID**
  - **Resend Request** and date, if applicable
  - **12-month outcome** and date
  - Preferred days and times for call
- Email CRA
- File forms in cabinet A

Revision Record

Printed 3/3/2015 1:01 PM

Current Filename:		Pre-Post Call Checklist - EMPOWER Study ver1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1		D. Rinehart	Initial Development
1.1	6/14/12	Procedure Team	Formatting and content refinement
1.2	2/18/15	R. Massey, T. Thomas	Content Revision: Remove references to workbook and add directives for SI Assignments db and LTFU Pt db

Pre-Post Call Checklist - EQUAL Study Calls

Background

This procedure lists the key steps that should occur before and after EQUAL telephone calls. See the SOP titled **EQUAL Study Calls** for more detailed information on making EQUAL calls.

Procedures

BEFORE THE CALL: Review all available data.

- CCSS SI Assignments database
  - Assignments list
  - Determine # of studies for each participant
- CCSS LTFU Participants database
  - Header
    - ✓ Name (including pronunciation)
    - ✓ **Spanish Status**
    - ✓ DOB/**Current Age** (>18)
    - ✓ Gender
    - ✓ Alive status – No calls to deceased pts.
    - ✓ Diagnosis and Diagnosis Date
    - ✓ LAR status
    - ✓ **CCSS Study Outcome** and date
    - ✓ Hold status and date
    - ✓ **Contact Log History**
    - ✓ **Trace History**
  - Participant tab
    - ✓ Address/Phone/Email Date and Source
    - ✓ **Notes**
    - ✓ **Tracing Code** and date
    - ✓ Time zone
    - ✓ **Date Last Phone Call**
    - ✓ Preferred name and contact time
  - FU5 Tracking – Reconsent needed?
  - Associates tab – All associates and the contact status
- MS Word **Phone Contact Log** (if available)
- EQUAL Database – Tracking tab
  - **EQUAL Outcome** – Do not call if populated.
  - **Notes**
  - **Date Intro Packet Sent** and resend dates

AFTER THE CALL:

- Email
  - Case (if enrollment email was requested)
  - Research Scientist and Project Coordinator (for eligibility determination for disabled cases)
- CCSS LTFU Participants database
  - Contact log or trace log
    - ✓ Call documentation
    - ✓ Email documentation
    - ✓ **DB Change**
  - Contact information – participant and associate
  - **CCSS Hold** and **Hold Date**, if applicable
  - **Tracing Code** and date, if applicable
  - Refused all else documentation, if applicable
- EQUAL database
  - **Intro Packet resend request** and date
  - **EQUAL Outcome** and date, ONLY:
    - ✓ Refused EQUAL
    - ✓ Refused all else
    - ✓ Deceased
  - **Notes** – emails sent, refusals, suspected ineligibility, deceased, resends
- File **Expired Participant Info Sheet** in cabinet A, if applicable

Revision Record

Printed 5/18/2015 12:30 PM

[289]Current Filename:		Pre-Post Call Checklist - EQUAL Study Calls ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	3/10/2015	R. Massey	Initial Development
1.1	5/9/2015	R. Massey	Expanded post-call checklist

Pre-Post Call Checklist - Expansion Baseline Survey

Background

This procedure lists the key steps that should occur before and after expansion baseline survey calls. See the procedure titled **Expansion Baseline Survey Calls** for detailed information about making the calls and for the location of referenced files.

Procedures

BEFORE THE CALL: Review the following fields.

- CCSS SI Assignments database – locate assignments
- Expansion Tracking database
  - Header
    - ✓ Name
    - ✓ **Gender**
    - ✓ **Date of Birth**
    - ✓ **Survival Status**, **Date of Death**
    - ✓ **Diagnosis** and **Diagnosis Date**
    - ✓ LAR status/date
    - ✓ **Spanish Status**
    - ✓ Call and trace history
  - Quest tab
    - ✓ Rollover dates
    - ✓ Address/Phone/Email Date and Source
    - ✓ Phone ranks
    - ✓ **Comments**
    - ✓ Tracing and hold status
    - ✓ **Time Zone**
  - Baseline tab
    - ✓ Eligibility status
    - ✓ Dates packets sent (resends and emails)
    - ✓ **Date Survey Returned**
    - ✓ Outcome code/date
    - ✓ **Tracking Comments**
  - USC tab
    - ✓ **Date HIPAA received**
    - ✓ **Person who signed HIPAA**
    - ✓ **USC Note**
  - Reg tab
    - ✓ Spouse & parent contact info/status/notes
    - ✓ **Outcome** and **Outcome Date**
  - AgeOfMajority tab – Current age
  - Associates tab – contact info/status
- MS Word **Phone Contact Log** – historical notes

AFTER THE CALL: Update all appropriate fields

- Expansion Tracking database
  - Header – **Spanish Status**, LAR status/date
  - Call Log/Trace Log
    - ✓ Fully document each communication
    - ✓ Requests for change in DOB, **Gender**, name, eligibility, or **Survival Status** or partial completion of survey or completion of Spanish survey in **DB Change** field
    - ✓ Refusals in **Outcome** field
  - Quest tab
    - ✓ Contact information for case
    - ✓ **Send Q-Aire To** field
    - ✓ **CCSS Hold** and **Hold Date** fields
    - ✓ **Tracing Status** and **Tracing Date** fields
    - ✓ **Comments** field
  - Baseline tab
    - ✓ **Baseline Outcome** field and date for refusals (uncompleted surveys only)
    - ✓ Document survey link sent via email
  - Associates tab – Associate contact info/status/notes
  - Reg tab
    - ✓ Spouse & parent contact info/status/notes
    - ✓ **Outcome** field and date for refusals
- **Informed Consent**, if applicable
  - Document pt copy information
  - Document date consent obtained
  - Document date survey completed, if applicable
- File **Informed Consent** and **Expired Participant Information Sheets**, if applicable
- Deliver Spanish insert & email CRAs, if applicable
- Email closing monitor, if applicable
- Update Call Center calendar, if applicable
- Update Dry Erase Board, if applicable
- Update **Journal**, if applicable

Explanation and Rationale

1. Baseline Call Assignments database – List of cases assigned to each SI
2. Name: Allows SI to properly address the case.
3. Gender: Allows the caller to properly address the case. If gender is missing (e.g. Dana Farber cases), the SI should attempt to gather this data.
4. Date of Birth: Used to verify identity and establish rapport. If DOB is missing (e.g. Dana Farber cases), the SI should attempt to gather this data.
5. Survival Status: Helps the SI identify whether calling for the case or a proxy
6. Date of Death: SIs should avoid calling on or near the anniversary of a case's death
7. Diagnosis and Diagnosis Date: Diagnosis may flag cases as higher potential for cognitive disability, diagnosis date helps establish eligibility
8. LAR status and date: Status allows SI to address the correct party. Date provides context.
9. Spanish Status: If this field is populated with code "1" or "3", case needs a Spanish-speaking SI.
10. Call History, Trace History: Review call and trace historical notes to build participant profile.
11. Rollover Dates: Date case rolled over from Recruitment to Expansion Tracking and from Expansion Tracking to LTFU Pts. Helps establish stage of participation.
12. Address/Phone/Email Date and Source: Identify how current our data is, helps SI maintain data integrity
13. Phone ranks: Documents order of priority for calling numbers, flags numbers that should not be called
14. Comments: Provides historical record of recruitment efforts, other contacts, and/or other critical information
15. Tracing Status: Used to flag cases as having invalid contact information and/or to indicate that the paper survey should be resent
16. Hold Status: Do not call if field is populated.
17. Time Zone: Used to identify appropriate hours (9am – 9pm in the case's time zone) for calling.
18. Eligibility Status: Do not call if case has been flagged as ineligible
19. Dates packets sent (including resends and emails): (1) Used to determine if/when a requested package has been mailed and/or (2) used to determine when to begin making follow-up calls
20. Date Survey Returned: Do not call if they have returned the Baseline survey.
21. Baseline Outcome Codes: Do not call if field is populated. See the LSI team for assistance.
22. Tracking Comments: Used to document additional relevant information
23. Date HIPAA Received: (for cases recruited by USC) Used to note how long the baseline survey has been pursued
24. Person Who Signed HIPAA: Used to determine who initiated the enrollment (e.g., minor status, cognitive disability, LAR situation, etc.).
25. USC Note – Used to document additional relevant information
26. Parent and spouse contact info – If the case's contact information is invalid, this information may be a valid secondary method of contact.
27. Outcome and Outcome Date – Used to indicate overall study outcomes, such as refusals
28. Current Age – Used to determine minor or adult status.
29. Associates tab – If the case's contact information is invalid, this information may be a valid secondary method of contact.
30. **Phone Contact Log** – Provides historical record of calls, log is not actively in use

Revision Record
Printed 7/17/2015 2:22 PM

[52] Current Filename:		Pre-Post Call Checklist - Expansion Baseline Survey ver2_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/12/10	D. Rinehart	Initial Development
1.1	5/31/12	Procedure Team	Content and Format revisions
1.2	4/27/13	D. Rinehart, B. Carson, R. Massey	Content and Format revisions
1.3	4/29/13	J. Bates, D. Rinehart	Content clarification and formatting.
1.4	5/30/13	D. Rinehart	Content revision
1.5	7/10/13	R. Massey	Content Revision: Add Call Outcomes Log Items
2.0	9/3/14	R. Massey	Content Revision: Content Revision to reflect major update of procedures
2.1	7/10/15	R. Massey	Content Revision: additions/deletions to reflect changes in database

Pre-Post Call Checklist – Expansion Recruitment Calls

Background

This procedure lists the key steps that should occur before and after Expansion cohort Recruitment phone calls. See the SOP titled **Expansion Recruitment Process for Survey Interviewers** for more detailed information about making the calls and for the location of referenced files.

Procedures

BEFORE THE CALL: Review all available data.

- CCSS SI Assignments Database – locate assignments
- Recruitment Database
  - Header
    - ✓ Already recruited?
    - ✓ Institution – See **Decoding CCSSID** SOP.
    - ✓ Case name
    - ✓ Birth date and current age
    - ✓ LAR/proxy status
    - ✓ Diagnosis and diagnosis date
    - ✓ Gender
    - ✓ Alive status and date of death, if applicable
    - ✓ **Spanish Status**
    - ✓ **Contact Log History**
    - ✓ **Trace History**
  - Quest tab
    - ✓ **Date Last Contact**
    - ✓ Address date and source
    - ✓ Phone number rank, date, source
    - ✓ Time zone
    - ✓ **Comments**
  - Tracking tab
    - ✓ Eligibility status
    - ✓ Tracing and outcome codes
    - ✓ Date packets sent including resends
    - ✓ Recruit Notes
    - ✓ Tracing Notes
  - Parent tab – Parent names, **Contact Status**, contact information, **Notes**
  - Spouse tab – **Marriage Status**, spouse name, **Contact Status**, ph#s, **Notes**
  - Associates tab – all records containing associate name, relationship, contact information and status, notes

AFTER THE CALL:

- Recruitment Database
  - Log call in contact log (confirmed numbers) or trace log (unconfirmed numbers)
    - ✓ Appropriate outcome
    - ✓ **DB Change** request, if applicable
  - Update case's contact information, dates, and sources
  - **Spanish Status**, if applicable
  - Update parent/spouse/associate contact information and contact status, if applicable
  - Tracing and/or outcome codes, if applicable
- Email enrollment link and document in contact log, if appropriate
- File **Expired Participant Information Sheet**, if applicable
- Verbal HIPAAs –
  - Update www.longtermfollowup.org (non-Riley cases) or paper HIPAA and email (Riley cases)
  - Dated note in Quest tab's **Comments** field, copied to Tracking tab's **Recruit Notes** field
  - Update Tracking tab's **Verbal MR INT ID**, **Resend Request**, **Date Resend Request** fields
  - Check **Date Packet Sent** and **Date HIPAA Only Sent** fields on Tracking tab
  - Update dry erase board
  - Update calendar for scheduled HIPAAs
  - Email closing monitor for unscheduled HIPAAs
  - Email survey link and document in contact log, if appropriate
  - Write survey appt on calendar and set Outlook survey reminder, if applicable
  - Request survey appt assignment, if appropriate

Revision Record Printed 7/19/2015 8:27 AM

(36) Current Filename:		Pre-Post Call Checklist - Expansion Recruitment Calls ver1_5.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/12/10	D. Rinehart	Initial Development
1.1	5/31/12	Procedure Team	Content and Format revisions
1.2	6/22/12	D. Rinehart, M. Jackson	Content revision
1.3	1/22/2013	M. Jackson	Content revision: additional contacts
1.4	12/9/2014	R. Massey	Content Revision
1.5	6/27/15	R. Massey	Content Revision – Updated fields from database modifications

Pre-Post Call Checklist - Expansion Sibling Permission Calls

Background

This procedure lists the key steps that should occur before and after Expansion Sibling Permission phone calls. See the procedure titled **Expansion Sibling Cohort Permission Calls** for more detailed information about making the calls and for the location of referenced files.

Procedures

BEFORE THE CALL: Review the following.

- In the **Sibling Cohort Recruitment Call Assignments** workbook:
  - Locate the case to be called
  - Confirm **Call Purpose** column = permission
- In the *sibling's* Expansion Tracking database record, Permission Tab:
  - Permission Tracking box – all fields
  - *Case* address and ph#s
  - **Comments** field
  - **Call History**
- In the *case's* LTFU Participant database record:
  - Case's preferred name/gender/age/LAR status/vital status/Death Date/**Spanish Status**
  - Study outcome
  - Holds applied
  - Contact information
  - **Call Log History**
  - Time zone
  - Tracing status/**Tracing History**
  - **Notes**
- Review call history in the case's MS Word **Phone Contact Log** (if one exists)
- Have permission forms ready to fill out
- Review all available scripts and call guidance
- Prepare to request alternate sources of the information (e.g., "When can I call you back to give you time to look up that information?", "Is there someone else, maybe your parents, who may have that information?") or ask about calling the sibling directly if case grants permission but cannot provide sibling's contact information

AFTER THE CALL: Take the following action.

- Update the LTFU Participant database:
  - Case's contact information
  - Case hold status/tracing status/LAR status/Spanish status, if applicable
  - Associate contact information
  - Call Log
- Update the Expansion Tracking sibling record:
  - Permission tab case contact information if permission effort unresolved
  - Permission Tracking box if permission effort resolved (gained or denied)
  - Tracing Status, if applicable
  - Call Log
  - **Comments** field, if applicable
  - Header, if permission gained
  - Sib Info tab (update print tables), if permission gained
- Complete the sibling permission form, if permission gained or denied
- Update the **Sibling Cohort Recruitment Call Assignments** workbook
  - Update **Pending Status** column
  - Update name, **DOB**, and **Call Purpose** if permission gained
- File the permission form, if applicable
- File **Expired Participant Information Sheet**, if applicable
- Update **Call Outcomes Log**, if applicable
- Email closing monitor, if permission gained
- Update Call Center calendar, if applicable
- Update Dry Erase Board, if applicable

Revision Record Printed 7/18/2014 3:27 PM

[242] Current Filename:		Pre-Post Checklist - Expansion Sibling Permission Calls ver1_5.docx	
Revision No.	Date	Responsible Author	Change Description
1	5/5/2013	C. Lee, A. Oyuela, P. Ludwig, D. Rinehart	Initial Development
2	5/20/2013	R. Massey, D. Rinehart	Content revision
3	5/21/2013	J. Bates	Content revision
1.4	6/6/13	R. Massey, J. Bates	Content Revision and Reorder Points
1.5	7/17/2014	R. Massey	Content Revision, esp. for LTFU Pt database

Pre-Post Call Checklist – Follow Up 5 Survey Calls

Background

This procedure lists the key elements that should receive attention before and after Follow-Up 5 (FU5) survey phone calls. See the procedures titled **Follow Up 5 Survey – Outgoing Calls** and **Follow Up 5 Survey – Incoming Calls** for more detailed information about the calls and the locations of referenced files.

Procedures

BEFORE THE CALL: Review the following fields.

- CCSS SI Assignments database – Call assignments, number of studies, related sibling
- LTFU Participant database
  - Header
    - ✓ Name (including pronunciation)
    - ✓ **Spanish Status**
    - ✓ DOB/**Current Age**
    - ✓ Gender
    - ✓ Alive status
    - ✓ **Death Date**
    - ✓ Diagnosis and Diagnosis Date
    - ✓ LAR status
    - ✓ **CCSS Study Outcome** and date
    - ✓ **Last Survey Completed** and date
    - ✓ Hold status and date
    - ✓ **Contact Log History** and **Trace History**
  - Participant tab
    - ✓ Address/Phone/Email Date and Source
    - ✓ **Notes**
    - ✓ **Tracing Code** and date
    - ✓ Time zone
    - ✓ **Date Last Phone Call**
    - ✓ Preferred name and contact time
  - FU5 Tracking tab
    - ✓ FU5 outcome and date
    - ✓ Dates packets sent (including resends)
    - ✓ **Date Survey Returned** (Do not call if they have returned the FU5 survey.)
    - ✓ **Notes**
    - ✓ **Reconsent Needed/Reconsent Outcome**
  - Associates tab
    - ✓ Associate contact info
    - ✓ **Contact Status**
    - ✓ **Notes**
- MS Word **Phone Contact Log** (if available)

AFTER THE CALL:

- LTFU Participant database
  - Contact log and/or trace log, including any needed info in **DB Changes** and **Notes** fields
  - Header
    - ✓ **Spanish Status** field
    - ✓ **LAR/Proxy** checkbox and date fields
    - ✓ **CCSS Study Outcome** and date fields
    - ✓ **CCSS Hold** and **Hold Date** fields
  - Participant tab
    - ✓ **Preferred Name**
    - ✓ Contact information for case, including confirmation date and source
    - ✓ **Tracing Code** and **Tracing Date** fields
    - ✓ **Notes** field
    - ✓ **Preferred Contact info/time** field
  - FU5 Tracking tab
    - ✓ **FU5 Outcome Code** field and date
    - ✓ **Survey Interviewer ID**
    - ✓ **Resend Request** and **Request Date** fields
    - ✓ **Reconsent Outcome** and related fields
    - ✓ **Notes**
  - Associate tab - Contact information, relationship, notes, and contact status for parents, spouse, additional contacts, and other associates
- File **Expired Participant Information Sheets**.
- If applicable:
  - ✓ Outlook calendar reminder(s)
  - ✓ Email closing monitor
  - ✓ Email team regarding Spanish survey
  - ✓ Create Spanish thank-you card and deliver to CRA2 team
  - ✓ Update Call Center calendar (Email for reassign)
  - ✓ Update Dry Erase Board
  - ✓ Update **Journal**

Revision Record

Printed 5/1/2015 10:42 AM

[280] Current Filename:		Pre - Post Call Checklist - FU5 Survey Calls ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/12/2014	R. Massey, D. Rinehart	Initial Development
1.1	4/24/2015	R. Massey	Minor content revision

Pre-Post Call Checklist – Follow Up 6 Survey Calls

Background

This procedure lists the key elements that should receive attention before and after Follow-Up 6 (FU6) survey phone calls. See the procedure titled **Follow-Up 6 Survey Non-Responder Calls** for more detailed information and the locations of referenced files.

Procedures

BEFORE THE CALL: Review the following fields.

- CCSS SI Assignments database – Call assignments, number of studies, related sibling
- LTFU Participant database
  - Header
    - ✓ Name (including pronunciation)
    - ✓ **Spanish Status**
    - ✓ DOB/**Current Age**
    - ✓ Gender
    - ✓ Alive status
    - ✓ **Death Date**
    - ✓ Diagnosis and Diagnosis Date
    - ✓ LAR status
    - ✓ **CCSS Study Outcome** and date
    - ✓ **Last Survey Completed** and date
    - ✓ Hold status and date
    - ✓ **Contact Log History** and **Trace History**
  - Participant tab
    - ✓ Address Date/Source Phone/Email Rank
    - ✓ **Notes**
    - ✓ **Tracing Code** and date
    - ✓ Time zone
    - ✓ **Date Last Phone Call**
    - ✓ Preferred name and contact time
  - FU6 Tracking tab
    - ✓ FU6 outcome and date
    - ✓ Dates packets sent (including resends)
    - ✓ **Date Survey Returned** (Do not call if they have returned the FU6 survey.)
    - ✓ **Notes**
    - ✓ **Reconsent Needed/Reconsent Outcome**
  - HIPAA – Participation History tab
    - ✓ **View FU5 Tracking Form**
    - ✓ **Notes**
  - Associates tab
    - ✓ Associate contact info
    - ✓ **Contact Status**
    - ✓ **Notes**
- MS Word **Phone Contact Log** (if available)

AFTER THE CALL:

- LTFU Participant database
  - Contact log and/or trace log, including any needed info in **DB Changes** and **Notes** fields
  - Header
    - ✓ **Spanish Status** field
    - ✓ **LAR/Proxy** checkbox and date fields
    - ✓ **CCSS Study Outcome** and date fields
    - ✓ **CCSS Hold** and **Hold Date** fields
  - Participant tab
    - ✓ **Preferred Name**
    - ✓ Contact information for case, including confirmation date and source
    - ✓ **Tracing Code** and **Tracing Date** fields
    - ✓ **Notes** field
    - ✓ **Preferred Contact info/time** field
  - FU6 Tracking tab
    - ✓ **FU6 Outcome Code** field and date
    - ✓ **Survey Interviewer ID**
    - ✓ **Resend Request** and **Request Date** fields
    - ✓ **Reconsent Outcome** and related fields
    - ✓ **Notes**
  - Associate tab - Contact information, relationship, notes, and contact status for parents, spouse, additional contacts, and other associates
- File **Expired Participant Information Sheets**.
- If applicable:
  - ✓ Outlook calendar reminder(s)
  - ✓ Email closing monitor
  - ✓ Email team regarding Spanish survey
  - ✓ Create Spanish thank-you card and deliver to CRA2 team
  - ✓ Update Call Center calendar (Email for reassign)
  - ✓ Update Dry Erase Board

Survey Interviewers

Revision Record

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[318]Current Filename:		Pre - Post Call Checklist - FU6 Survey Calls v1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	6/7/2017	A. Cobble	Initial Development

Pre-Post Call Checklist - Health eHeart

Background

This procedure lists the key items that should be reviewed before and after Health eHeart telephone calls. See the document titled **Health eHeart Study Calls**, located in the SOP Library, for detailed information about making these calls and for the location of referenced files.

Procedures

BEFORE YOU CALL: Review all available data.

- CCSS SI Assignments database
- Health eHeart database
  - ✓ **HeH Outcome** and date – Do not call if populated.
  - ✓ **Date Intro Packet Sent** and resend dates
  - ✓ **Date Information Received from HeH**– Do not call if populated.
  - ✓ **Notes**
- CCSS LTFU Participants database
  - ✓ Participant ID
  - ✓ Name and **Preferred Name**
  - ✓ **Spanish Status**
  - ✓ Survival status – Do not call if deceased.
  - ✓ **Date of Birth** and **Current Age** (>18)
  - ✓ Gender
  - ✓ **LAR/Proxy** checkbox and date
  - ✓ **CCSS Study Outcome** and date
  - ✓ **CCSS Hold** and **Hold Date**
  - ✓ Participant contact information
  - ✓ Time zone
  - ✓ **Tracing Code** and date
  - ✓ **Notes**
  - ✓ **Date Last Phone Call**
  - ✓ Reconsent needed?
  - ✓ Associates and related contact status
  - ✓ Contact and trace history
  - ✓ **Preferred Contact info/time**

AFTER YOU CALL: Enter all data concisely and completely.

- Email:
  - ✓ HeH Coordinator – for website issues
  - ✓ Participant – with enrollment information
- CCSS LTFU Participants Database
  - ✓ Contact or trace log
    - Call documentation
    - Email documentation
    - DB Change
  - ✓ Contact information – participant and associate
  - ✓ **Tracing Code** and date, if applicable
  - ✓ **CCSS Hold** and **Hold Date**, if applicable
  - ✓ Refused all else documentation, if applicable
- Health eHeart database
  - ✓ **Resend Request**
  - ✓ **Outcome Code** and **Outcome Date** – only:
    - 2 – Refused (HeH only)
    - 3 – Refuse All Else
    - 4 - Deceased
  - ✓ **Notes** – emails sent, refusals, suspected ineligibility, deceased, resends
- If applicable:
  - ✓ File **Expired Participant Information Sheet**
  - ✓ Notify Call Center Coordinator if participant was already enrolled in HeH

Revision Record — Printed 5/18/2015 12:20 PM

[287] Current Filename:		Pre-Post Call Checklist - Health eHeart ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	2/20/2015	T. Hardin, D. Rinehart, R. Massey	Initial Development
1.1	5/8/2015	R. Massey	Expanded pre- and post-checklists

Pre-Post Call Checklist - INSURE Study

Background

This procedure lists the key steps that should occur before and after INSURE phone calls.

Procedures

BEFORE THE CALL: Review all available data

INSURE Database

- Check "Date calls can begin" before calling.
- Check for alternative phone number in the "View address from CCSSreg database" button
- SRC Interviewer Call Notes:
  - Read notes to determine previous call outcome history.
  - Read notes to become knowledgeable of any important information that you need to be aware of prior to making your call.

PARTICIPANT CALL LOG (MS WORD)

- Review the participant's call log located on Z-drive

AFTER THE CALL: Enter all data concisely and completely in the participant's call log, Assignment Spreadsheet, and in the INSURE database

Update Original Cohort Participant (Word) Call Log on Z:drive

Database

- Always include the date, time, and your initials when entering notes from your call.
- Study Status: Change the study status as needed, to reflect the outcome of the call.
- Update notes accordingly, per conversation.
- Please be sure to archive contact information prior to updating an address or phone number.
- Please include updated addresses and phone numbers in notes.

Update Call Assignment Spreadsheet

Revision Record

Printed 7/13/2012 11:35 AM

Current Filename:		Pre-Post Checklist - INSURE Calls ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/23/10	D. Rinehart	Initial Development
1.1	6/14/12	Procedure Team	Formatting and content refinement

Pre-Post Call Checklist - Low Grade Brain Tumor Study

Background

This procedure lists the key steps that should occur before and after the Low Grade Brain Tumor Study recruitment phone calls. See the procedure called *Brain Tumor (Ris) Study Recruitment* for more detailed information about making the calls.

Procedures

BEFORE THE CALL: Review all available data

PROJECT DATABASE

- QUEST TAB
  - Name
  - Birth date
  - Current age
  - Date of last phone call
  - Phone/Address date and source
  - Gender
  - Time zone and state
  - Phone number(s): Rank, Relationship, Date, Source
  - View call log's in database
  - Comments - Review all information
- TRACKING TAB
  - Date packet sent
  - Closest testing center
  - Resend requests and dates
  - Outcome code and date
  - Recruit notes
  - Tracing code and date
  - Date PT Info sent to Baylor (should only be populated for recruited or refused)
- SPOUSE TAB
  - Name; Address; Phone
- PARENT TAB
  - Name; Address; Phone

PARTICIPANT CALL LOGS (WORD)

- View call logs located in the Participants Call Log Folder on Z-drive: previous dates, outcomes, SI Id.'s, and notes on previous calls

AFTER THE CALL

- Enter all data comprehensibly, concisely and completely in the participants call log and database
  - Update Word Call Log on Z:drive
  - Database
    - Update address, email, and/or phone numbers if needed
    - Update source and dates for phones, address, and email
    - Update Outcome code and date
    - Update notes accordingly per conversation
    - Update call log for every call (including disconnects)
    - Update Tracing code and date if applicable
    - Update reason not interested if applicable
    - Update preferred days and times for call if applicable
    - Update alternate contact information if applicable
    - Always include the date and your SI ID in notes
  - Update Call Assignment Spreadsheet

Revision Record

Printed 7/13/2012 11:37 AM

Current Filename:		!Pre-Post Checklist - Low Grade Brain Tumor Calls ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/21/10	D. Rinehart	Initial Development
1.1	5/31/12	Procedure Team	Content and formatting revisions

Pre-Post Call Checklist – myLTFU/Follow-Up 7 Survey Calls

Background

This procedure lists the key elements that should receive attention before and after myLTFU/Follow-Up 7 (FU7) survey phone calls. See the procedure titled **myLTFU and Follow-Up 7 Survey Non-Responder Calls** for more detailed information and the locations of referenced files.

Procedures

BEFORE THE CALL: Review the following fields.

- CCSS SI LTFU Assignments database – Call assignments, number of studies, related sibling
- CCSS LTFU Participants Database
  - Header
    - ✓ Name (including pronunciation)
    - ✓ Spanish Status
    - ✓ DOB/Current Age
    - ✓ Gender
    - ✓ Alive status
    - ✓ Death Date
    - ✓ Diagnosis and Diagnosis Date
    - ✓ LAR status
    - ✓ CCSS Study Outcome and date
    - ✓ Last Survey Completed and date
    - ✓ Hold status and date
    - ✓ Contact Log History and Trace History
  - Participant tab
    - ✓ Address Date/Source
    - ✓ Phone/Email Rank
    - ✓ Notes
    - ✓ Tracing Code and Tracing Date
    - ✓ Time zone
    - ✓ Date Last Phone Call
    - ✓ Preferred name and contact time
  - HIPAA – Participation History tab
    - ✓ Reconsent Needed/Reconsent Outcome
  - Associates tab
    - ✓ Associate contact info
    - ✓ Contact Status
    - ✓ Notes
  - APP-TEXT tab
    - ✓ DatStat Connect fields
- CCSS Follow-Up Survey Tracking database
  - FU7 Tracking tab
    - ✓ FU7 Outcome and date
    - ✓ Dates packets sent (including resends)
    - ✓ Date Survey Returned (Do not call if this field is populated)
    - ✓ Notes
  - FU5 and FU6 Tracking tab fields

AFTER THE CALL:

- LTFU Participant database
  - Contact log and/or trace log, including any needed info in DB Changes and Notes fields
  - Header
    - ✓ Spanish Status field
    - ✓ LAR/Proxy checkbox and date fields
    - ✓ CCSS Study Outcome and date fields
    - ✓ CCSS Hold and Hold Date fields
  - Participant tab
    - ✓ Preferred Name
    - ✓ Contact information for case, including confirmation date and source
    - ✓ Tracing Code and Tracing Date fields
    - ✓ Notes field
    - ✓ Preferred Contact info/time field
  - Associate tab –
    - ✓ Contact information, relationship, notes, and contact status for parents, spouse, additional contacts, and other associates
- CCSS Follow-Up Survey Tracking database
  - FU7 Tracking tab
    - ✓ FU7 Outcome Code field and date (if applicable)
    - ✓ Survey Interviewer ID
    - ✓ Resend Request and Request Date fields
    - ✓ Age of Majority fields
    - ✓ Notes
- File Expired Participant Information Sheets.
- If applicable:
  - ✓ Outlook calendar reminder(s)
  - ✓ Email closing monitor
  - ✓ Update Call Center calendar (Email for reassign)
  - ✓ Update Dry Erase Board

Survey Interviewers

Revision Record Printed

Current Filename:		Pre-Post Call Checklist - myLTFU-FU7 Survey Calls ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	11/8/2019	A. Cobble, D. Rinehart, R. Daniels, J. Ford.	Initial Development

Pre-Post Call Checklist - Saliva Kit

Background

This procedure lists the key items that should be reviewed before and after Saliva Kit telephone calls. See the document titled **Saliva Kit Follow Up Calls** for detailed information about making these calls and for the location of referenced files.

Procedures

BEFORE YOU CALL: Review all available data.

- CCSS Survey Interviewer Call Assignments database
- CCSS LTFU Participants database
  - ✓ **CCSSID** or **SIBID**
  - ✓ Name and **Preferred Name**
  - ✓ **Alive** status
  - ✓ **CCSS Study Outcome** and **Date**
  - ✓ **CCSS Hold** and **Hold Date**
  - ✓ **Current Age**
  - ✓ **Spanish Status**
  - ✓ **LAR/Proxy** checkbox and date
  - ✓ Gender
  - ✓ Contact and trace history
  - ✓ **Preferred Contact info/time**
  - ✓ **Tracing Code** and **Date**
  - ✓ **Notes**
  - ✓ Associate names and contact status
- CCSS DNA Tracking database
  - ✓ **Outcome Code** – Do not call if populated on most recent record.
  - ✓ Number of kits sent
  - ✓ **Date Kit Sent**
  - ✓ **Date Kit Returned** – Do not call if populated on most recent record.

AFTER YOU CALL: Enter all data concisely and completely.

- CCSS LTFU Participants Database
  - ✓ Contact or trace log
    - Call documentation
    - **DB Change**
  - ✓ Contact information – participant and associate
- CCSS DNA Tracking database
  - ✓ **Notes**
  - ✓ **Outcome Code** and **Outcome Date**
  - ✓ **Resend Request**
- If applicable, file **Expired Participant Information Sheet**

Revision Record

Printed 9/4/2014 8:50 AM

Current Filename:		Pre-Post Checklist - Saliva Calls ver1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/12/10	D. Combs	Initial Development
1.1	6/21/12	Procedure Team	Content and Format revisions
1.2	8/30/14	B. Lewis, D. Rinehart, R. Massey	Content and Format revisions

Pre-Post Call Checklist – Sibling Survey Calls

Background

This procedure lists the key steps that should occur before and after Expansion Sibling Survey phone calls. See the procedure called **Expansion Tracking Sibling Cohort Survey Calls** for more detailed information about making the calls and for the location of referenced files.

Procedures

BEFORE THE CALL: Review the following.

- **Sibling Cohort Recruitment Call Assignments** workbook
- Expansion Tracking database
  - Sib Baseline tab
    - ✓ Eligibility Status
    - ✓ Date Survey Completed (Do not call if they have returned the Sibling survey.)
    - ✓ Outcome Codes
    - ✓ Dates packets sent (including resends and emails)
    - ✓ Tracking Comments
  - Sib Info tab
    - ✓ Address/Phone/Email Date and Source
    - ✓ Comments
    - ✓ Tracing Codes
    - ✓ Hold Codes
    - ✓ Time Zone
  - Header
    - ✓ Gender
    - ✓ DOB
    - ✓ Death Date
    - ✓ Survival Status
    - ✓ Spanish Status
  - Permission tab
    - ✓ Date Permission received
    - ✓ Permitting Entity
    - ✓ Comments field
  - Sib Reg tab
    - ✓ Sibling Study Outcome box
    - ✓ Parent contact info
  - Sib AddlContact Info tab
  - CALL History

AFTER THE CALL: Update all appropriate fields, documents.

- **Sibling Cohort Recruitment Call Assignments** workbook
- Expansion Tracking database
  - CALL Log
  - Sib Info tab
    - ✓ Contact information, dates, sources
    - ✓ **Send Q-Aire To** field
    - ✓ **Sib CCSS Hold** and **Hold Date** fields
    - ✓ **Tracing Status** and **Tracing Date** fields
    - ✓ **Comments** field
  - Sib Baseline tab
    - ✓ **Baseline Outcome** field and date for refusals (uncompleted Sibling surveys only)
    - ✓ Document survey link sent via email
  - Sib AddlContact Info tab
  - Sib Reg tab
    - ✓ Parent contact information
    - ✓ **Sibling Outcome** field and date for all refusals
  - Header section - Change in DOB, **Gender**, name, **Spanish Status**
- **Call Outcomes Log**
    - ✓ Change in **Survival Status**, name, DOB, gender
    - ✓ Refusal or ineligible
    - ✓ Completion of survey in Spanish
- **Partially Completed Survey Tracking Log**, if applicable.
- File the **Informed Consent Expansion Sibling**, if applicable.
- File the **Expired Participant Information Sheet**, if applicable.
- Email, if applicable:
    - ✓ Closing Monitor (for unscheduled surveys)
    - ✓ CRA2 (for completed Spanish surveys)
    - ✓ LSI team (appts to be assigned, calls hold requests)
- Update Call Center calendar, if applicable.
- Update Dry Erase Board, if applicable.
- Update **Journal**, if applicable.
- Update **Informed Consent Copy Request Log**, if applicable.

Revision Record Printed 12/4/2013 9:46 AM

[243] Current Filename:		Pre-Post Checklist - Sibling Survey Calls ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	5/21/13	R. Massey, A. Oyuela, D. Rinehart	Initial Development
1.1	12/3/13	R. Massey	Content revision, post-call: add Informed Consent log, add events to Call Outcomes Log, add LSI team for emails

Preventing Ineligible Cases in Recruitment from Rolling Over

Background

Occasionally, after a Verbal HIPAA has been obtained, the Survey Interviewer will realize the case is NOT eligible to participate in the study (ex. participant did not survive 5 years after diagnosis, etc.). If the SI makes this determination and notifies the CRA2 prior to rollover, the case can be blocked from rolling into Expansion. This procedure outlines the steps in blocking the case ***before*** the roll over occurs and the documentation necessary when this procedure is conducted.

If the case does roll over, the CRA2 will note the ineligibility in the Expansion Tracking database with the appropriate documentation.

Procedure

1. Follow the steps in the morning procedures as usual:
    - import the daily worksheet into the Recruitment database, using the designated append query (appends to tblOnlineHIPPAinfo)
    - run the query, qupdZZZHIPPAinfo
    - open the frmAdmin_JBx_PreRollover and follow instructions
2. After all necessary data "clean-up" has been conducted, but BEFORE rolling the records over to the expansion database, open the record for the participant that has been found to be ineligible:
    - Go to the tracking tab and remove data from the following fields:
        - Outcome Code
        - Outcome Date
        - Inst MR Status
        - Date INST MR Signed
        - Inst MR Source
        - Verbal MR Int ID
    - In the Recruit Notes section, note that SI learned of ineligibility while enrolling the participant, therefore the case had been prevented from rolling over. Date and initial the notes.
    - Move off the record to save the changes.
    - Continue with the rollover process.
    - When the rollover is complete, verify the case did not roll into Expansion.
3. Important Note: DO NOT use the rollover process again **on the same day** you conducted the procedure. If you do, the case will rollover. Should this occur, go to Expansion tracking and use the ineligible outcome code to prevent further contact.
4. Inform all others who may use the rollover process to prevent rollovers from occurring on the same day the prevention procedure was used.

Revision Record

Current Filename:		Preventing Ineligible Cases in Recruitment from Rolling Over ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	5/24/2012	L.Harrison	Initial Development

Printing INDIVIDUAL Expansion Baseline Surveys

Background

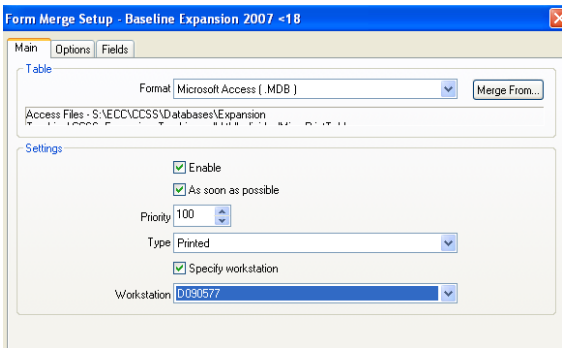
This procedure is used to (a) print surveys for early recruitment cases which do not have a record in the print table or to (b) print surveys one-by-one rather than in batch mode.

Procedure

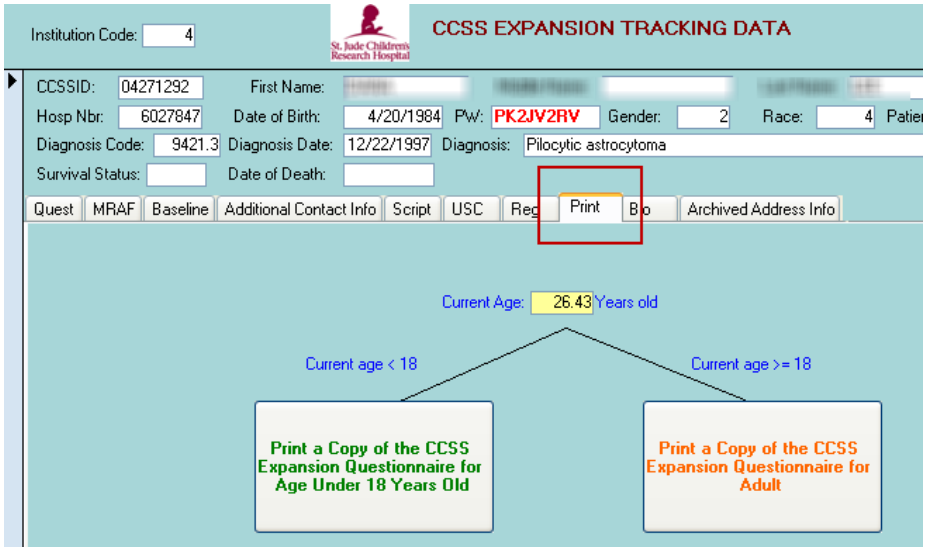
1. In Teleform AutoMerge Publisher, locate the appropriate Baseline Expansion 2007 form (Adult or <18). Be sure to choose the one that references the INDIVIDUAL Access print table. E.g.,

   Baseline Expansion 2007 Adult — CCSSExpansion - CCSS_Expansion_Tracking\tblIndividualAdultPrintTable
   Baseline Expansion 2007 <18 — CCSSExpansion - CCSS_Expansion_Tracking\tblIndividualMinorPrintTable

2. Right-click the form name, and select **Enable** (this checks Enable button, so that form will print)
3. Right-click again and select **Properties**. In the Properties box, pick your workstation number from the **Workstation** dropdown box. Click **OK** to close the Setup window. (Says print from THIS station)



4. From the toolbar **File** menu, select **Print Setup**. In the print setup dialog, select the appropriate printer (epi_c-copier_1 or epi_c-copier_2). Then click Properties… for the printer. From Favorite Setting, select **Booklet**. Click OK. (Says how/where to print)
5. Locate the case by CCSSID in the expansion tracking database.
6. Click on the **Print** tab. Based on the age shown in **Current Age**, click the appropriate **Print a Copy** button. This adds a record for this case to the specific INDIVIDUAL print table, and codes Record_sta with "23". Since AutoMerge publisher is set up to accept jobs from your workstation, printing should start right away. During the printing process, the Record_sta value should go from 23 to 22 and then to 20 (20 means it was printed).



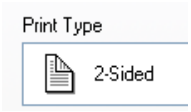
7. When printing is finished, in AutoMerge Publisher, right-click the form you printed, click the Enable toggle to uncheck it.

Current Filename:		Printing Individual Expansion Baseline Surveys ver 2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/17/10	J.Bates	Initial Development
2	7/7/11	J.Bates	Update imperative explanation

Printing Merged HIPAA Documents

Background

Some institutional HIPAA documents mail merged with the participant name and date of birth are printed one-sided (front side only) and others are printed two-sided (both front and back sides), as outlined in this document.



Procedures

#	Institution	1 or 2 sided?	Other Remarks
01	University of Minnesota	One-sided	Spanish not yet available
02	Denver Childrens	One-sided	
03	Pittsburgh	Two-sided	NO stapling needed. SPANISH: print one-sided
04	Children's Hospital at Stanford	One-sided	
06	Emory	One-sided	
07	Washington National	One-sided	Spanish not yet ready; on hold
08	U.T.M.D. Anderson Cancer Center	One-sided	
09	Memorial Sloan Kettering Cancer Center	Two-sided	Contact information sheet is part of MSK's HIPAA. Spanish not available
11	UCSF	To be determined	
12	Seattle Children's Hospital	One-sided	
13	Toronto	To be determined	Consent (HIPAA) only documents not yet ready; no Spanish needed
15	St. Jude Children's Research Hospital	One-sided	No Spanish needed
16	Nationwide	One-sided	
17	Roswell Park	One-sided	
19	Minneapolis	One-sided	
20	Children's Hospital of Philadelphia	One-sided	
21	StLouis Childrens	One-sided	No Spanish needed
22	Childrens Los Angeles	Two-sided	BLANK page prints at the end
23	UCLA	Two-sided	BLANK page prints at the end
24	Riley (Indiana)	Two-sided	UPDATED 10/26/11 so contact info sheet prints on 3rd sheet. BLANK page will print at the end. No Spanish available. Living and deceased the same
25	UAB	One-sided	No Spanish needed
26	Michigan	Not applicable	We current do NOT generate HIPAA-only document for Michigan. (if that changes, will be a two-sided print job).
27	UT Southwestern	One-sided	
28	Texas Childrens	One-sided	
29	City of Hope	One-sided	

PLEASE NOTE:

- SOME two-sided documents will have extra (BLANK) page(s). These pages force the document to have an even number of sheets, so when you merge your file directly to the printer, each person's document can be separated.
- AFTER you print the documents having more than one sheet, **please STAPLE the pages for an INDIVIDUAL PERSON together**.

Revision Record Printed 8/14/2012 7:37 AM

Current Filename:		Printing Merged HIPAA Documents ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	12/2/11	J.Bates	Initial Development
1.1	8/14/12	J.Bates	Clarify one vs two sided

Printing Surveys with Teleforms Automerge Publisher

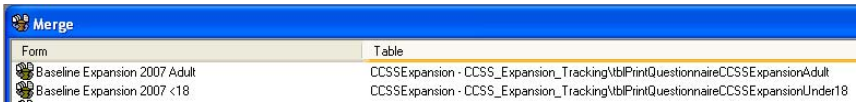
Background

We print survey booklets using the Cardiff Teleform program. Automerge Publisher merges respondent-specific information into the survey booklet and then prints the survey. Publisher must print surveys one by one. The merged information comes from the survey-specific print table typically located in the study's tracking database. What is merged depends on the survey design. At the very least, Publisher ALWAYS inserts the CCSSID at the bottom of each page. You will use the survey-specific print table during the Automerge Publisher process. You will also ordinarily have a data file listing the cases to be printed as well as a key to find that record in the print table. (This key is often labeled "SeqNo.")

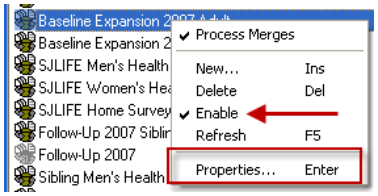
Procedure

1. Start Cardiff Teleform, Automerge Publisher from your Start menu.

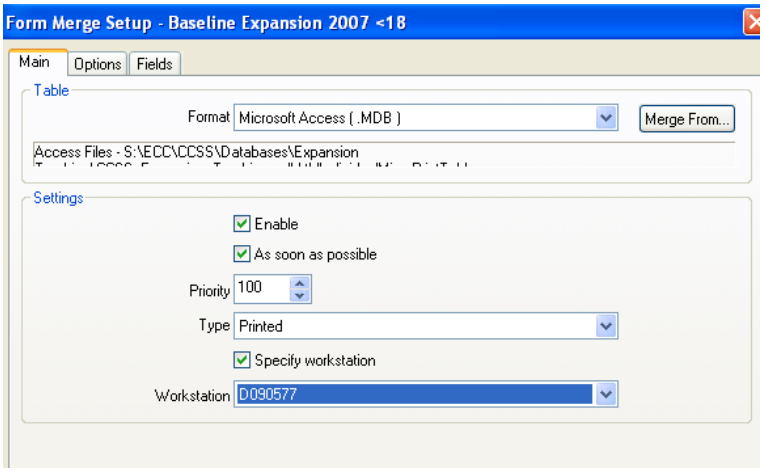
2. On the Merge screen, locate the applicable form. If you do not know the form name for the survey, consult the project manager. (Note: surveys may have multiple versions.)



3. Right-click the name of the form, to be sure **Enable** is checked (if it is NOT checked, then click Enable).



4. Right-click the form name again and select **Properties**. .. This opens the Form Merge Setup window.

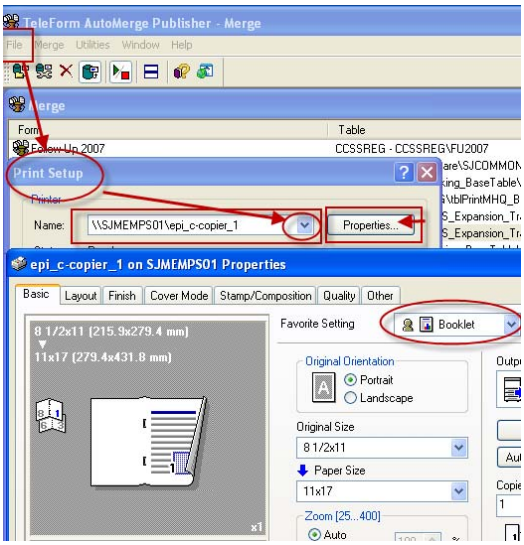


   a. In the Form Merge Setup window, be sure Specify workstation is checked. Then click the **Workstation** dropdown arrow. Select the PCA number of the printer you are printing from to tell Teleforms to accept print commands from your workstation. Ensure that "**As soon as possible**" is checked.
   b. Click **OK** to close the setup window.

5. In Teleform Automerge Publisher's menu, select File, then Print Setup.
   a. In the **Print Setup** dialog, select the **Name** of the appropriate printer (e.g., epi_c-copier_1 or epi_c-copier_2) from the dropdown list.

   b. Select Properties… for that printer.

   c. On the Properties screen's **Basic** tab, select **Booklet** from the dropdown box for **Favorite Setting.** *Note: if you do NOT have a "Booklet" setting, refer to the procedure on creating booklet settings for the color copiers. Without this setting, you will have to set the print properties EACH TIME you want to print a survey booklet.*
   d. Click OK (twice)



6. Open the database containing the print table for the survey and then open the appropriate print table
   a. For the print table records assigned to you (refer to SeqNo or CCSSID) set the printing flag to a **23** in the Record_sta column to place the record in the print queue.
   b. Automerge Publisher should start printing the survey. While printing, Automerge changes the 23 to 22. Printing is finished when Automerge changes the number back to 20.

tblPrintQuestionnaireCCSSExpansionAdult

Seq_No	Record_sta	Remote_cmp
10108		20468415
10113	20	06310691
10114		12318203
10115	20	12495821

7. If you encounter printing difficulties (e.g., Record_sta gets "stuck" with a number 19 or the job never completes), the Teleform specialist may need to provide assistance.

8. When you finish printing surveys for all your assigned cases, go to the AutoMerge Publisher Merge screen and right-click the form you printed. Then "uncheck" the Enable toggle to un-enable it.

9. NOTE: you may queue a series of booklets to print. To do so, change Record_sta to 23 for each survey you need to print. We recommend you monitor the booklets as they are printed to check color quality, stapling, and paper supplies. If the survey prints with an incorrect FONT, you will need to check with IT to have the necessary fonts installed on the workstation you use.

Revision Record Printed 12/11/2012 9:29 AM

Current Filename:		Printing Surveys-Teleforms Automerge ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	2/22/12	J.Bates	Initial Development
1.1	12/11/12	J.Bates	Mark "as soon as possible"

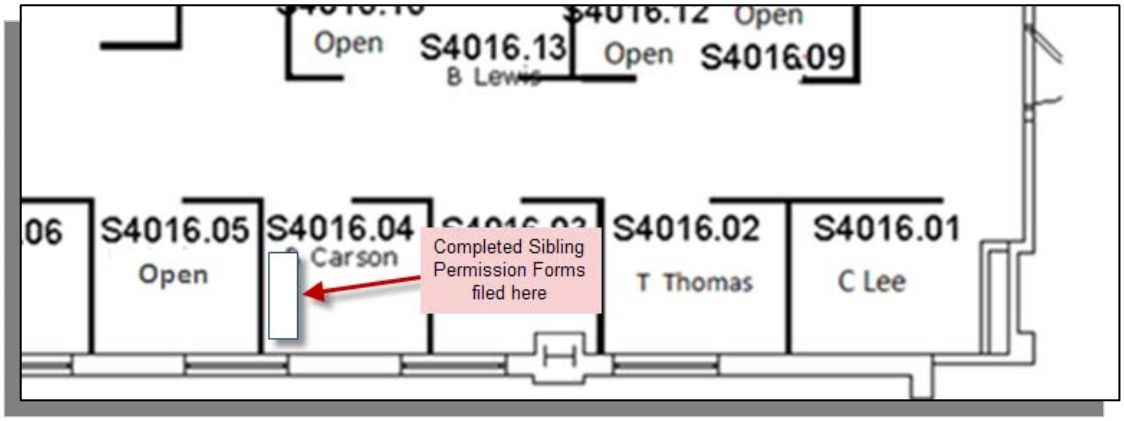
Processing Completed Sibling Permission Forms Post Interview

Background

Permission may be obtained by phone by a Survey Interviewer (SI) either through follow-up calls to non-responders or by the permitting entity's call to the Coordinating Center after receiving the permission packet. When an SI obtains permission or a denial, all information is collected on a paper copy of the sibling permission form. Completed sibling permission forms are then stored in a locked file cabinet and retained for future reference. The Lead Survey Interviewer (LSI) reviews the forms for accuracy and consistency with database entry. This procedure outlines the role of the LSI in reviewing and storing the sibling permission forms.

Procedures

Sibling permission forms completed during a phone interview are placed by the SI in the file folder labeled "Completed Permission Forms - Siblings" located the top drawer of the two-drawer file cabinet next to the printer on the 4th floor, in cubicle S4016.04.



The Lead Survey Interviewer will complete the following steps daily:

1. Retrieve the completed forms.
2. Perform a quality assurance (QA) check for data entry accuracy and completion:
    a. On the permission form
    b. In the sibling and case records in the Expansion Tracking database
    c. In the case's MS Word **Phone Contact Log**

3. Errors or omissions discovered during the QA process will be used as training opportunities, reviewed with the applicable SI, and logged in the **SI Training Opportunities** workbook located at: *Z:\...\Interviewers\LSI\QA Audits*.

4. Sort the forms numerically by SIBIDNO.

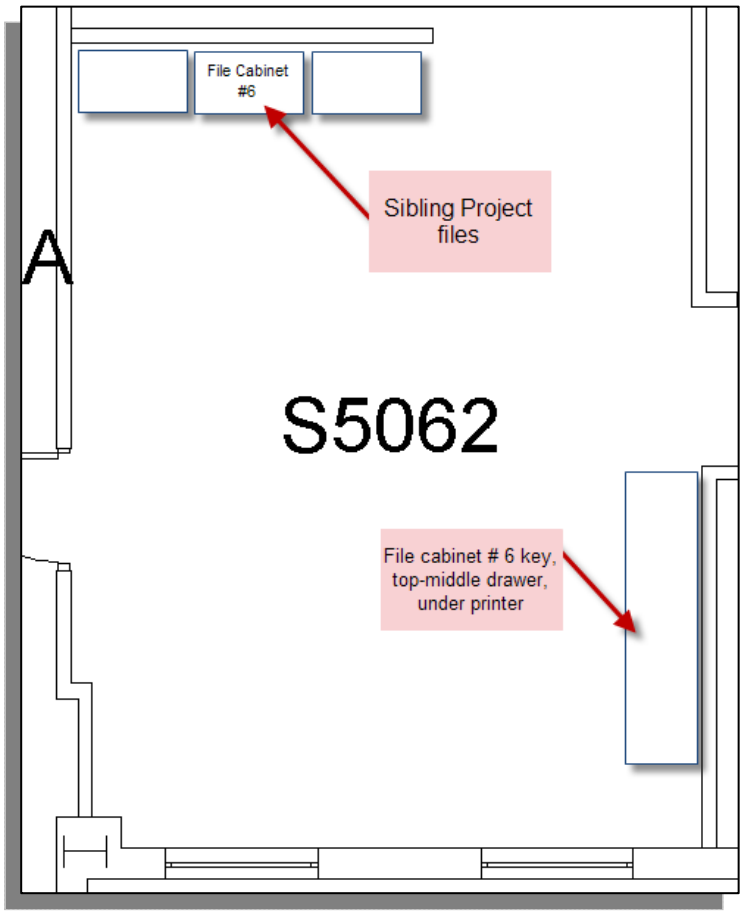
5. File the Permission forms in the folder labeled "Verbal Permissions" in the top drawer of file cabinet number 6, located on the 5th floor in room S5062.

   a. Locate the key to this cabinet at the Windows XP Workstation. It is in the top drawer under the scanner, left front section, on the key ring with the pink bead.

   b. Unlock and open the cabinet, remove the folder titled "Verbal Permissions", and lay it open on the table.

   c. Using the SIBIDNO as reference, insert the newly completed forms into the file in numeric order.

   d. Replace the folder, lock the cabinet, and place the key back in its location at the Windows XP Workstation.



Revision Record
Printed 10/23/2013 9:02 AM

Current Filename:		Processing Completed Sibling Permission Forms Post Interview.1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	5/24/13	D. Rinehart	Initial Development

Processing Follow-Up 5 Thank You Cards

Background

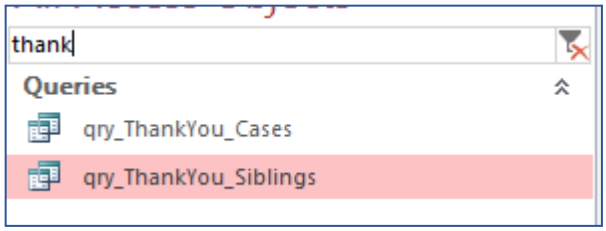
When a participant or his/her representative completes the Follow-Up 5 (FU5) survey on paper, online, or via telephone, the Long-Term Follow-Up (LTFU) Study sends a card to thank the subject for his or her participation. This procedure outlines the process for generating thank you cards sent following completion of the FU5 survey.

Procedures

NOTE: This procedure is ideally done once weekly AFTER the Call Center has completed the daily database updates.

<u>Generate the Set of Participants</u>

1. Open the CCSS LTFU Participants database, located at *https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*.
2. Run the query named qry_ThankYou_Cases, and use the Access filter to check for data entry issues including:

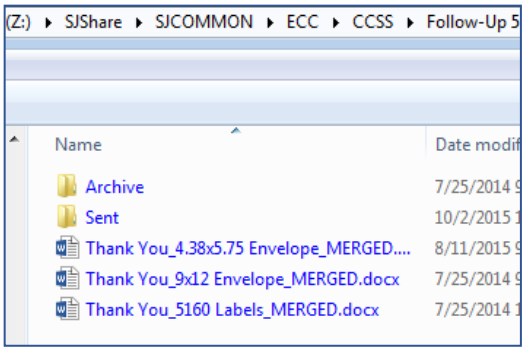


   A. LAR – If the participant has an LAR, ensure the Care of field is properly populated.
   B. Confirm the address is complete.
      i. Confirm the ZIP code is present for all addresses.
      ii. Confirm that any record with a ZIP code indicating an international address also has a populated country field.
   C. Review the outcome code field to determine if the outcome code should be removed and to confirm a thank you card should be sent.
   D. Review the Spanish indicator. Determine if a Spanish insert is available or needed, where appropriate.
3. Sort the data so that all international addresses are grouped at the top or bottom of the list.
4. Export the query as an Excel file. The file should have the same name as the query name. Save it at *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5\Thank You Card*.
5. Run the query named qry_ThankYou_Siblings, and repeat the entire process.

<u>Print and Mail the Cards</u>

1. Mail merge each file.
   A. If no additional documents (e.g. reconsent form, etc.) need to be included in the envelope with the card, merge the file with **Thank You_4.38x5.75 Envelope_MERGED**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5\Thank You Card*.

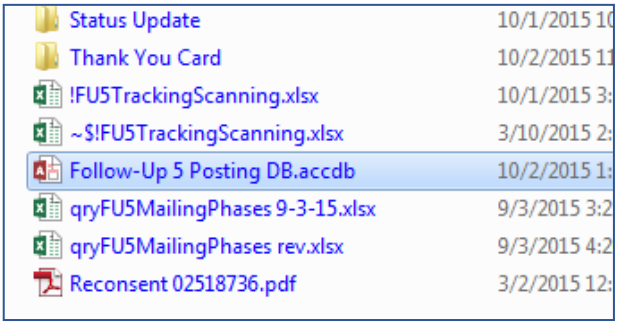
B. If other documents (e.g. reconsent form, etc.) need to be included in the envelope with the card, merge the file with **Thank You_9x12 Envelope_MERGED**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5\Thank You Card*.



2. Print each merged file to the appropriately sized envelopes.
3. Separate the international addresses from the domestic addresses.
4. Stuff each printed envelope with pre-printed thank you cards from the storage room, and then seal the envelope.
5. Bundle international cards together with a note to the mail room that they are being mailed internationally.
6. Place stuffed and sealed envelopes in the outgoing mail.

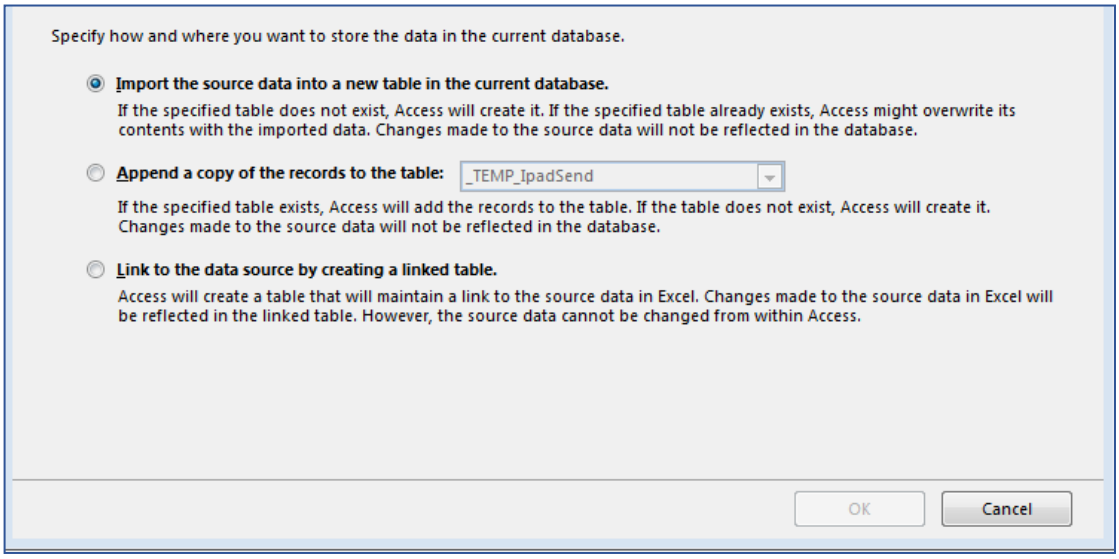
<u>Update the CCSS LTFU Participants Database</u>

1. Open the Excel files **qry_ThankYou_Cases** and **qry_ThankYou_Siblings**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5\Thank You Card*.
2. In **qry_ThankYou_Cases**, create a new tab named "_ThankYouSent".
3. Copy the participant ID column, including the heading, from the qry_ThankYou_Cases tab, and paste it into column A of the new _ThankYouSent tab.
4. Copy the participant ID column, without the heading, from the **qry_ThankYou_Siblings** workbook, and paste it into column A of the _ThankYouSent tab of the **qry_ThankYou_Cases** workbook beginning at the first blank row. This should create a single column, with heading, in the new tab, and the column should contain all participant IDs.



5. Open the Follow-Up 5 Posting DB database, located at *Z:\SJShare \SJCOMMON\ECC\CCSS\Follow-Up 5*.
6. Import **qry_ThankYou_Cases** into the Follow-Up 5 Posting DB database.
   A. Click the Excel icon in the Import & Link group of Access's External Data tab.
   B. In the Get External Data – Excel Spreadsheet box:
      i. Browse to *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5\Thank You Card* and select **qry_ThankYou_Cases** to open.

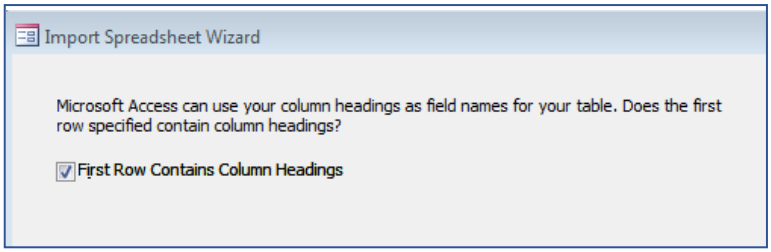
ii. Select the **Import the source data into a new table in the current database** radio button.



iii. Click **OK** to open the Import Spreadsheet Wizard.

a. Select the _ThankYouSent tab, and click **Next>**.

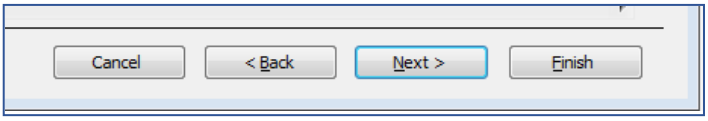
b. On the next page, check the **First Row Contains Column Headings** checkbox, then click **Next>**.



c. On the next page, click **Next>** to accept the default Field Options settings.

d. Again, on the next page, click **Next>** to accept the default primary key settings.

e. The next page will display the tab name as the table name. Accept this by clicking **Finish**.



f. A message will appear asking whether to overwrite the existing table or query. Click **Yes**.

g. In the next window, click the **Close** button.

7. In the Follow-Up 5 Posting DB database, run the update query named qupd_ThankYouSent. This query uses the imported table to update the FU5 table in the CCSS LTFU Participant database with the current date.

Archive the Workbooks

1. Rename the Excel files **qry_ThankYou_Cases** and **qry_ThankYou_Siblings**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5\Thank You Card*, to include the current date at the end of the name.
2. Drag each renamed file to the Sent folder, *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5\Thank You Card\Sent*.

Confirm Success (Optional)

To confirm the process was successful, run the queries qry_ThankYou_Cases and qry_ThankYou_Siblings in the CCSS LTFU Participants database again, and confirm only new participants are returned.

Revision Record
Printed 10/22/2015 12:23 PM

Current Filename:		Processing Follow-Up 5 Thank You Cards ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/22/2015	J. Ford, R. Massey	Initial Development

Processing Institutional HIPAAs

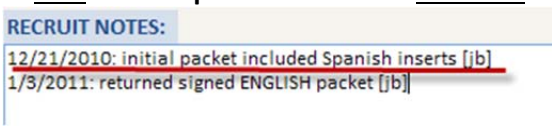
Background

Institutional HIPAAs returned in the US mail are processed in the Recruitment database, and possibly in the Expansion Tracking database. Different procedures are used depending on whether the case has already rolled over into Expansion Tracking. Contact information is updated. If a verbal HIPAA has been obtained, scan the signed paper HIPAA to pdf.

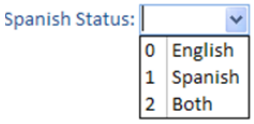
Procedure

1. Date-stamp the HIPAA in upper right corner. Write your initials after the date.
2. Verify the HIPAA is properly signed and dated.
    a. If it is NOT, give it to CRA2 for further action.
    b. CRA2 will mail new blank HIPAA with explanatory cover letter and return envelope, documenting as a resend in the recruitment database. The letter and the signed HIPAA are filed in the "Hold for HIPAA" cabinet.
3. Find the case in the **Recruitment** database.

4. If the case **has NOT yet ROLLED OVER** to expansion, then:
    a. Complete in-processing in recruitment database same as you would for full survey recruiting method. I.e.,
        i. Record **Outcome code** (1=recruited), **outcome date** (date received), **Inst MR status** (complete)**, Date Inst MR signed**, **Inst MR Source** (2= paper).
        ii. CLEAR any **Resend Request/date** AND Tr**acingCode/Date**.
        iii. Update **contact information** if new (address, phone, email). Data source is HIPAA. Be sure to archive address *before* updating.
    b. Read the Recruit Notes (Tracking tab) to see *if we ever mailed* **Spanish materials.** If we DID mail Spanish materials, then review which signed HIPAA was returned (English, Spanish, or Both).



        i. If SPANISH was signed: select "1" from Spanish Status dropdown and then document in Recruit notes (e.g., "returned signed SPANISH packet").
        ii. If ENGLISH was signed: select "0: from Spanish Status dropdown and document in Recruit notes.
        iii. If BOTH were signed, select "2" from Spanish Status dropdown and document in Recruit notes.



    c. If the individual indicates a **NAME CHANGE**, on QUEST tab
        i. Annotate in Comments (e.g., mm/dd/yy: notified of name change via returned HIPAA [inits])
        ii. Enter the full name in **To whom Letter sent**
        iii. Ask the CRA2 to make the name change in the **PTFirst/PTlast** fields.

iv. Ideally, change names BEFORE the record is rolled over into expansion tracking. If not, then update in Expansion, and update the print table names in expansion.

5. If the **case HAS already rolled over**, this is either because (1) a verbal HIPAA was obtained or (2) the participant completed the process online. *IN EITHER CASE:*
   a. Annotate that we received signed Inst HIPAA, in **both** databases: (e.g.,"signed InstHIPAA received mm/dd/yy") in **Recruitment's** RecruitNotes and in **Expansion's** Quest tab, Comment field.
   b. Refer to the *Contact Information Update* page. If information differs from current info on file in **Expansion**, archive existing address, update address, and use the Update Print Table ADDRESS button. (No need to update the Recruitment database address.)
   c. **Scan the signed HIPAA to pdf** (see Scanning and Logging Institutional HIPAAs for Data Managers).
      i. Note: you will NOT be able to log the scanning.
      ii. Give the signed HIPAA to the CRA2, who will:
         1. Manually add the record to the Paper Institutional HIPAA Scanning WorkList
         2. Log the scan into the Scanning Worklist
         3. File the logged/scanned document in the Signed Inst HIPAA file drawer.

6. **IF the respondent requested that we mail a survey**, then enter the resend request in the Expansion Tracking database (after the record is rolled over).

7. **Staple** the Contact page behind the completed HIPAA
8. **FILE** both in the Signed Inst HIPAA file drawer, sorted by CCSSID.

Revision Record Printed 8/31/2012 8:01 AM

Current Filename:		Processing Institutional HIPAAs ver 1_5.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/11/11	J.Bates	Initial Development
1.1	2/14/11	J.Bates	Additional in processing detail
1.2	5/10/11	J.Bates	Streamlining; name changes
1.3	5/24/11	J.Bates	Ck Spanish status
1.4	6/15/11	J.Bates	Remove 82 coding step
1.5	8/31/12	J.Bates	vHIPAA cases-scan to pdf

Processing Invoices for Medical Records and Tissue Requests

Background

The Subsequent Neoplasm (SN) project and Blood and Tissue (B&T) project seek to obtain materials from outside facilities for CCSS-approved research. There are occasions where the outside facility requires a payment in exchange for the materials (medical records, tissue samples) that the projects request. This SOP (1) describes the steps necessary to obtain approval for the payment and to issue approved payments and (2) outlines the required documentation during the approval and payment process.

Procedures

1. When an invoice is received:
   A. **Add the invoice to the appropriate Excel invoice tracking spreadsheet**:
      i. Medical Records Invoice for the SN Project – **Path Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice Tracking*

Invoicing Institution	Invoiced For	Invoice Amount	Date Invoice Receive
Barnes Jewish Hospital	Path Report	$ 6.50	7/3/2017

      ii. Tissue Invoice for the B&T Project – **Tissue Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices*
   B. Make **notes in the appropriate tracking database** documenting the requested payment. *Example: 7/3/2017: Received $6.50 invoice from Barnes-Jewish Hospital for breast cancer records. [RM]*
      i. SN Project – The SNT database can be found at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
      ii. B&T Project – The Blood & Tissue database can be found at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
   C. If the invoice is from a **vendor/facility outside the US**, find out how many US dollars to send. (e.g. If the invoice is for 50 Canadian dollars, or C$50, how many US dollars should be sent?) Our check will be in US dollars.
2. **Request approval** from the Research Scientist to pay the invoice.

A. Provide the Research Scientist with the CCSSID in question, the type of information the CCSS is requesting from the invoicing entity (e.g. pathology report, complete breast cancer records, tissue sample, etc.), and the amount of the invoice.
B. S/he may direct the Clinical Research Associate (CRA) to seek approval from the Project Director.

3. If **payment IS NOT approved**:
   A. Update the Status and Notes columns of the appropriate Excel invoice tracking workbook:
      i. SN Project – **Path Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice Tracking*
      ii. B&T Project – **Tissue Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices*
4. If **payment IS approved**:
   A. Update the appropriate **Excel invoice tracking workbook** with the approval date, approving entity, and new status.
      i. SN Project – **Path Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice Tracking*
      ii. B&T Project – **Tissue Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices*

Date of Approval	Approved By
7/6/2017	Aaron McDonald PhD

   B. Update the appropriate **project tracking database** with the approval. *Example: 7/6/2017: The $6.50 invoice from Barnes-Jewish Hospital was approved for pymt by AJM today. [RM]*
      i. SN Project – The SNT database can be found at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
      ii. B&T Project – The Blood & Tissue database can be found at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
   C. **Obtain the proper tax form** from the vendor/facility.
      i. For US vendors/facilities, find out from the department's Administrative Director if a W-9 form is on file for the invoicing entity.
         a. If yes, skip to the next step.
         b. If no, obtain a completed W-9 form from the invoicing entity. A blank W-9 form can be found at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice Tracking* (SN project) or *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices\W9 or W-8 info* (B&T project).
      ii. For vendors/facilities outside the US, find out from the department's Administrative Director if a W-8BEN-E form is on file.
         a. If yes, skip to the next step.
         b. If no, obtain a completed W-8 form from the invoicing entity. A blank W-8BEN-E form can be found at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice*

Tracking (SN project) or *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices\W9 or W-8 info* (B&T project).

D. **Scan a copy** of the invoice along with the completed tax form, if obtained, into a PDF file.
   i. SN Project – Save path report invoices at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice Tracking\Received Path Request Invoices*.
   ii. B&T Project – Save tissue request invoices at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices*.

E. **Request the check** from the Administrative Director.
   i. Email the invoice and W-9 or W-8BEN-E, if applicable, to the Administrative Director to request that the payment be processed. *Example: Please process payment for the attached $6.50 invoice from Barnes-Jewish Hospital Copy Service, approved by Aaron McDonald on 7/6/17. This invoice is for 188 pages of medical records for CCSSID 18149747 for the CCSS's subsequent neoplasm (SN) project. The W-9 for the facility was received today and is included in the invoice file.*
   ii. Update the appropriate Excel invoice tracking workbook with the date the invoice was submitted to the Administrative Director and the new status.
      a. SN Project – **Path Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice Tracking*
      b. B&T Project – **Tissue Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices*

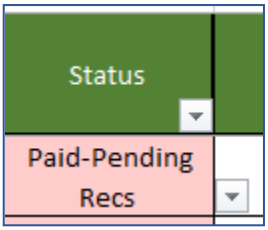
Date to Administrative Director	Date of Payment
7/21/2017	8/3/2017

   i. Update the appropriate project tracking database to indicate the invoice was submitted to the Administrative Director. *Example: 7/21/2017: Requested $6.50 invoice payment to Barnes-Jewish from the Admin Dir today. [RM]*
      a. SN Project – The SNT database can be found at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
      b. B&T Project – The Blood & Tissue database can be found at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.

F. When the check for the invoice is received from the Administrative Director, **send the payment** to the facility.
   i. Confirm all information on the check matches the data on the invoice.
      a. Invoice Number
      b. Amount
      c. Payee
      d. Payee address
   ii. **Make a copy of the check** and add it to the invoice file.

a. SN Project – Save the copy at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice Tracking\Paid Path Req Invoices*.
b. B&T Project – Save the copy at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices*.

iii. **Mail the original invoice and check** to the invoicing entity.
iv. Update the **tracking sheet** with the date the payment was made and the new status.
v. Update the **tracking db** with the date the payment was made. *Example: 8/3/2017: Mailed $6.50 check for invoice 112479 for breast cancer records to Barnes-Jewish Hospital today. [RM]*



G. Make an Outlook reminder to **ensure records/tissue paid for are received**.
H. When the materials are received, update the appropriate Excel invoice tracking workbook with the new status (Status = Closed).
i. SN Project – **Path Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Invoice Tracking*
ii. B&T Project – **Tissue Invoice Tracking** located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Blood and Tissue\Tissue Invoices*

Revision Record
Printed 8/3/2017 3:11 PM

Current Filename:		Processing Invoices for Medical Records and Tissue Requests ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	8/3/2017	R. Massey	Initial Development

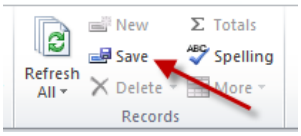
Processing LTFU Expansion Baseline Dana Farber

Background

Processing baseline surveys from Dana Farber (institution code 05) involves several additional steps. These include entering the date of birth and gender from the survey into the database, making a copy of the signed HIPAA, giving incomplete HIPAA documents to the CRA2, and filing deceased booklets separately from surveys.

Procedure

Date of Birth and Gender

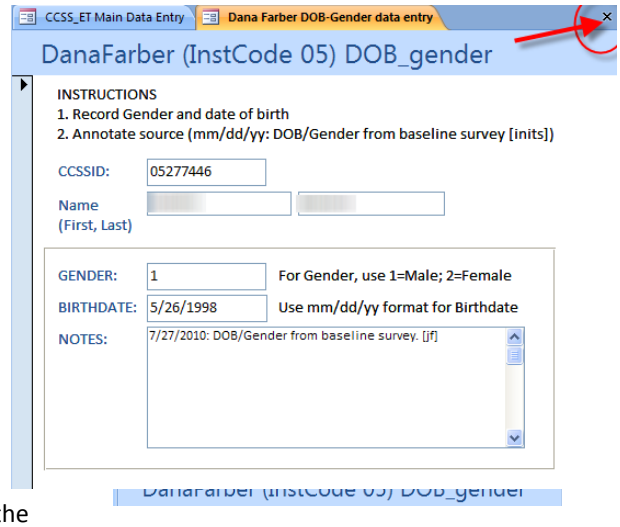


1. Locate the participant in the CCSS Expansion Tracking database.

2. Save any edits made to the record using the Save icon in the Records group of the Access Ribbon's Home tab.

3. On the Baseline tab, click **Dana Farber DOB Gender** button.

4. Verify the correct case is displayed in the Dana Farber DOB-Gender data entry form. If not, search in the **CCSSID** field.



5. On the Dana Farber DOB-Gender data entry form, key in:
   A. **Gender** – Obtain the correct gender from question A2. Enter "1" for male or "2" for female.

   B. **BIRTHDATE** – Obtain the correct date of birth from the completed survey (in question A1 or on the signature page of the consent and/or SJ HIPAA).

   C. **NOTES** – Document the gender and DOB data changes and the source of the information. If verbiage already exists in the field, make the documentation AFTER the existing notes. Do NOT clear existing notes. Example: "*1/30/2015: Gender/ DOB entered from baseline survey [jf]*"

6. Close the Dana Farber DOB-Gender data entry form to return to the CCSS_ET Main Data Entry form.

7. To see the changes, use the Refresh button in the Records group of the Ribbon's Home tab. Otherwise, the change will display after the database is closed and reopened.

Signed LTFU HIPAA Authorization

Photocopy the SIGNED LTFU HIPAA authorization page, and give this to the CRA2. The CRA2 files this with signed DF HIPAAs, to be sent to the data manager.

Incomplete or UNSigned LTFU HIPAA Authorization

If the HIPAA signature is MISSING or NOT DATED or SIGNED BY A MINOR:

1. On the Baseline tab:
   a. **MR Status** – Populate with 6-Send Medical Release.
   b. **Date MR Signed** – Leave blank (unless they did date it). For questions, see the CRA2.

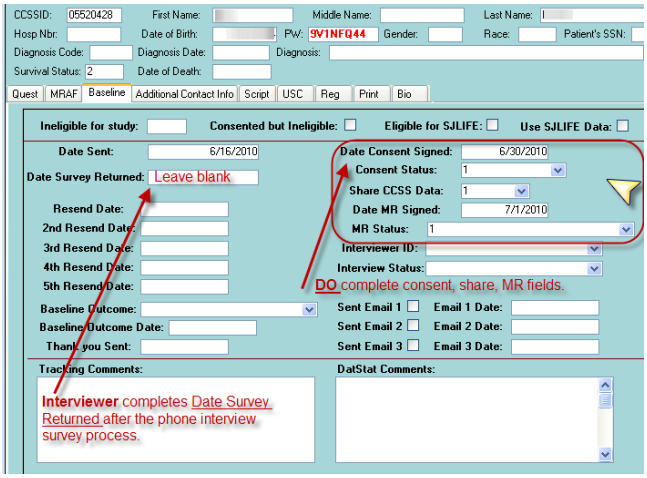
2. AFTER *completely* in-processing the survey, give the survey to the CRA2 for a signature request letter. Do NOT put it in the "coding" drawer.

DECEASED Dana Farber Booklets

1. **Date Survey Returned** (Baseline tab) – Leave blank.

2. DO populate the **Date Consent Signed**, **Consent Status**, **Share CCSS Data**, **Date MR Signed**, and **MR Status** fields on the Baseline tab.

3. FILE the packet in the Expansion Deceased file drawer. We do not code the Deceased packets.



Revision Record — Printed 1/15/2015 8:57 AM

Current Filename:		Processing LTFU Expansion Baseline Dana Farber ver 1_6.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/29/10	J. Bates	Initial Development
1.1	7/26/10	J. Bates	Elaborate on deceased processing
1.2	8/30/10	J. Bates	DOB/Gender button; incomplete HIPAA change
1.3	12/6/10	J. Bates	Copy of signed HIPAA
1.4	6/16/11	J. Bates	Rework handling of signature request letters
1.5	7/8/11	J. Bates	CRA2 info to separate document
1.6	12/27/14	R. Massey	Content and Formatting Update

Processing LTFU Expansion Cohort Baseline Questionnaires

Background

Processing the intake of expansion baseline surveys from survivors (cases) involves documenting the receipt of the survey, filling out various tabbed pages in the CCSS Expansion Tracking Data database, and checking whether responses warrant follow up due to reports of second cancers, suicide ideation, or other indications of immediate attention. Over 18 expansion surveys for cases use a light blue box with black lettering on the top left corner. Under 18 surveys use a dark blue box with light lettering in the top left corner. The steps for processing the two questionnaires are the same with a few exceptions that are noted in this procedure.

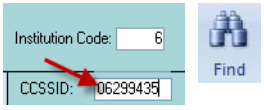
Procedures

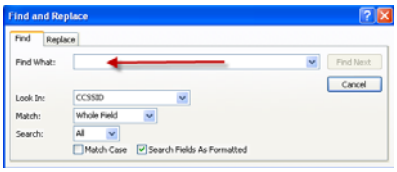
Initial intake processing

1. Open the envelope and stamp the first page of the questionnaire with the date it was received
   a. If the questionnaire is blank, see the CCSS CRA2 for guidance.

2. Check to see if the "Keep for your files" consent documents were returned to us.
   a. If the person returned their copy of the consent documents, we need to mail these back to them.
   b. Check first to be sure that the consent/HIPAA forms in the bound questionnaire are signed.
   c. Consult the CCSS CRA2 for further action.

3. Open the Expansion Tracking Database and find the record for the case.
   a. Place cursor in the CCSSID field
   b. Click on the **Find** icon. (Binoculars on the tool ribbon/bar)
   c. In the **Find and Replace** dialog box, in the **Find what:** space, type in the CCSSID number found on the bottom left corner of the survey. UNcheck the "Search Fields As Formatted" box. Then click **Find Next**





4. Once you locate the record, verify the name of the participant to make sure it matches the name on the questionnaire.

5. ***For MINORs:*** Check to see who completed the survey and signed the consent and the LTFU HIPAA. The minor is NOT the appropriate person for this. If the minor completed the survey and also signed the forms, (1) find case in database, in Tracking Comments on Baseline tab, annotate (***"mm/dd/yy: rec'd survey completed and signed by minor; not logged/processed at this time [inits]"***); (2) give survey to CRA2. Check with CRA2 for *any variations similar* to this.

6. ***For CCSSIDs starting with 05 (Dana Farber):*** See additional procedure **Processing LTFU Expansion Baseline Dana Farber**.

SECTION I – Processing SURVEY in the Tracking Database

Quest Tab

1. **Send Q-aire To**
   a. For Over 18 Questionnaires, you will choose most likely "1 = patient" from drop down menu. There may be exceptions if participant has a legal guardian or parent that completed the questionnaire.
   b. For Under 18 Questionnaires, choose one of the following options listed in the drop-down: "2 = mother only, 3 = father only or 4 = both parents." Determine answer based on contact information/comments provided on the back of the survey.

2. **Tracing Status** – remove anything listed unless it is "Resend Newsletter" (also clear **Tracing Date**).

3. **CCSS Hold** – remove anything listed in the CCSS Hold field AND the value in **Hold Date**.

4. If the participant indicated a name change anywhere on the survey (check signature pages)
   a. Change the name in the **To Whom Letter Sent** field
   b. Click the **Save Record** icon, then click the update **Print Table Name** button
   c. Notify CRA II of the change (email or photocopy of page showing change)

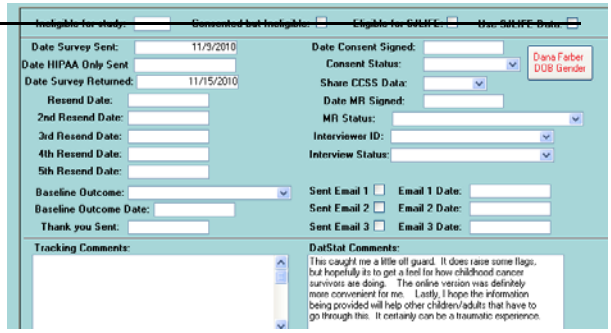
5. **Address/phone/email information updates**. Look at the back page of the questionnaire. [for SloanKettering *also* look at last page of SK's HIPAA form (pg. 6)] Compare with information on Quest tab.
   a. If Quest tab address/phone information is the SAME, and they checked that this information is correct (on back page of survey), enter the date the survey was received (date stamped on front) for **Addr Date** and Survey as the **Addr Source**. Then skip to the Baseline Tab section.
   b. However, *if they indicated changes on survey*:
      i. Click the **Archive Contact Info** button **if** you will be editing a revised address, phone, or email change. Click the Archive button *before* you make the changes.
      ii. Update/Enter Address, City, State, and/or Zip if changes were indicated. Only if address is outside the USA, update/enter a country name.
      iii. Enter the date the survey was returned in the **Addr Date** field (return date will be stamped on the front of the booklet).
      iv. In **Addr Source** field select "survey" from drop-down list.
      v. *After* changing *address*, click the **Save record** icon, then click **Update Print Table Addresses** button.

6. Update/Enter **Phone** field if indicated on the back of the survey (update/enter all phone numbers provided).
   a. If a new phone number is provided on the survey, enter it in an available phone number field.
   b. Use the date survey returned for **Phone Date** and "Survey" as **Phone Source** for all phone numbers added or confirmed by the survey.
   c. Select appropriate **Phone Rank** (e.g., 1 or 2),

7. Update/Enter **Email** as indicated on the back of the survey.
   a. In **Email Date** enter the date the survey was returned.
   b. In **Email Source** field use the drop-down to choose "survey."
   c. Select "1" for the **email RANK** for any email address obtained from the survey.

Important note –
If you change/edit any contact information for over 18 St. Jude participants (CCSSID numbers beginning with "15"), take a screen shot of the new information and give it to SJLife project manager

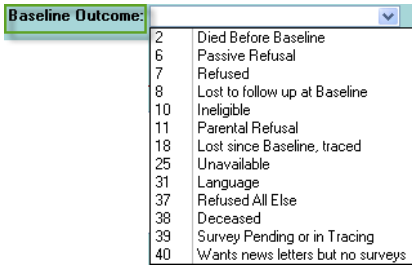
Baseline Tab



1. *If there **ALREADY IS a date** in Date Survey Returned, STOP! Give the packet to CRA2 for further determination.*

2. Update/Enter **Date Returned** with the date stamped on front of survey.

   a. *Exception:* for Deceased Recruited individuals, **leave the Date Survey Returned blank**. This will be filled in later, by the interviewer who administers the survey to the parent(s). The only other thing to process for Deceased Recruits is to check for address/contact information (and this is only for Sloan-Kettering cases.) Deceased Recruited packets are filed in a special location.



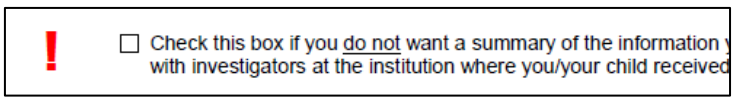
3. On the Baseline tab, check for values in **Baseline Outcome**. If anything is listed, remove it so that Baseline Outcome is blank, and clear **Baseline Outcome Date**.

4. If **Use SJL Data** is checked – uncheck it.

5. Locate the **LTFU Consent form signature page** in the survey. Check to see if the Consent Form has been signed and dated **properly**. A *properly completed consent* will have the signature of *either* the adult research participant *or* the legally authorized representative (parent) for minor survivor. A date should also be written (make sure the date is not the participant's birth date). Use the following chart to determine appropriate data entry. NOTE: For consent discrepancies, consult with CRA2 (and see **Handling LTFU Consent Discrepancies**).

SIGNATURE	SIGNATURE DATE	For **Date CONSENT Signed,** do this:	For **CONSENT Status,** enter
1. Signed properly	Dated	Enter date from the form	1 (complete)
2. Signed properly	NOT dated	Date stamp when received. Enter date received	1 (complete)
3. NOT signed	Dated	Enter date from the form	2 (implied)
4. NOT signed	NOT dated	Do NOT use a date stamper. Enter date received	2 (implied)
5. MINOR survivor OR PARENT of adult survivor signed		Leave blank. See **Handling LTFU Consent Discrepancies** and consult with CRA2	Leave blank

4. For the **Share CCSS Data** field on the Baseline tab, locate the red exclamation point on the LTFU Consent form in the questionnaire.



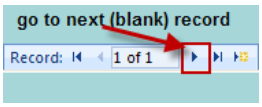
   a. If check box is blank, ***and the consent is properly signed***, then select 1 (Yes) for Share CCSS Data. If check box is blank, and consent is NOT signed, leave Share CCSS Data blank.
   b. If check box is MARKED (consent signed or not), select 2 (No) for Share CCSS Data.

5. Locate the **LTFU HIPAA Authorization page**. Check to see if the Medical Release (HIPAA) form has been signed and dated correctly. Use the following chart to determine the appropriate data entry.

Situation	For **Date MR Signed,** do this:	For **MR Status,** enter
1. MINOR signed MR	Leave blank. Add tracking comment:"Minor signed MR"	10 (incomplete)
2. Signature and date are correct	The date on the form	1 (complete)
3. Signed, but NOT dated	Date stamp when received and enter that date	1 (complete)
4. NOT signed, but dated	Leave blank	10 (incomplete)
5. NOT signed and NOT dated	Leave blank	3 (No Medical Release)
6. Wrote "refused" or similar notation	See CRA2 for guidance, and Leave blank	7 (Refused medical Release)

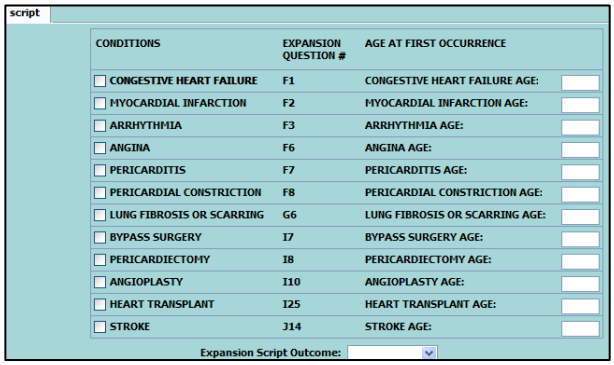
Additional Contact Info Tab (Last page of questionnaire)

1. If no contact information is listed, then no action needed. Skip to the **Script Tab** section.
2. If the contact information provided on the survey is NOT for a parent (mother/father), enter the information on the Additional Contact Info tab:
   a. If this is *the first contact person* for this participant, then enter the appropriate information in the current blank database record (record 1).
   b. If information in the questionnaire is *the same* as what is already in the database, then just update the **Last updated on** field with the current date.
   c. If the contact person is the same, but they *have new contact information* (i.e., address, phone), then enter the new information and update the **Last updated on** field
   d. If the *contact person is different* from what is currently in the database, go to the next blank record and enter the appropriate information. To go the next blank record, click the "next record" icon on the record counter at the bottom of the insert contact information page, or tab through the fields on the form until a new (blank) record appears.



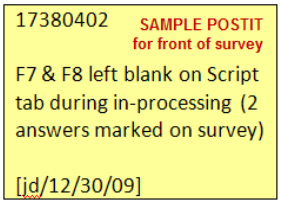
3. If the contact information provided on the survey IS for a parent (mother/father), then:
   a. Check the Reg tab for information we currently have on file for the specified parent.
   b. Using the Comments section of the Quest tab,
      i. Document that we are authorized to use the specified parent as additional contact
      ii. If there was a *different* address on file for the identified parent (on the Reg tab), record this previous address (in Quest Comments).
      iii. E.g., "**m/d/yy: Pt asked to use parent (name) as additional contact. Updated parent's adrs on Reg tab FROM OldAddress, City State ZIP to address provided on survey [inits]**"
   c. Go to the applicable parent on the Reg tab (e.g., either Father or Mother)
      i. Enter any CHANGED or NEW address information for that parent.
      ii. Phone number(s)
         1. If the provided phone number differs from the Reg tab, and a phone field *is available*, use the next available phone field.
         2. If no phone field is available, note an "undated" phone number (or the oldest number if all are dated), add this old number into the note on the Quest tab, and key in the number from the survey in the vacated field.
         3. Key in the survey date in the phone date field, Use "Survey" as source.

Script Tab



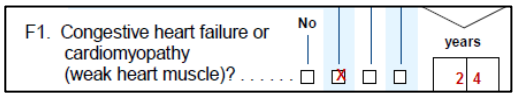
1. Based on replies to certain survey items, we check the related CONDITION and indicate the age from the survey. The survey items on the Script tab are the following:
   a. F1, F2, and F3
   b. F6, F7, and F8
   c. G6; I7 and I8
   d. I10 and I25
   e. J14

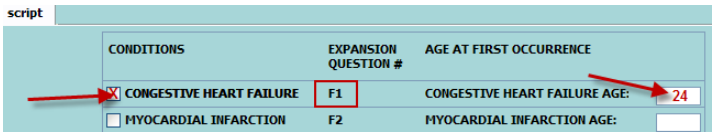
2. For each item:
   a. If respondent marked <u>"no" together with any other response</u>, the answer is ambiguous. When we scan this, we will leave the item blank. Add a 3x3 post-it on front of survey to notify person who scans survey. (See sample)



   b. If respondent <u>just</u> marked "<u>No</u>" or left the item blank, then review the responses for the next item listed on the Script tab.

   c. If respondent marked ANY of the *other* response choices (e.g., <u>Yes, still present</u>; <u>Yes, no longer present</u>; and/or <u>Not sure</u>), then
      i. Click the <u>Condition</u> checkbox for the item on the Script tab.
      ii. If an age is listed, enter in the corresponding "age" box. If age indicated is not a "whole age", then round up or down using the months (6 months or over you round up).





SECTION II –2nd MALIGNANCIES, COMMENTS, SUICIDE IDEATION, DATE OF BIRTH verification

1. **2nd MALIGNANCIES:** Locate section L (<u>Cancer, Leukemia, or Tumors</u>). If the participant indicated "yes" on item L1, (or checked No but wrote *any other information on that page*) indicating that they <u>did</u> have another cancer, leukemia or tumor, then you need to do the following:
   a. Photocopy
      i. the <u>L1 page</u>
      ii. <u>last page (if the last page has any comments)</u>.
      iii. The medical release/HIPAA form (if it is *is signed/ dated correctly)*.
   b. File the HIPAA form copy in the appropriate file cabinet in CCSSID numeric order.
   c. Give the copies of the L1 page and the last page to CRA responsible for SMN processing.

2. **COMMENTS**: Turn to the last page in the booklet. If the Comment Box contains anything, make a copy of the page and give it to the CRA2

3. **SUICIDE IDEATION: IMPORTANT**: For the *Over 18 Questionnaires*, be sure to check question **K4** (Thoughts of ending your life).
   a. If the participant has marked Moderately, Quite a Bit, or Extremely , photocopy the following:"
      i. K4 page
      ii. the survey page that identifies who completed the questionnaire [for recruiting booklets, this will be an inside page, after the LTFU HIPAA Authorization Form]
      iii. the HIPAA page
      iv. contact info page (last page)
   b. Give these copies to Melanie Jackson to handle.

4. **Date of Birth Verification**. Compare the date of birth on record in the Expansion Tracking database with the survey response to question A1 (What is your date of birth). If they are different,
   a. Photocopy the front page of the survey and the page with question A1.
   b. Give to the CRA2 with a note to "check date of birth in database."

FINISHING UP (When all processing tasks are completed)

1. Initial and date the survey on the first page, bottom LEFT of the survey in purple ink to note processing is complete.
2. File the questionnaire in the appropriate cabinet *in CCSSID order*.
   a. **Deceased Recruits**: special file cabinet
   b. **Others**: in the "To be coded" file cabinet; divide by over or under 18.

Revision Record Printed 2/19/2013 1:05 PM

(56) Current Filename:		Processing Expansion Questionnaires ver 5_0.doc	
Rev #	Date	Responsible Author	Change Description
1	6/5/09	T. Overacker/A. McDonald	Initial Development
2	6/16/09	A. McDonald	Script age rounding/consent form entry
3	6/19/09	A. McDonald	Expanded Contact Info section
4.	7/7/09	A. McDonald	Added Suicide Ideation process
4.1	10/2/09	A. McDonald	Country name for non-US addresses
4.2	10/9/09	A. McDonald	USC only recruits; handling blank questionnaires
4.3	12/18/09	J.Bates	Add Sloan Kettering HIPAA contact info
4.4	12/30/09	J.Bates	Adding postit note during Script Tab process
4.5	1/13/2010	J.Bates	Checking who completed under18 survey
4.6	1/22/2010	J.Bates	Formatting, streamlining
4.7	1/25/2010	J.Bates	Edits per Jola
4.8	2/1/10	J.Bates	When date received already entered
4.9	2/2/10	J.Bates	Recruited Deceased: omit dt returned on Baseline; where to file
4.10	3/8/10	J.Bates	Stop notes for Deceased Recruited; undated/unsigned consent
4.11	4/21/10	J.Bates	Updating AddrDate/Source on Quest tab
4.12	4/23/10	J.Bates	Clarification for suicide ideation, pages to copy
4.13	11/17/10	J.Bates	Screen updates
4.14	3/30/11	J.Bates	When minor signs consent/HIPAA; parent or minor completed survey
4.15	12/16/11	J.Bates	Check date of birth
4.16	3/29/12	J.Bates	Clear CCSS Hold
4.17	5/30/12	J.Bates	Clarify consent signature; MR; layout
5.0	2/19/13	J.Bates	Consent discrepancies; chg to AddlContact (parents); 05 cross ref

Processing Newsletter Resend Requests

Background

On occasion, a Long-Term Follow-Up (LTFU) Study participant may request a resend of the most recent LTFU newsletter. These requests will be entered into the LTFU Participant database's Tracing Code field using code 83-Resend Newsletter. At least once weekly a member of the Lead Survey Interviewer (LSI) team or the Coordinator's designee will harvest these requests and process them according to this SOP.

Procedures

Identify the participants requesting a resend of the newsletter:

1. Open the CCSS Call Center Admin Database, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI\Tech\CCSS Call Center Admin DB*.
2. Locate and run the query qry_RM_NewsletterResends.
3. For each participant, check the contact log notes in the LTFU Participant database to determine if the newsletter was requested via email or via hard copy.

For participants who have requested an emailed copy:

1. Open a new Outlook email.
2. In the **Subject:** line, type "Long-Term Follow-Up Study Newsletter" without quotation marks.
3. Attach the most recent newsletter, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Newsletter*.
4. In the body of the letter, copy and paste the following, without the quotation marks:

   "Thank you for your interest in the Long-Term Follow-Up Study. As you requested, please find a copy of our most recent newsletter attached. This newsletter along with all prior newsletters can also be found at the study website: https://ltfu.stjude.org/newsletters.html

   If we can be of further assistance, please call us toll free at 1.800.775.2167 or reply to this email.

   Sincerely,"

5. Copy the participant's email address from the Participant tab, and paste it into the **To…** field of the email.
6. Check the email for any needed formatting corrections, and then click the **Send** button to send the email to the participant.
7. Document the email correspondence in the contact log, as indicated in the SOP titled **LTFU Participant Database Data Entry**.
8. Clear the newsletter resend request from the **Tracing Code** and **Tracing Date** fields of the participant record in the LTFU Participant database.
9. In the Notes form on the Participant tab, make a dated note with SI ID documenting the tracing code changes. Click the **Notes** button to access the form.

For participants who have requested a hard copy:

1. Gather a physical copy of the most recent newsletter, as provided by the CRA2 team.
2. Prepare the mailing envelope:
    A. Open the **Envelope** document, located at Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies.
    B. Type the participant's name, address, and CCSSID into the envelope template.
        i. For minors, the envelope is addressed to "The Parents of" the participant.
        ii. For deceased participants, the envelope is addressed to "The Family of" the participant.
    C. Print the envelope using St. Jude envelopes.
    D. Close the **Envelope** document without saving the changes.
3. Insert the physical copy of the newsletter into the envelope, and seal.
4. Put the envelope in the outgoing mail to send the copy to the participant.
5. Document the outgoing correspondence in the contact log using **Contact Mode** = 5-Mail. See the SOP titled **LTFU Participant Database Data Entry** for instructions on using the contact log.
6. Clear the newsletter resend request from the **Tracing Code** and **Tracing Date** fields of the participant record in the LTFU Participant database.
7. In the Notes form on the Participant tab, make a dated note with SI ID documenting the tracing code changes. Click the **Notes** button to access the form.

Revision Record Printed 12/16/2014 10:51
AM

[283] Current Filename:		Processing Newsletter Resend Requests ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	12/11/14	R. Massey, J. Ford, A. McDonald	Initial Development

Processing Radiation and Surgical Photocopies

Background

Collaborating institutions send the CCSS Coordinating Center photocopies of radiotherapy, brachytherapy, and/or surgical treatment records for participants who completed the institution's HIPAA form. The data manager includes a checklist as the cover sheet for each CCSSID. (Radiotherapy, brachytherapy, and surgery each have distinct checklists.) We maintain a separate file folder for each CCSSID for whom we receive photocopied treatment records. We review photocopies to be sure PHI is removed. We also prepare radiotherapy and bracytherapy photocopies and transmit them for imaging for dosimetry. This procedure outlines in-processing, transmission of radiotherapy records, and filing.

Procedures

IN-PROCESSING AND FILING

1. Open the Expansion Tracking Database. You will be using the MRAF tab.

2. Locate participant by searching via CCSSID. Verify correct case by comparing date of birth to DOB on checklist.

3. **FILE FOLDERS/LABELS**: Determine whether you need a manila file folder for the CCSSID:
   a. Click on the **MRAF** tab.
   b. If *both* **RT_Records** *and* **Surgery_Records** are blank or indicate "No," we likely DO NOT have a file folder for this CCSSID. To make a folder label:

      i. One method is to paste the CCSSID into a running list in Excel. You can then sort by CCSSID and then mail merge into a Word label file for Avery 5366 labels. Having the labels sorted by CCSSID will make filing easier.
      ii. Another method is to paste the CCSSID directly into a Word file set up for 5366 labels.
      iii. See the MRAF file cabinet for label examples.

   c. After processing a batch of photocopies, print the labels, attach each to a file folder, and insert the CCSSID's records into the folder. **File** by CCSSID in the MRAF cabinet.

4. **CHECK** each page **for PHI that has not been de-identified**: Has PHI (protected health information) been de-identified on the photocopies?

   a. Skim each photocopied page for patient name, SSN, parent names, address.
   b. Use a black marker to blacken any PHI you find.
   c. If *a large amount of PHI* needs to be de-identified, you may FedEx the photocopy to data manager so data manager can take care of it.
      i. Email the data manager to explain why you will be returning the photocopies.
      ii. Depending on which record type (e.g., Surgery or RT),
         1. Code the [typ]**_Records** as "Incomplete"
         2. Code the [typ]**_InquiryType** (use USPS for FedEx)
         3. Document "returned for deidentification" in [typ]**_notes**.

5. Check that all pages are **numbered** (page x of y, with checklist as page 1) have the **CCSSID** clearly labeled and are in order. Egregious omissions can be returned to the data manager for correction. Verify that page numbering is sequential and that no pages are missing. Refer missing pages to data manager for further action.

CRA

6. REVIEW THE CHECKLIST IDENTIFYING INFORMATION

a. Do the Medical record number and date of birth on the checklist match what we have in the database?

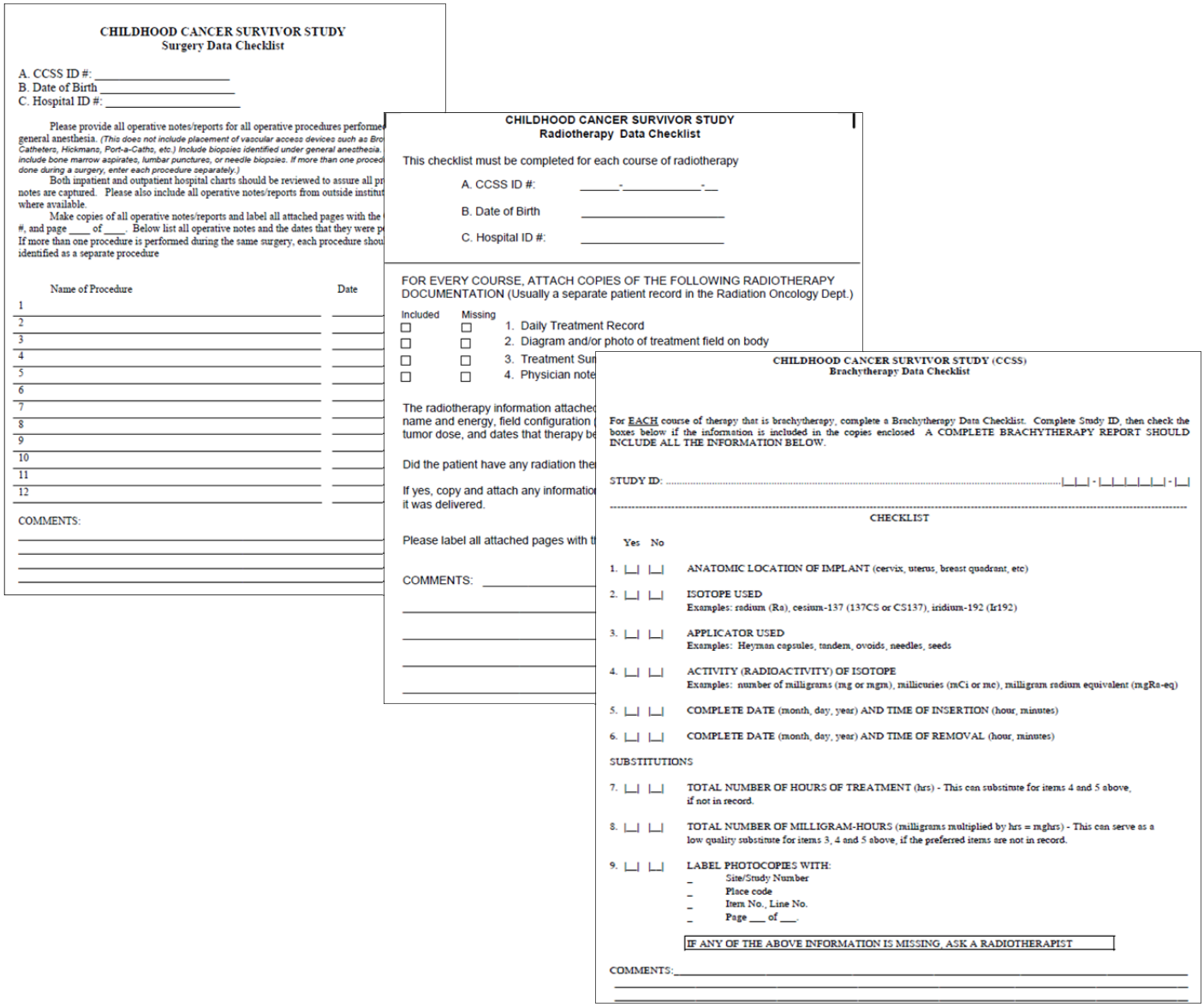
b. IF NOT,

i. email the data manager to verify which is correct (what was written on the checklist, or what is in our database). E.g.,

Cklst CCSSID	Cklst Hosp# ID	Chklst DOB	Issue(s)
26404122	21930799	12/24/1983	DOB on checklist does not match our records (11/24/1983); please verify correct DOB [jf]

ii. Do NOT file the copies until you hear from the data manager. When you hear from the data manager:

1. If the checklist was incorrect, draw a single line through the incorrect data, write the corrected information beside it, and annotate in the Comments portion of the checklist (e.g., mm/dd/yy: Correct DOB is 11/24/1983 per data manager [initials])
2. If OUR records were incorrect, follow the associated procedure to correct the database and annotate the correction in the Comments field on the Quest tab.



CHILDHOOD CANCER SURVIVOR STUDY
Surgery Data Checklist

A. CCSS ID #: _____
B. Date of Birth _____
C. Hospital ID #: _____

Please provide all operative notes/reports for all operative procedures performed
general anesthesia. *(This does not include placement of vascular access devices such as Bro*
Catheters, Hickmans, Port-a-Caths, etc.) Include biopsies identified under general anesthesia.
include bone marrow aspirates, lumbar punctures, or needle biopsies. If more than one proced
done during a surgery, enter each procedure separately.)
Both inpatient and outpatient hospital charts should be reviewed to assure all pr
notes are captured. Please also include all operative notes/reports from outside institut
where available.
Make copies of all operative notes/reports and label all attached pages with the
#, and page ____ of ____. Below list all operative notes and the dates that they were p
If more than one procedure is performed during the same surgery, each procedure shou
identified as a separate procedure

	Name of Procedure	Date
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		

COMMENTS:

CHILDHOOD CANCER SURVIVOR STUDY
Radiotherapy Data Checklist

This checklist must be completed for each course of radiotherapy

A. CCSS ID #: _____-_____-__
B. Date of Birth _____
C. Hospital ID #: _____

FOR EVERY COURSE, ATTACH COPIES OF THE FOLLOWING RADIOTHERAPY DOCUMENTATION (Usually a separate patient record in the Radiation Oncology Dept.)

Included	Missing	
☐	☐	1. Daily Treatment Record
☐	☐	2. Diagram and/or photo of treatment field on body
☐	☐	3. Treatment Sur
☐	☐	4. Physician note

The radiotherapy information attache
name and energy, field configuration
tumor dose, and dates that therapy be

Did the patient have any radiation the

If yes, copy and attach any informatio
it was delivered.

Please label all attached pages with t

COMMENTS: _____

CHILDHOOD CANCER SURVIVOR STUDY (CCSS)
Brachytherapy Data Checklist

For EACH course of therapy that is brachytherapy, complete a Brachytherapy Data Checklist. Complete Study ID, then check the boxes below if the information is included in the copies enclosed. A COMPLETE BRACHYTHERAPY REPORT SHOULD INCLUDE ALL THE INFORMATION BELOW.

STUDY ID: .....|_|_|-|_|_|_|_|_|_|-|_|

CHECKLIST

	Yes	No	
1.	☐	☐	ANATOMIC LOCATION OF IMPLANT (cervix, uterus, breast quadrant, etc)
2.	☐	☐	ISOTOPE USED Examples: radium (Ra), cesium-137 (137CS or CS137), iridium-192 (Ir192)
3.	☐	☐	APPLICATOR USED Examples: Heyman capsules, tandem, ovoids, needles, seeds
4.	☐	☐	ACTIVITY (RADIOACTIVITY) OF ISOTOPE Examples: number of milligrams (mg or mgm), millicuries (mCi or mc), milligram radium equivalent (mgRa-eq)
5.	☐	☐	COMPLETE DATE (month, day, year) AND TIME OF INSERTION (hour, minutes)
6.	☐	☐	COMPLETE DATE (month, day, year) AND TIME OF REMOVAL (hour, minutes)

SUBSTITUTIONS

7.	☐	☐	TOTAL NUMBER OF HOURS OF TREATMENT (hrs) - This can substitute for items 4 and 5 above, if not in record.
8.	☐	☐	TOTAL NUMBER OF MILLIGRAM-HOURS (milligrams multiplied by hrs = mghrs) - This can serve as a low quality substitute for items 3, 4 and 5 above, if the preferred items are not in record.
9.	☐	☐	LABEL PHOTOCOPIES WITH: _ Site/Study Number _ Place code _ Item No., Line No. _ Page ___ of ___.

IF ANY OF THE ABOVE INFORMATION IS MISSING, ASK A RADIOTHERAPIST

COMMENTS:_____

CRA

7. Surgery Records: LOG RECEIPT and REVIEW PHOTOCOPY

a. Check all photocopied pages for PHI, de-identifying as necessary. Check that all pages are present, numbered, in order and have the CCSSID clearly labeled.

b. Use the right side of the database MRAF screen to document Surgery records

i. Record **Surgery_Date Received** (date we actually received photocopy)

ii. Record **Surgery_Date Reviewed** (date we reviewed the photocopy)

iii. Refer to the checklist to determine number of surgeries. The data manager will itemize on the checklist the procedures (one per line), and indicate the procedure date. Count the number of unique dates. This represents the number of surgeries. Enter the number in **Surgery_Number of Records Received**. Verify that the photocopies include a surgery record for each date itemized. If any are missing, open an inquiry with the data manager and code the record as Incomplete.

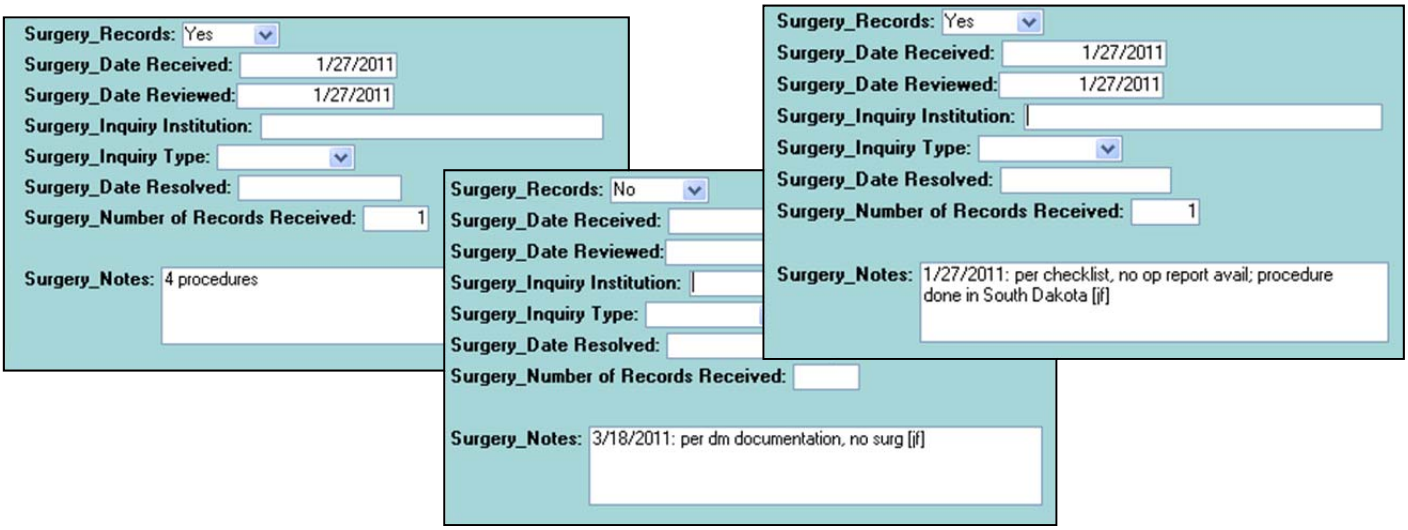
iv. Coding **Surgery_Records**: Code as Yes, No, or Incomplete, *after* you have reviewed the pages.

1. Leave **Surgery_Records** blank if we have no information about surgical treatment
2. *IF data mgr explicitly reports NO surgery was performed*, enter "NO" and annotate in **Surgery_Notes**
3. If records are received and complete, enter "YES." (If checklist indicates some surgery records were sent but comments indicate others were not available, then we code this as YES (not Incomplete), annotating in **Surgery_Notes**.)
4. If records are incomplete (missing pages, cut-off pages, record returned for de-identifying PHI), select "Incomplete" and select the appropriate **Surgery_Inquiry Type** (how you communicate with data mgr to rectify the situation).
5. After an open inquiry is resolved, enter the date resolved in **Surgery_DateResolved** and annotate in **Surgery_notes**.

v. **Surgery_notes**

1. If total number of procedures is different from number of surgeries, enter procedure count in **Surgery_notes** (e.g., 4 procedures).
2. Enter any data manager comments in **Surgery_Notes**.
3. If an inquiry to data manager is opened, annotate in **Surgery_notes**.

vi. We do not currently use **Surgery_Inquiry Institution** (assumed as parent institution)



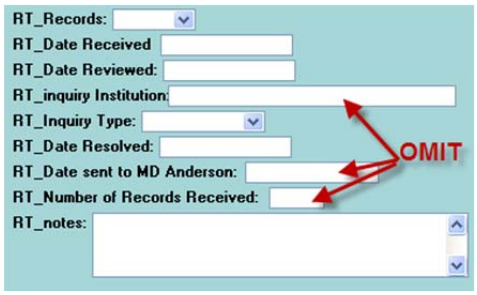
8. **FILE surgery records** by CCSSID in the MRAF cabinet.

CRA

9. RT and Brachytherapy Records: LOG RECEIPT and REVIEW PHOTOCOPY

a. Check all photocopied pages for PHI, de-identifying as necessary. Check that all pages are present, numbered, in order and have the CCSSID clearly labeled.

b. Use the left side of the database MRAF form for RT and Brachytherapy records:

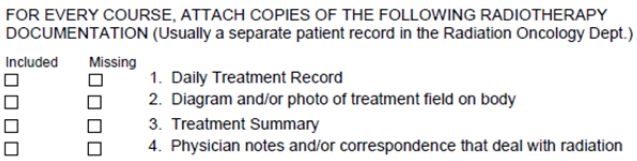


i. OMIT: *RT_inquiry Institution*, *RT_Date sent to MD Anderson*, and *RT_Number of Records Received*. We do not currently use these fields.

ii. Record **RT_Date Received** (date we actually received photocopy)

iii. Record **RT_Date Reviewed** (date we reviewed the photocopy)

iv. Coding **RT_Records**: Code as Yes, No, or Incomplete, *after* you have reviewed the photocopied pages. Note that the RT checklist indicates 4 types of required documentation. The data mgr should mark either "included" or "missing" for each type.



1. Leave **RT_Records** blank if we have no information about RT treatment
2. *IF data manager explicitly reports NO radiotherapy was administered*, code **RT_Records** "NO" and annotate in **RT_Notes**.
3. If records are received and complete, code **RT_Records** "YES." (If the RT checklist marks some items "missing", then we code **RT_Records** YES and indicate in **RT_notes** what was missing per checklist. E.g., "per cklist, missing daily tx record; tx summary"; "per cklist, missing diagram/photo".
4. If records are incomplete , code **RT_Records** "Incomplete", and select the appropriate **RT_Inquiry Type** (how you communicate with data mgr). Annotate in **RT_notes**. E.g., "no indication on cklist whether or not any documents are included or missing from packet; pgs need recopying; returned to institution [jf]"
5. After an open inquiry is resolved, enter the date resolved in **RT_DateResolved** and annotate in **RT_notes**.

c. If the photocopy quality of any page is poor, make a note on the Comments section of the checklist. E.g., "mm/dd/yy: handwriting on pg3 is very faint [inits]"; "image on pg7 is almost totally black".

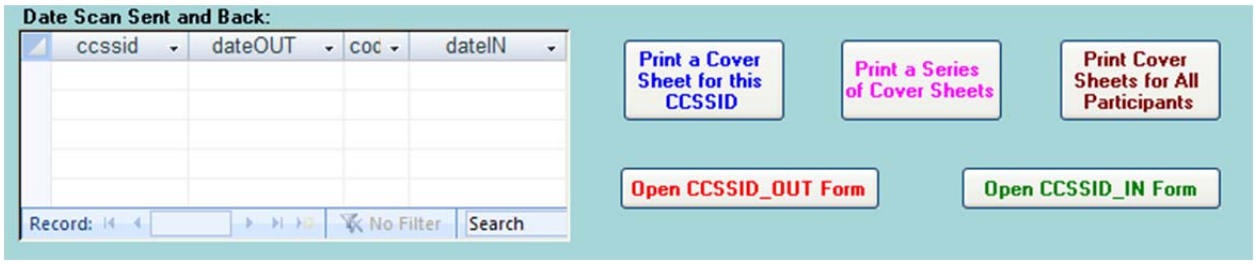
d. Use **Print a Cover Sheet for this CCSSID** button to generate a barcode sheet; print the sheeet. **Clip** the cover sheet on top of the Radiation photocopies (do NOT staple). If more than one set of records for a CCSSID exists in the batch, print a barcode sheet for each set. Hand write "Set 1 of 2" or "Set 2 of 2" on the Cover Sheet face.

e. Identify pages that will require special attention when imaged by our business associate. These pages are pages with an image, a photograph, and/or text printed/written on a shaded background. Flag these pages for special attention by stamping them with the red "**COLOR**" stamp.

CRA

PREPARING RADIATION/BRACHYTHERAPY RECORDS FOR IMAGING AND TRANSMITTAL

MDAnderson dosimetrists use the Radiation and Brachytherapy records to calculate the radiation dosage (dosimetry) for each case. A business associate creates electronic images from the photocopies. We check out the photocopies by scanning the barcoded Cover Sheet, and send them to the business associate in batches of not more than 50. The business associate images and then uploads the images to its secure ftp website. After we review each uploaded file, we notify MD Anderson that files are available for review, and upload a batch reference list to the St Jude Share site for MDAnderson. We give the business associate permission to return the originals to us, which we check back in and then file in the MRAF cabinet by CCSSID.

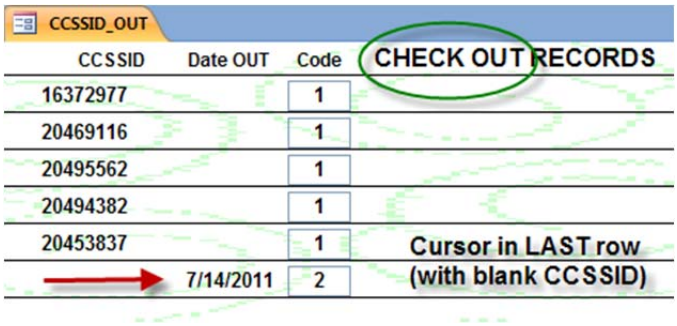


Sending Records to Iron Mountain

The dosimetry team requests we upload no more than 50 files per batch. Thus, after we accumulate radiation photocopies for 50 CCSSIDs, we prepare a batch, check the files out, package them and ship them to the business associate. The current business associate is Iron Mountain.

1. CHECKING OUT THE RECORDS BY SCANNING
   a. On MRAF tab, click Click **Open CCSSID_OUT Form** button (at the bottom of the screen; you may need to scroll to see the button). Be sure to use the "OUT" form button.

   b. When the CCSSID_OUT form opens, scroll the form so you can see the last row and place the cursor in the last row. This will be below the last record whose barcode was scanned (either scanned out or in). The last row should be populated with today's date and a "2" which represents scanned out.



   c. Use the hand scanner to scan bar code on EACH cover page. This will place the CCSSID in the last row and add a new blank record, ready for your next scan.

   d. Continue to scan all cover sheets you are sending at this time.

   e. When finished, close the CCSSID_OUT form.

CRA

Preparing Batch for Iron Mountain pick-up

1. Ensure records have been (1) logged into the database and (2) scanned "out" to Iron Mountain.

2. Run a **PACKING LIST** query to list the CCSSIDs that are in the batch with the Date OUT.
   a. Use **qry_JB_MRAF-CheckedOut**, In design view, change the date in the dateOUT field to match the date the records were scanned (e.g.,3 /21/11).
   b. Save the query design change and then run it.
   c. Export the query to Excel, saving in **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Iron Mountain\CheckedOut**. Add the date and the n-count to the end of the file name.
   d. Print a copy of the Excel file. You will include this in with the Cover Memo when you pack the box.

3. Select a pre-numbered (ex. 540342534) Iron Mountain **orange-rimmed box label** from the fan-folded supply to use for the job. Fill in the customer ID (MT071) on the label.

4. **Call Iron Mountain** to place a "pick-up" order: 1-800-327-8345
   a. Customer ID: MT071
   b. Tell the customer service representative "This is an imaging pick-up order" AND "we need the boxes returned to us after imaging." If you can give them a prior order number, this will help them figure out how to enter the order.
   c. They will provide an order number. Insert this into the cover memo (see below).
   d. They will pick up the records within 48 hours

IRON MOUNTAIN LOG										
CUSTOMER NUMBER	MT071									
Dt order submit	Order Number	Box # (orange lbl)	Volume	Date pickup	Date IM upload available	Date MDA notified	Return Requested	Return Received	Returns Filed	Remarks
4/7/2011	151648709	540342529	48	3/22/2011	4/21/2011	4/22/2011	yes	5/3/2011	yes	
5/11/2011	152582081	540342530	49	ORDER NOT PICKED UP BY IRON MOUNTIAN; ORDER CANCELLED BY IRON MOUNTAIN REP.						
5/18/2011	152762108	540342530	49	5/20/2011	5/25/2011	6/2/2011	yes	6/3/2011	yes	26399473 missing page 3 in 5/25/11 batch. Rescanned in 6/1/11 batch.
6/2/2011	153166128	540342531	55	6/3/2011	6/8/2011	6/17/2011	yes	6/14/2011		

   e. Log transaction in the Excel !IM Order Processing Log. (at **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Iron Mountain**)

5. Prepare **COVER MEMO** identifying the job. You will need the order number you received from placing the order.

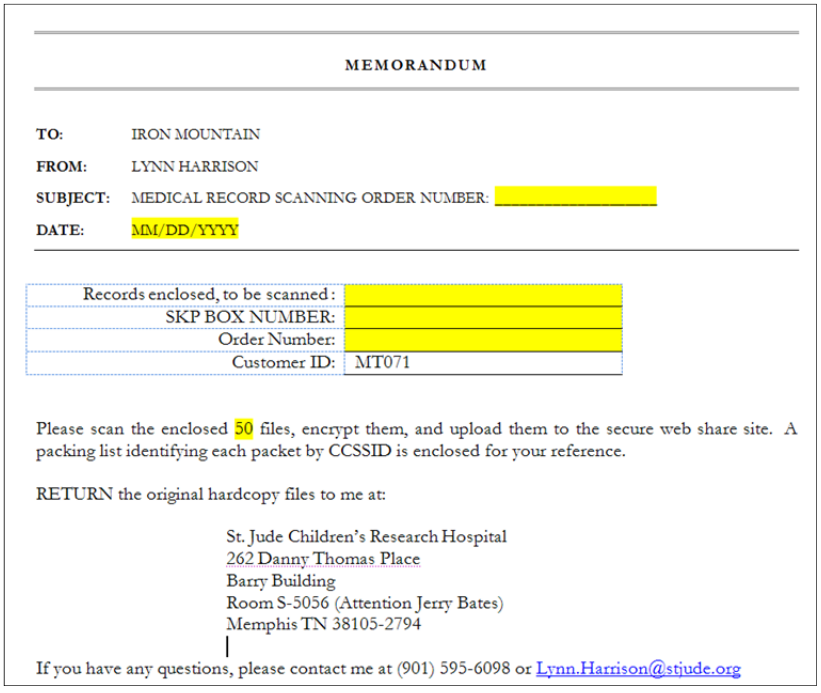
   a. Change/verify the "Records enclosed" value, and update the number in the first paragraph

   b. Update the **SKP BOX NUMBER** (number from orange label).

   c. Fill in the **ORDER NUMBER**, both in the subject line and the table.

   d. Tear off the bottom portion of the Iron Mountain label (the part with the bar code on it), and attach it to the bottom of the cover memo.

   e. See **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Iron Mountain\IM Correspondence** for sample. Save the memo in this same location.



MEMORANDUM

TO: IRON MOUNTAIN

FROM: LYNN HARRISON

SUBJECT: MEDICAL RECORD SCANNING ORDER NUMBER:

DATE: MM/DD/YYYY

Records enclosed, to be scanned:	
SKP BOX NUMBER:	
Order Number:	
Customer ID:	MT071

Please scan the enclosed 50 files, encrypt them, and upload them to the secure web share site. A packing list identifying each packet by CCSSID is enclosed for your reference.

RETURN the original hardcopy files to me at:

St. Jude Children's Research Hospital
262 Danny Thomas Place
Barry Building
Room S-5056 (Attention Jerry Bates)
Memphis TN 38105-2794

If you have any questions, please contact me at (901) 595-6098 or Lynn.Harrison@stjude.org

6. Pack the box

a. Stack the packets of RT records neatly in the box. Be sure each CCSSID has its own bar-coded cover sheet safely paperclipped or binder-clipped to its front. If a CCSSID has more than one packet, be sure the coversheet is annotated (e.g., 1 of 2, 2 of 2), and that both packets are sent in the same batch.

b. Place the **Cover memo** and the **Excel packing slip** on top of the packets..

c. Add packing fill to keep the contents from shifting in transit.

d. Securely tape the box shut.

e. Put the orange Iron Mountain label on the box. Be sure the customer ID (MT071) is on the label.

f. Attach a "Hold for Pick Up by IRON MOUNTAIN" sticker to the box and fill in the current order number. (See **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Iron Mountain** for labels)

g. Put the box upstairs on the 6th floor by the main door.

h. Log the transaction in the IM Order Processing Log.

7. Email Iron Mountain operations manager

a. To ensure our the Iron Mountain operation manager knows an order is coming, send him a simple email that says we placed an order. Give him the order number and the number of records. Also ask him to let us know when the records are uploaded, so we can check the files before authorizing their return.
b. Operations manager is MARK KING. (Mark.King@ironmountain.com)
c. Check to be sure the box is picked up when promised. Contact Mark by email or phone if anything is amiss.

Mark J. King
Operations Manager
Memphis District - Hybrid
440 Stateline Road East
Southaven, MS 38671
Office 662-393-3229 x.201
Fax 662-393-7259

CRA

Downloading and Extracting IronMountain Files (See also IronMountainScannedRTfiles)

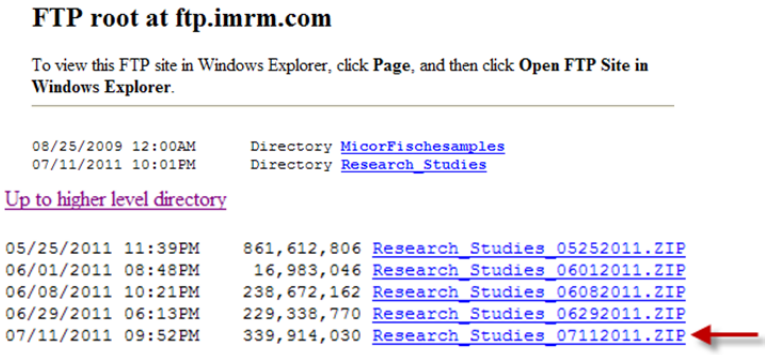
After scanning the records, **Iron Mountain** posts a zipped file containing the scanned images to its secure ftp web site ftp.imrm.com. They usually notify us by email that a file is ready for our review. Filename of the uploaded files will by default contain the upload date (e.g., "Research_Studies_09282009.ZIP). If we have not heard from them in a week, we should check the website to see if the new file is available. They are supposed to wait for our review before returning the originals to us.

1. When the batch has been uploaded:
   a. Log on to the ftp website. Use the assigned username and password

   b. Open the folder **Research_Studies**

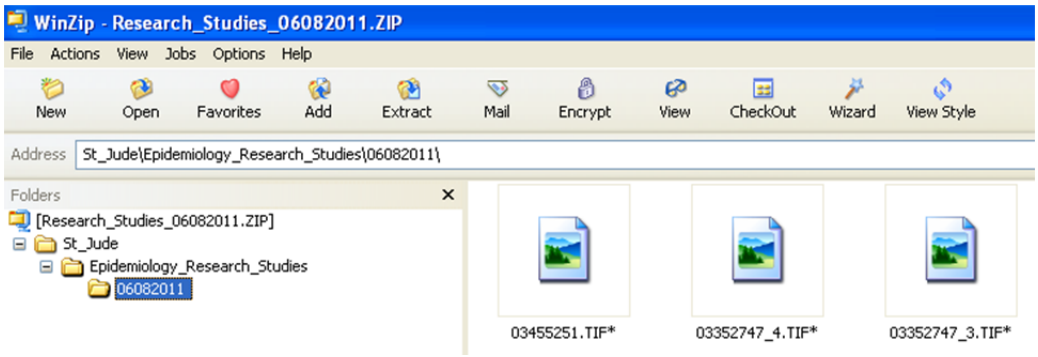
   c. Identify the new file. (e.g., Research_Studies_07112011.ZIP)

   d. Click on the file, and download (save) it to the server (**Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Iron Mountain**)



   e. When the download is complete, locate the downloaded file.

      i. Double-click the ZIP file and each successive folder until you arrive at the MMDDYYYY folder (folder name is the date the file was zipped).



      ii. Right-click on the MMDDYYYY folder and select "**Extract**…" (or select the folder and use the Extract icon in the WinZip toolbar).

      iii. When prompted, indicate where the extracted files should go. We initially put them in **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\Iron Mountain\FTP'd files**.

      iv. You will be prompted for the password to extract the files. (This is NOT the same password used for the FTP website)

      v. Winzip puts the extracted TIF files into a folder which it creates with the same name as the ZIPped MMDDYYYY folder.

      vi. The TIF file names are the CCSSID. If you sent more than one packet for a CCSSID, a suffix in the file name will differentiate between them. (E.g., 03352747_3.TIF, 03352747_4.TIF)

CRA

Reviewing the files with IrfanView

1. Use IRFANVIEW to do a thorough quality check of each page of each TIF document, to be sure everything is legible. (IRFANVIEW is a free downloadable viewer. It allows you to view the embedded "COLOR" pages in the image file, which the default Windows viewer was unable to do.)
   a. Be sure there is a file for every record in the batch.
   b. Be sure each file contains the appropriate number of pages. To tell how many pages should be in the document, refer to the Page x of y annotations in the document.
   c. Be sure pages are in order.
   d. Be sure pages stamped "COLOR" were imaged in color.
   e. Take note of checklist notes about faint copies and too-black images, to ascertain whether poor quality originated with the document or was a result of the imaging process.
   f. Report any quality issues to the account rep (Mark King) at Iron Mountain. Ask them to check the originals. It may be necessary to re-image specific file(s).

2. After **successfully** reviewing all the files,
   a. COPY the folder with its contents to **Z:\Archive\ECC\CCSS\ScannedRTrecords**

   b. Notify the IM account rep Mark King by email to ask him to have the originals returned to us. Log the activity in the Iron Mountain log. ***If the box is not returned in 3 days, contact the account rep again to ask him to check on the status***.

   c. Notify MD Anderson that files are ready to retrieve (see below).

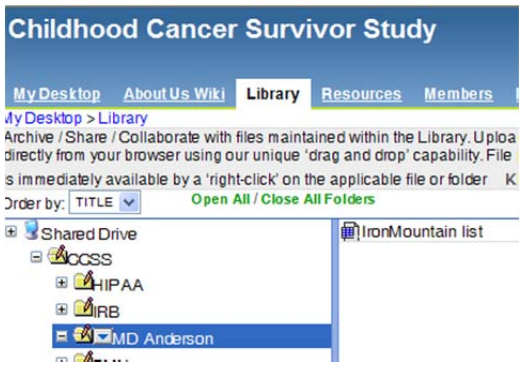
Notify MDA of files ready to retrieve

1. Generate a reference list of the cases in the batch
   a. Open qry JB-MRAF-MDA-DateSent In design view. Modify the criteria so that DateSent2IM (dateOUT) is *the check out date.* Save the query with the changes.

   b. Export the file to Excel and store it on the server at **…\ECC\CCSS\Jerry\Iron Mountain\UploadLists-forMDAreference.** Include the n and date sent in the file name. (e.g., qry_JB_MRAF-MDA-n49_DateSent-02-24-10)

   c. Upload this file to SJShare site in the CCSS\MD Anderson folder.

2. Send an email notification to Rita Weathers (rweather@mdanderson.org) and Samantha Murray (samurray@mdanderson.org) that a new file is ready for their review, and that the reference list is available on the SJShare site. E.g.,



We have another batch of records QA'd and ready for you to download.

The file name is Research_Studies_03112011.zip

We uploaded the cross reference file to the web group: Childhood Cancer Survivor Study on the St. Jude Share site.

- TITLE: qry_JB_MRAF-MDA-DateSent2IM 2011-03-07 n45.xlsx
- FOUND IN FOLLOWING DIRECTORY: /MD Anderson/CCSS

If you have any questions, please let us know.

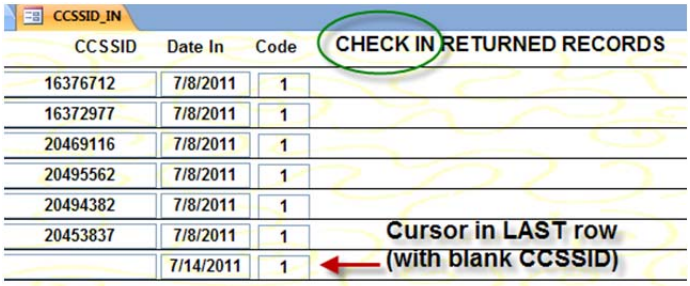
CRA

Processing Records returned by Iron Mountain

1. When Iron Mountain returns the originals, log them back in.

   a. Open the Expansion Tracking Database
   b. Click the **MRAF** tab
   c. Click the **Open CCSSID IN Form** (Be sure you are using the "IN" form button!)

   d. When the **CCSSID_IN** form opens, scroll the form so you can see the last row and place the cursor in the last row. This will be below the last record whose barcode was scanned (either scanned out or in). The last row should be populated with today's date and a "1" which represents scanned in.



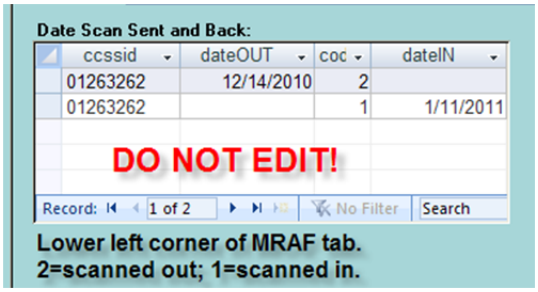
   e. Use the hand scanner to scan the bar code on EACH cover page. This will place the CCSSID in the last row and add a new blank record, ready for your next scan.

   f. Continue to scan all cover sheets you received at this time.

   g. When finished, close the CCSSID_IN form.

2. **FILE** the returned records in the MRAF cabinet, in the individual case folder. If you prepared the folder labels during in-processing, the folder should already be in the file cabinet.

NOTE: You can always view the scanning out/in detail for a particular CCSSID. Use the MRAF tab. Search for the CCSSID. The information appears in **Date Scan Sent and Back** window, which is in the lower left corner of the MRAF screen. CAUTION: do NOT edit the values in the window!



Revision Record Printed 7/6/2012 10:47 AM

Current Filename		Processing Radiation and Surgery Photocopies ver 2_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	6/1/2009	A. McDonald	Initial Development/Refinement for Manual
1a	9/16/09	J. Bates	Expanded notes re Iron Mountain; update differences between RT and surg tracking
1.2	9/29/09	J. Bates	Add annotated MRAF screen shot; update IM call information
1.3	2/24/10	J.Bates	Streamlining instructions
1.4	3/4/10	J.Bates	Notifying MDA with list, upload to SJShare
1.5	6/7/10	J.Bates	Adjusting checkout /IM notes
1.6	10/13/10	J.Bates	Documenting report of not applicable
2.0	7/12/11	L.Harrison/J.Bates	Renamed and added detail
2.1	8/2/11	J.Bates	Email IM operation manager rep when order placed

Processing Refusals: Participants, Proxies, and Associates

Background

It is important that refusals to participate in the Long-Term Follow-Up (LTFU) Study be recorded in the database so that additional surveys will not be sent and no further contact is attempted. Refusal notices arrive in various ways. For example, the mailed packet may be returned to sender with hand-written notice "Refused", the cover letter and/or survey may be returned with a note attached, telephone contact with the participant or a representative (i.e., LAR, proxy) may end with verbal refusal, or a refusal may occur online.

A participant or proxy (e.g. family member of a deceased LTFU Participant) who consents to the study and completes the baseline questionnaire may later refuse further all further participation, or s/he may refuse to participate in a specific follow-up survey or ancillary study without refusing future participation in the LTFU Study or other ancillary studies.

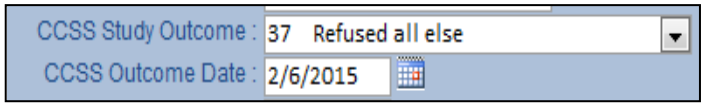
In some situations, an associate (family member, additional contact, etc.) of a participant or proxy will be contacted to re-establish communication with the participant. During this process, the associate or proxy may ask to be removed from our contact list, or the participant may ask that we remove an associate's contact information from our records. Associate and proxy refusals should be discussed with the Lead Survey Interviewer (LSI) team, Call Center Coordinator, CRA2, and/or the project coordinator as they occur.

The following procedure outlines how to record participant, proxy, or associate refusals in the appropriate database.

Participant and LAR/Proxy for Deceased Participant Procedure

LTFU Participant Database – Cases and Siblings

When a case, sibling participant, LAR, or proxy for a deceased participant completed the baseline questionnaire and then refused all further participation in the LTFU Study, the refusal is coded in the LTFU Participants database as follows:



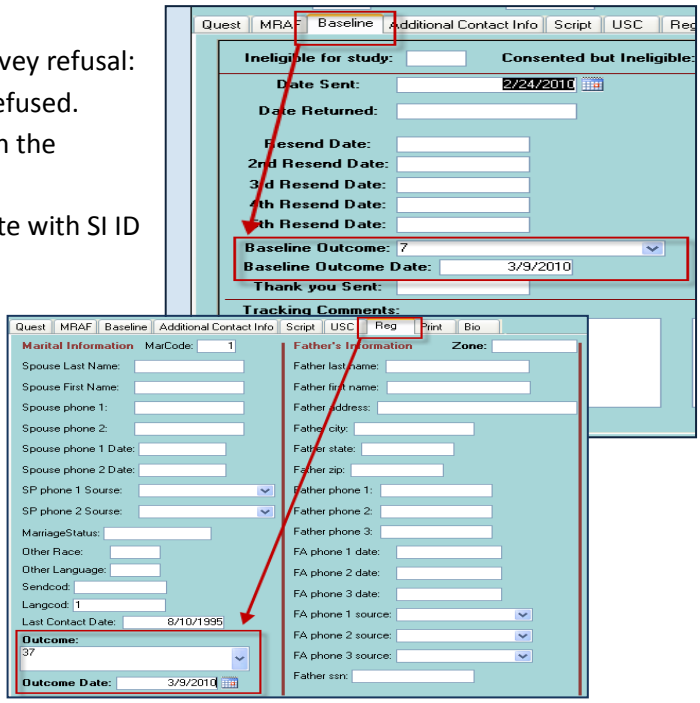
1. **CCSS Study Outcome** (header) – Populate with 37-Refused all else.
2. **CCSS Outcome Date** (header) – Populate with the current date.
3. **Notes** (Participant tab) – Enter a dated comment with SI ID or initials documenting the refusal.
4. Survey Interviewers (SIs) should document the refusal in the contact or trace log's **Outcome** and **Notes** fields. See the SOP titled **LTFU Participant Database Data Entry** for details.
5. If the participant refused all else in response to a particular project (e.g. FU5, EMSI, etc.), see also the project-specific SOP for documenting the project-level refusal.
6. *IMPORTANT*: Do NOT post a "refused all else" study outcome when a participant wants to stay in the LTFU Study but does not want to complete a particular follow-up survey (e.g. FU5) or participate

in a particular ancillary study (e.g. saliva). Instead, review the project-specific SOP for instructions on recording a refusal for that particular survey or ancillary study.

7. For deceased proxies: If you have access to the **LTFU Newsletter Additional Names** spreadsheet, located in *Z:\SJShare\SJCOMMON\ECC\CCSS\Newsletter*, search the Active tab for the proxy's name. If found, remove the information to avoid future mailings. If you do not have access to this spreadsheet, email the LSI team or a study CRA to take this action.

Expansion Tracking Database - Case

1. When a **case refuses the baseline survey** (i.e. refused to participate in the LTFU Study), document the refusal in the Expansion Tracking database:
   A. On the Baseline tab, document the baseline survey refusal:
      i. **Baseline Outcome** – Populate with 7-Refused.
      ii. **Baseline Outcome Date** – Populate with the current date.
      iii. **Tracking Comments –** Enter a dated note with SI ID or initials.
   B. On the Reg tab, document the study refusal (i.e. "Refused All Else"):
      i. **Outcome** – Populate with 37-Refused all else.
      ii. **Outcome Date** – Populate with the current date.
   C. SIs should:
      i. Document the refusal in the contact or trace log's **Outcome** and **Notes** fields. See the SOP titled **Expansion Baseline Survey Calls** for details.
      ii. **Comments** (Quest tab) – Add a dated note with SI ID.



2. **DatStat (Online) Refusals** – Expansion cases may refuse through DatStat, the online survey system. The LSI or designee is responsible for canvassing the online refusals on a regular basis and posting the appropriate codes in the Expansion Tracking database. (See the SOP titled **Extracting and Processing Expansion Baseline DatStat Refusals** for details.)

Expansion Tracking Database – Sibling

1. When a **sibling refuses the baseline survey** (i.e. refused to participate in the LTFU Study), document the refusal in the Expansion Tracking database:
   A. On the Sib Baseline tab, document the sibling baseline survey refusal:
      i. **Baseline Outcome** – Populate with 7-Refused.

ii. **Baseline Outcome Date** – Populate with the current date.

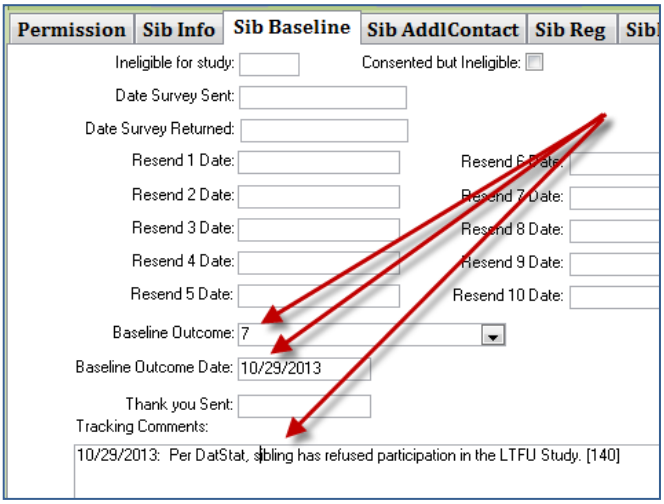
iii. **Tracking Comments** – Enter a dated note with SI ID.

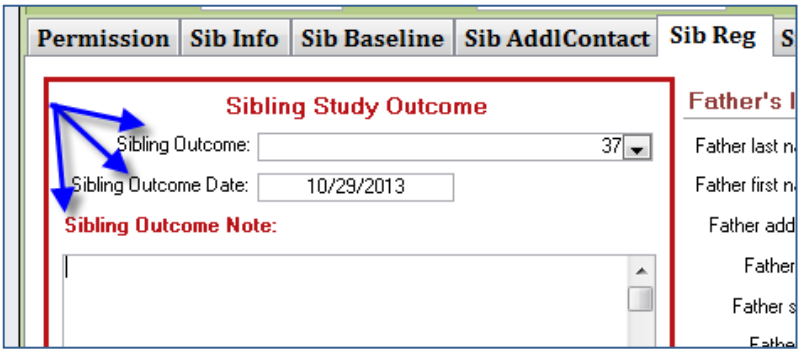
B. On the Sib Reg tab, document the study refusal (i.e. "Refused All Else"):

i. **Sibling Outcome –** Populate with 37-Refused all else.

ii. **Sibling Outcome Date –** Populate with the current date.

iii. **Sibling Outcome Note** – If appropriate, enter a dated note with SI ID or initials.





C. SIs should:

i. Document the refusal in the call or trace log's **Outcome** and **Notes** fields. See the SOP titled **Expansion Sibling Cohort Survey Calls** for details.

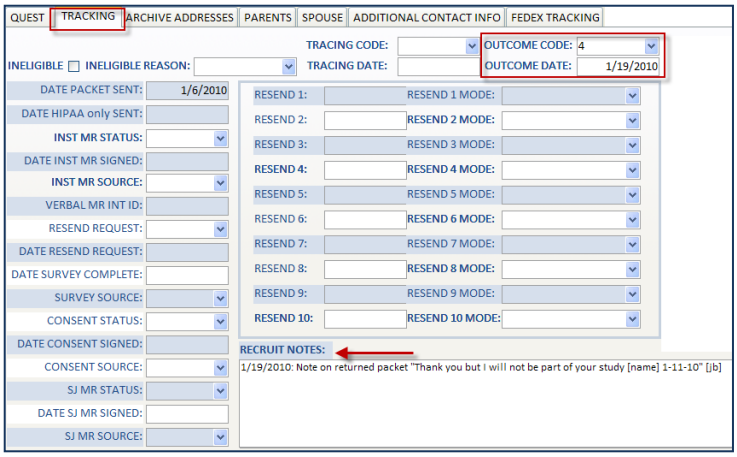
ii. **Comments** (Sib Info tab) – Add a dated note with SI ID.

2. **DatStat (Online) Refusals** – Expansion siblings may refuse through DatStat, the online survey system. The LSI or designee is responsible for canvassing the online refusals on a regular basis and posting the appropriate codes in the Expansion Tracking database. (See the SOP titled **Extracting and Processing Expansion Baseline DatStat Refusals** for details.)

Recruitment Database

Cases may refuse to participate during the recruitment process. Record these refusals in the Recruitment database. On the Tracking tab:

1. **Outcome Code** – Populate with 4-Refused.
2. **Outcome Date** – Populate with the date the notice is received.
3. **Recruit Notes** – Add a dated note with SI ID or initials.
4. SIs should copy the note from step 3 to the **Comments** field of the Quest tab.



Everyone

Ancillary Study Refusals

Refusing to participate in an ancillary study (e.g., Saliva, EMPOWER, Blood & Tissue, ASK, etc.) does not necessarily constitute a refusal to participate in "all else" from the LTFU Study. The ancillary study's CRA or SI should:

1. Evaluate the refusal message to determine the extent of the refusal.
2. Update the database and/or call log (SI only) appropriately.
3. Send an email to the study coordinator with the refusal information (as applicable).

See specific ancillary study procedures for details.

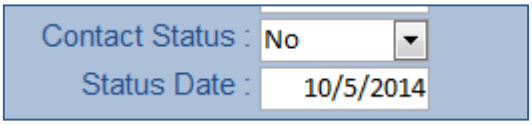
Associate and Proxy Procedure

If an associate or proxy has asked to no longer be contacted by the LTFU Study or if the participant has asked that we no longer contact a particular associate or proxy:

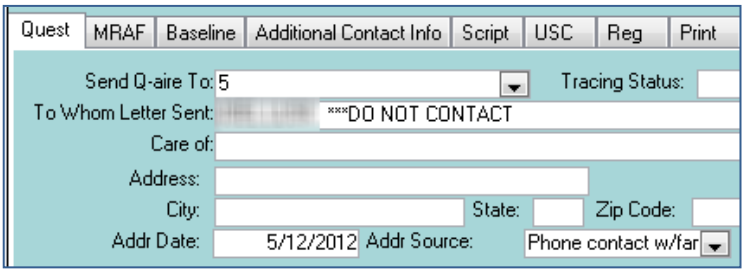
1. Open the appropriate parent database (i.e. Recruitment, Expansion Tracking, or LTFU Participant). It is ***crucial*** that these procedures are done in the parent database and NOT just an ancillary database.

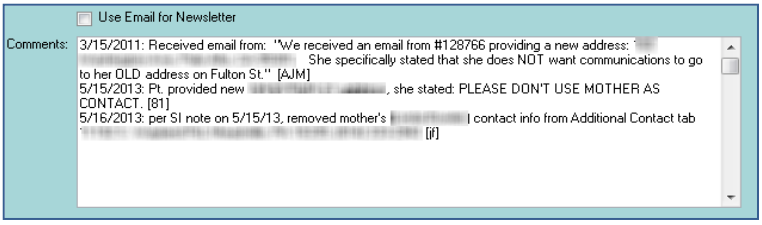
2. Search the Quest/Sib Info/Participant, Additional Contact Info /Associates, Reg/Sib Reg/Parents, Spouse, and Sibling tabs for associate/proxy contact information. An associate/proxy will often have contact information in multiple locations (e.g. Reg tab, Sib Reg tab, etc.), and it is important to capture all instances where the contact information is recorded.

3. For locations with a **Contact Status** field (e.g. Associates tab):
   A. **Contact Status** – Update to No.
   B. **Status Date** – Populate with the current date.
   C. **Notes/Comments** – Enter a dated note with initials or SI ID documenting the change in contact status.
   D. Where available, change the telephone and email ranks to "37" for the associate's contact information.



4. For locations without a **Contact Status** field (e.g. Quest tab):
   A. Leave the associate/proxy name in the name field, and enter "**DO NOT CONTACT**" next to the name.
   B. Move all contact information to the associated notes/comments field with a dated note explaining why the information was removed and informing others not to contact proxy or associated. Include your SI ID or initials.





Everyone

5. If you have access to the **LTFU Newsletter Additional Names** spreadsheet, located in *Z:\SJShare\SJCOMMON\ECC\CCSS\Newsletter*, search the Active tab for the proxy's name. If found, remove the information to avoid future mailings. If you do not have access to this spreadsheet, email the LSI team or a study CRA to take this action.

Revision Record Printed 3/3/2015 1:09 PM

[58] Current Filename:		Processing Refusals Participants Proxies Associates ver 2_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/6/2013	J. Ford, L. Harrison	Revision of Processing Refusals ver 2_4 and retitled to accurately describe contents.
2.0	10/29/2013	R. Massey	Update name of DatStat Refusal SOP, add expansion sibling directives, add newsletter directive for proxies, formatting.
2.1	2/18/2015	R. Massey, L. Harrison, J. Ford	Content Revision: Add LTFU Pt db directives, remove REG db directives, remove refs to Call Outcomes Log

Processing Returned Follow-Up 5 Paper Surveys

Background

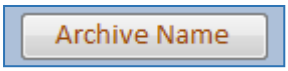
Follow-Up 5 (FU5) is the 5th follow-up survey conducted by the Long-Term Follow-Up (LTFU) Study. All participants from the original and expanded cohorts who were enrolled in the LTFU Study and who were eligible for participation at the time of FU5 recruitment were mailed an introductory letter inviting them to complete the survey online or via telephone. Participants who did not complete the survey online or via telephone within approximately 30 days were mailed a paper copy of the FU5 survey.

When the paper version of the FU5 survey is returned to the coordinating center, study personnel must update the LTFU Participant database to document receipt of the survey, contact information reported on the returned survey, and, if applicable, receipt of the LTFU HIPAA. The returned surveys must also be evaluated for key responses such as suicidal ideation and reports of subsequent malignant neoplasms (SMNs).

Procedures

For each returned FU5 paper survey:

1. Note whether there is contact data (e.g. return address) on the outside of the envelope. If so, determine whether this is needed to update the LTFU Participant database.
2. **Date-stamp** the front/cover page of the survey with the date it was received.
3. Locate the participant in the CCSS LTFU Participants database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
4. On the cover page of the survey:
   A. For adult participants, compare the "The questions in this survey relate to" value to the "Person completing this survey is" box.
      i. If these match, skip to next step.
      ii. If these fields are slightly different (e.g. first or last name is spelled differently, first name is the same but last name is different, etc.), on the PARTICIPANT tab of the record:
         a. **Archive Name** – Click the button.
         b. **Preferred Name** – Update the field.
         c. Make a copy of the survey's front page and give the copy to the Senior Coordinator-Clinical Research Operations or CRA2.

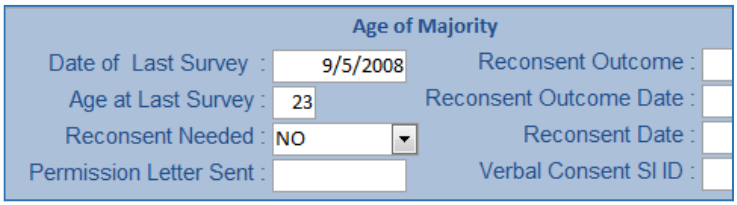


      iii. If these fields do not match at all, STOP and take the survey to the Senior Coordinator-Clinical Research Operations or CRA2.
   B. For minor participants, compare the "The questions in this survey relate to" value to the "Person completing this survey is" box.
      i. If these match, consult with the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.
      ii. If these fields do not match:

a. Determine the relationship of the person completing the survey to the participant.
   1) For parents, ensure the parent's name in the "Person completing this survey is" box matches a parent name in the Associates tab. If not, consult with the Senior Coordinator-Clinical Research Operations or CRA2.
   2) For non-parent relationships, consult with the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.

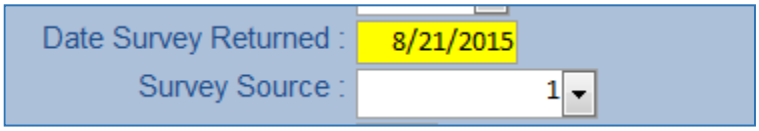
b. Record a dated note in the **Notes** field of the PARTICIPANT tab. Indicate the name and relationship of the party that completed the minor survey. *Example: 12/15/2015: Minor FU5 survey was completed by pt's mother, Sandra White. [initials]*

5. Navigate to the FU5 TRACKING tab.



A. **Reconsent** – Determine if the participant needs to be reconsented by reviewing the Age of Majority group.
   i. If no or not yet, skip to the next step.
   ii. If yes and someone other than the participant completed the survey:
      a. Take the survey to the Research Scientist or Senior Coordinator-Clinical Research Operations. If needed, s/he will notify the Call Center's Coordinator and LSI team via email that follow-up with the participant and/or the parent is required.
      b. Do NOT update the **Date Survey Returned** field.
   iii. If yes and the participant completed the survey, update the appropriate reconsent fields.
      a. **Reconsent Outcome** – Populate with "Consented."
      b. **Reconsent Outcome Date** – Populate with the date stamped on the front of the survey.
      c. **Reconsent Date** –
         1) HIPAA form is signed and dated – Populate with the HIPAA signature date.
         2) HIPAA form is signed but undated
            A) Populate with the handwritten date in the "Today's Date" boxes on the front of the survey.
            B) If the "Today's Date" boxes are blank, use the date stamp to date the HIPAA form with the date stamped on the front page of the survey, and populate the field with this date.
         3) HIPAA form is unsigned – If the participant wrote a date in the "Today's Date" boxes on the front of the survey, populate with this date. Otherwise, populate with the date stamped on the front of the survey.
   iv. If yes and the survey was returned without being completed, see the Senior Coordinator-Clinical Research Operations or CRA2 for direction.

B. **Date Survey Returned** – Enter the date that is stamped on the front page of the survey.



C. **Survey Source** – Select 1-Paper.

D. Open the survey booklet, and turn to the **HIPAA Authorization Form**.

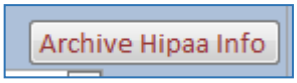
i. If the HIPAA is unsigned:

a. And the participant *did* write "Refused", "VOID", etc., populate **HIPAA Status** with 2-Refused.

b. And the participant *did not* indicate "Refused", "VOID", etc., skip to the next step.

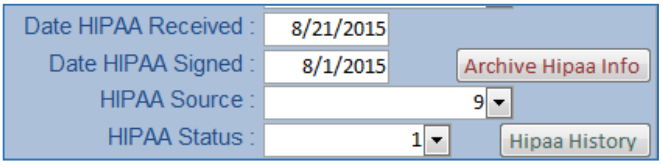
ii. If the HIPAA is signed by the participant or his/her legal representative:

a. IF the **Date HIPAA Received**, **Date HIPAA Signed**, **HIPAA Source**, and/or **HIPAA Status** fields *are populated*, click the **Archive Hipaa Info** button.



b. **Date HIPAA Received** – Enter the date that is stamped on the front of the survey.

c. **Date HIPAA Signed** – Enter the date the HIPAA was signed. If the participant did not date the HIPAA, date-stamp the Date blank with the date that is stamped on the front page of the survey, and populate the field with this date.



d. **HIPAA Source** – Populate with 9-Follow-Up 5.

e. **HIPAA Status** – Populate with 1-Complete.

iii. If the HIPAA is signed by someone other than the participant or his/her legal representative, consult with the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.

6. Navigate to the PARTICIPANT tab, and go to the contact information page of the survey.
NOTE: When someone other than the participant completes the FU5 survey (e.g. minor surveys), all steps to update contact information in the PARTICIPANT tab should be repeated in the ASSOCIATE tab record for the party that completed the survey.

A. If the participant provided an **email address**, determine whether the email address is already in the database.

i. If yes:

a. **Rank** – Select "1." If needed, adjust the **Rank** of other email addresses.

b. **Email Date** – Enter the date that is stamped on the front of the survey.

c. **Email Source** – Populate with "Survey."

ii. If no:

a. Enter the email address in the next available row.

b. **Rank** – Select "1." If needed, adjust the **Rank** of other email addresses.

c. **Email Date** – Enter the date that is stamped on the front of the survey.

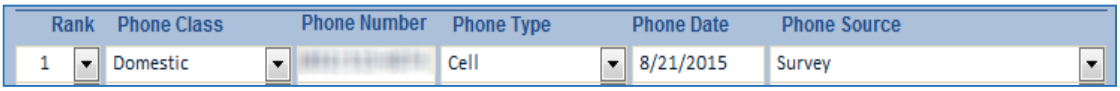
d. **Email Source** – Populate with "Survey."

B. If the participant indicated that the **survey contact information is correct**:

i. Verify that the address information printed on the survey matches the address in the database.
   a. If yes:
      1) **Address Date** – Enter the date that is stamped on the front of the survey.
      2) **Address Source** – Populate with "Survey."
   b. If no, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

ii. Verify that the phone information printed on the survey matches one of the phone numbers in the database.
   a. If yes:
      1) Find the phone number in the database.
      2) **Phone Date** – Enter the date that is stamped on the front of the survey.
      3) **Phone Source** – Populate with "Survey."
   b. If no, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

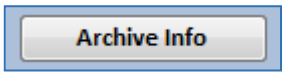
iii. If additional phone numbers were provided and these ARE already in the database:
   a. **Rank** – Adjust, if needed.
   b. **Phone Type** – Select the appropriate option.
   c. **Phone Date** – Enter the date that is stamped on the front of the survey.
   d. **Phone Source** – Populate with "Survey."



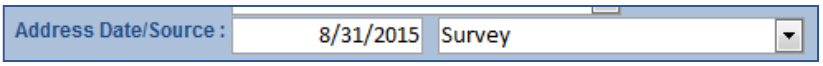
iv. If additional phone numbers were provided and these ARE NOT in the database:
   a. Enter the first new phone number in the next available row.
   b. **Rank** – Rank the new number according to your best judgment. Adjust the rank of other numbers, if appropriate.
   c. **Phone Class** – Select either "Domestic" (for US numbers) or "International" (for non-US numbers).
   d. **Phone Type** – Select the appropriate option.
   e. **Phone Date** – Enter the date that is stamped on the front of the survey.
   f. **Phone Source** – Select "Survey."
   g. Repeat this process until all new numbers are recorded.

C. If the participant indicated that the **survey contact information is NOT correct**:

i. Verify that the address information printed on the survey matches the address in the database.
   a. If yes:
      1) Click the **Archive Info** button.
      2) Update the address information.
      3) **Address Date** – Enter the date that is stamped on the front of the survey.
      4) **Address Source** – Select "Survey."
   b. If no, compare the handwritten address to the address in the database.



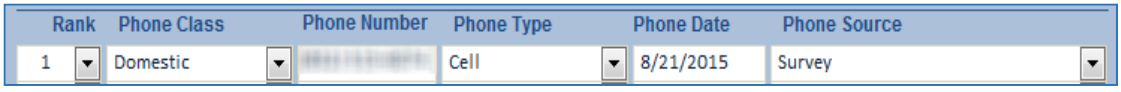
1) If they match:
   A) **Address Date** – Enter the date that is stamped on the front of the survey.
   B) **Address Source** – Select "Survey."



2) If they do not match, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

ii. Verify that the phone information printed on the survey matches one of the phone numbers in the database.
   a. If yes and the participant DID NOT scratch through the number or write a note such as "Don't call this number," skip to the next step.
   b. If yes and the participant DID scratch through the number or write a note such as "Don't call this number":
      1) Find the phone number in the database.
      2) **Rank**
         A) If the participant specifically indicated we should NOT call the number, update to 37-Do Not Call.
         B) If the participant scratched through the number or otherwise indicated it is incorrect without specifically indicating that we should NOT call it, update to 11-Wrong Number.
      3) **Phone Date** – Enter the date that is stamped on the front of the survey.
      4) **Phone Source** – Select "Survey."
   c. If no, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

iii. If additional phone numbers were provided and these ARE already in the database:
   a. **Rank** – Adjust, if needed.
   b. **Phone Type** – Select the appropriate option.
   c. **Phone Date** – Enter the date that is stamped on the front of the survey.
   d. **Phone Source** – Select "Survey."



iv. If additional phone numbers were provided and these ARE NOT in the database:
   a. Enter the first new phone number in the next available row.
   b. **Rank** – Rank the new number according to your best judgment. Adjust the rank of other numbers, if appropriate.
   c. **Phone Class** – Select either "Domestic" (for US numbers) or "International" (for non-US numbers).
   d. **Phone Type** – Select the appropriate option.
   e. **Phone Date** – Enter the date that is stamped on the front of the survey.
   f. **Phone Source** – Select "Survey."

g. Repeat this process until all new numbers are recorded.

D. If the participant indicated that s/he is **moving**:

i. Verify that the address information printed on the survey matches the address in the database.

a. If yes and the participant DID NOT provide an alternative address, skip to the next step.

b. If yes and the participant DID provide an alternative address, make a copy of the contact information page and give the copy to the Senior Coordinator-Clinical Research Operations or CRA2.

c. If no, compare the handwritten address to the address in the database.

1) If they match:

A) **Address Date** – Enter the date that is stamped on the front of the survey.

B) **Address Source** – Select "Survey."

2) If they do not match, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

ii. Verify that the phone information printed on the survey matches one of the phone numbers in the database.

a. If yes and the participant DID NOT scratch through the number or write a note such as "Don't call this number," skip to the next step.

b. If yes and the participant DID scratch through the number or write a note such as "Don't call this number":

1) Find the phone number in the database.

2) **Rank**

A) If the participant specifically indicated we should NOT call the number, update to 37-Do Not Call.

B) If the participant scratched through the number or otherwise indicated it is incorrect without specifically indicating that we should NOT call it, update to 11-Wrong Number.

3) **Phone Date** – Enter the date that is stamped on the front of the survey.

4) **Phone Source** – Select "Survey."

c. If no, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

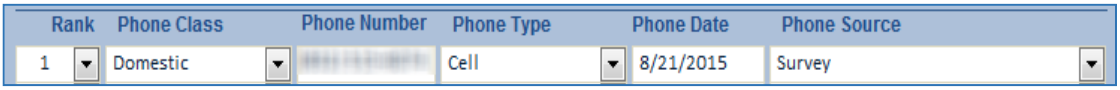
iii. If additional phone numbers were provided and these ARE already in the database:

a. **Rank** – Adjust, if needed.

b. **Phone Type** – Select the appropriate option.

c. **Phone Date** – Enter the date that is stamped on the front of the survey.

d. **Phone Source** – Select "Survey."

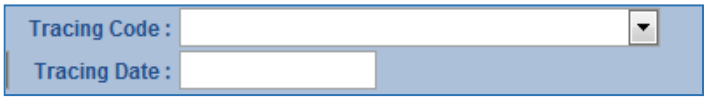


iv. If additional phone numbers were provided and these ARE NOT in the database:

a. Enter the first new phone number in the next available row.
b. **Rank** – Rank the new number according to your best judgment. Adjust the rank of other numbers, if appropriate.
c. **Phone Class** – Select either "Domestic" (for US numbers) or "International" (for non-US numbers).
d. **Phone Type** – Select the appropriate option.
e. **Phone Date** – Enter the date that is stamped on the front of the survey.
f. **Phone Source** – Select "Survey."
g. Repeat this process until all new numbers are recorded.

E. If the participant **neither confirmed nor corrected the survey contact information**:
   i. Determine if a return address was indicated on the envelope to confirm the mailing address. If so, use this to make the appropriate updates.
   ii. If the **Tracing Code** field is populated with an address-related tracing code AND **Address Source** is set to "Lexis Nexis":
      a. Clear or adjust the **Tracing Code** and **Tracing Date** fields, as appropriate, to remove the address-related tracing code.
      b. Record a dated note in the **Notes** field of the PARTICIPANT tab that the survey was returned via paper after mailing to the Lexis Nexis address and that the Lexis Nexis address is therefore presumed correct.
      c. **Address Date** – Enter the date that is stamped on the front of the survey.
      d. **Address Source** – Select "Survey."

7. Clear or adjust the **Tracing Code** and **Tracing Date** fields on the PARTICIPANT tab after updating the contact information. See the SOP titled **Outcome and Tracing Code Guidelines** or check with the Senior Coordinator-Clinical Research Operations or CRA2.



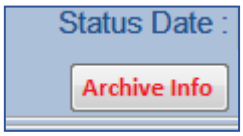
8. Review the **CCSS Study Outcome** and related **CCSS Outcome Date** fields in the header to determine if they should be cleared. When in doubt, consult with the Senior Coordinator-Clinical Research Operations or CRA2.

9. Navigate to the ASSOCIATES tab.
   A. If the participant DID NOT provide associate contact information, skip to the next step.
   B. If the participant DID provide associate contact information, determine whether the associate on the survey matches one of the associates in the database by comparing the name and relationship.
      i. If a full or partial match IS found:
         a. Compare the **associate names**.
            1) If they match, skip to the next step.
            2) If they do not match (e.g. last name change):
               A) **Notes** – Enter a dated note explaining the name change. *Example: 1/29/2016: Mother's name changed from Jane Doe to Jane Smith, per FU5 survey. [your initials]*

B) **Name** – Update to the new name.

b. Compare the **relationship**. This is the associate's relationship to the case or sibling participant.
   1) If they match, skip to the next step.
   2) If they do not match (e.g. ex-mother-in-law, ex-wife):
      A) **Notes** – Enter a dated note explaining the relationship change. *Example: 1/29/2016: Changed Jane Doe's relationship from Spouse to "Other" as she is now an ex-spouse per the FU5 survey. [your initials]*
      B) **Relationship** – Update the field.

c. Compare the **associate address** on the survey to the information in the database.
   1) If they match:
      A) **Address Date** – Enter the date that is stamped on the front of the survey.
      B) **Address Source** – Select "Survey."
   2) If they do not match:
      A) Click the **Archive Info** button.
      B) Update the address information.
      C) **Address Date** – Enter the date that is stamped on the front of the survey.
      D) **Address Source** – Select "Survey."

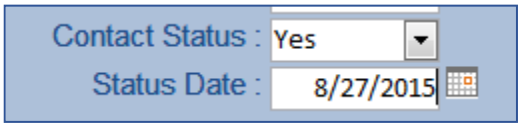


d. Compare the **associate phone information** on the survey to the information in the database.
   1) For phone numbers provided on the survey that ARE already in the associate's record:
      A) **Rank** – Adjust, if needed.
      B) **Phone Type** – Select the appropriate option.
      C) **Phone Date** – Enter the date that is stamped on the front of the survey.
      D) **Phone Source** – Select "Survey."
   2) For phone numbers provided on the survey that ARE NOT already in the associate's record:
      A) Enter the first new phone number in the next available row.
      B) **Rank** – Rank the new number according to your best judgment. Adjust the rank of other numbers, if appropriate.
      C) **Phone Class** – Select either "Domestic" (for US numbers) or "International" (for non-US numbers).
      D) **Phone Type** – Select the appropriate option.
      E) **Phone Date** – Enter the date that is stamped on the front of the survey.
      F) **Phone Source** – Select "Survey."
      G) Repeat this process until all new telephone numbers are recorded.

e. If the participant provided an **associate email address**, determine whether the email address is already in the associate's record.

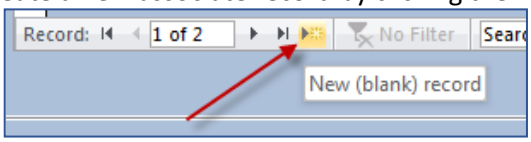
1) If yes:
   A) **Rank** – Select "1." If needed, adjust the rank of other email addresses.
   B) **Email Date** – Enter the date that is stamped on the front of the survey.
   C) **Email Source** – Select "Survey."
2) If no:
   A) Enter the new email address in the next available row.
   B) **Rank** – Select "1." If needed, adjust the rank of other email addresses.
   C) **Email Date** – Enter the date that is stamped on the front of the survey.
   D) **Email Source** – Select "Survey."

f. Document the authorized **contact status**:



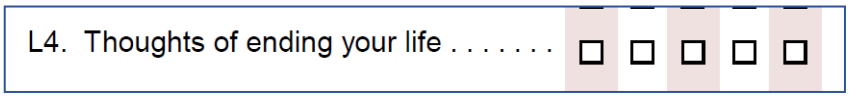
1) **Contact Status** – Populate with or update to "Yes."
2) **Status Date** – Enter the date that is stamped on the front of the survey.

ii. If a full or partial match IS NOT found, create a new associate record by clicking the **New (blank) record** icon at the bottom of the screen.

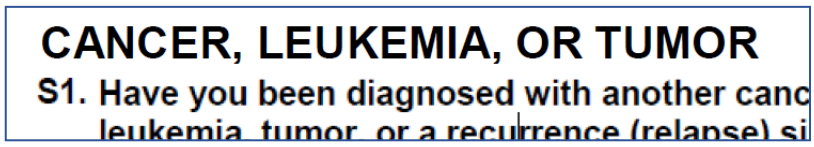


a. **Relationship** – You MUST select a relationship. If one is not provided, select "Other," and enter a dated note explaining the "Other" value. *Example: 1/29/2016: Associate relationship not provided on FU5 survey. Entered Relationship = Other. [your initials]*
b. **Contact Status** – Select "Yes."
c. **Status Date** – Enter the date that is stamped on the front of the survey.
d. Enter all available contact information.

10. For adult surveys, open the survey to section L-Feelings/Emotions and **review question L4**, "Thoughts of ending your life." If the participant responded "Moderately," "Quite a bit," or "Extremely" to this question:
    A. Make a copy of the page indicating the answer to L4, the survey cover page, the contact information page, and the HIPAA page (if signed).



    B. Give the copies to the Senior Coordinator-Clinical Research Operations or CRA2.
11. Turn to section S (for adult surveys) or section Q (for minor surveys) – **Cancer, Leukemia, or Tumor**. If the participant responded "Yes" to S1 and/or S6 (for adult surveys) OR to Q1 and/or Q6 (for minor surveys), "Have you been diagnosed with another cancer…" OR provided any information in section S (for adult surveys) or Q (for minor surveys):



    A. Make a copy of the S/Q page(s) and the HIPAA (if signed).
    B. Give the copies to the SMN project coordinator (if s/he is in the office) or place the copies in the SMN project coordinator's hanging folder (if s/he is not in the office).

12. **Review Comments** – Review the participant's comments. If they include anything that requires or is suspected to require addressing, copy the page with the comments and give the copy to the Research Scientist for review.
13. **Initial and date** the **Edit** box on the paper survey cover page. Use purple ink, when possible.
14. **Route the survey booklet** for further processing.
    A. For adult cases, determine if the survey is a skin cancer (SC) survey.
        i. If yes, give the in-processed survey to the project coordinator for the ASK Study for further processing.
        ii. If no, give the in-processed survey to the Senior Coordinator-Clinical Research Operations.
    B. For adult sibling participants, give the in-processed survey to the Senior Coordinator-Clinical Research Operations.
    C. For minor participants, give the in-processed survey to the Senior Coordinator-Clinical Research Operations.

Revision Record Printed 9/17/2015 12:44 PM

Current Filename:		Processing Returned FU5 Paper Surveys ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	9/17/2015	J. Ford, L. Harrison, R. Massey, A. McDonald	Initial Development

Processing Returned Follow-Up 6 Paper Surveys

Background

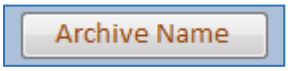
Follow-Up 6 (FU6) is the 6th follow-up survey conducted by the Long-Term Follow-Up (LTFU) Study. All participants from the original and expanded cohorts who were enrolled in the LTFU Study and who were eligible for participation at the time of FU6 recruitment were mailed a postcard alerting them of the upcoming follow-up paper survey mailing, followed by a paper copy of the FU6 survey within 2-4 weeks.

When the paper version of the FU6 survey is returned to the coordinating center, study personnel must update the LTFU Participant database to document receipt of the survey, contact information reported on the returned survey, and, if applicable, receipt of the LTFU HIPAA and Age of Majority info. The returned surveys must also be evaluated for key responses to subsequent malignant neoplasms (SMNs).

Procedures

For each returned FU6 paper survey:

1. Note whether there is contact data (e.g. return address) on the outside of the envelope. If so, determine whether this is needed in order to update the LTFU Participant database.
2. **Date-stamp** the front/cover page of the survey with the date it was received.
3. Locate the participant in the CCSS LTFU Participants database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
4. On the 2nd page of the survey:
   A. For adult participants, compare the "The questions in this survey relate to" value to the "Person completing this survey is" box.
      i. If these match, skip to next step.
      ii. If these fields are slightly different (e.g. first or last name is spelled differently, first name is the same but last name is different, etc.), on the PARTICIPANT tab of the record:
         a. **Archive Name** – Click the button.
         b. **Preferred Name** – Update the field.
         c. Make a copy of the survey's front page and give the copy to the Senior Coordinator-Clinical Research Operations or CRA2.

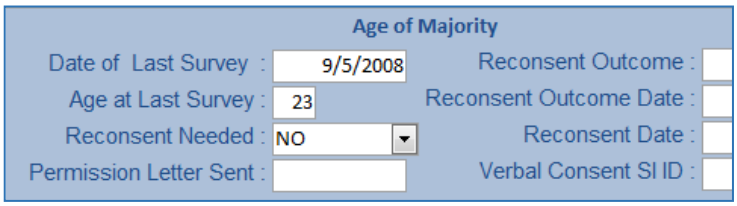
      

      iii. If these fields do not match at all, STOP and take the survey to the Senior Coordinator-Clinical Research Operations or CRA2.
   B. For minor participants, compare the "The questions in this survey relate to" value to the "Person completing this survey is" box.
      i. If these match, consult with the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.
      ii. If these fields do not match:
         a. Determine the relationship of the person completing the survey to the participant.

1) For parents, ensure the parent's name in the "Person completing this survey is" box matches a parent name in the Associates tab. If not, consult with the Senior Coordinator-Clinical Research Operations or CRA2.
2) For non-parent relationships, consult with the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.

b. Record a dated note in the **Notes** field of the PARTICIPANT and FU6 TRACKING tab. Indicate the name and relationship of the party that completed the minor survey. *Example: 12/15/2017: Minor FU6 survey was completed by pt's mother, Sandra White. [initials]*

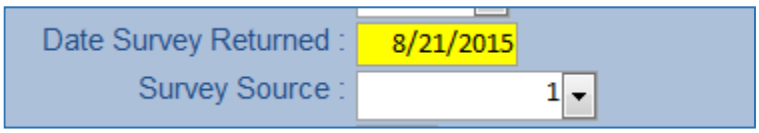
5. Navigate to the FU6 TRACKING tab.



A. **Reconsent** – Determine if the participant needs to be reconsented by reviewing the Age of Majority group.

i. If no or not yet, skip to the next step.
ii. If yes and someone other than the participant completed the survey:
   a. Take the survey to the Research Scientist or Senior Coordinator-Clinical Research Operations. If needed, s/he will notify the Call Center's Coordinator and LSI team via email that follow-up with the participant and/or the parent is required.
   b. Do NOT update the **Date Survey Received** field.
iii. If yes and the participant completed the survey, update the appropriate reconsent fields.
   a. **Reconsent Outcome** – Populate with "Consented."
   b. **Reconsent Outcome Date** – Populate with the date stamped on the front of the survey.
   c. **Reconsent Date** –
      1) HIPAA form is signed and dated – Populate with the HIPAA signature date.
      2) HIPAA form is signed but undated
         A) Populate with the handwritten date in the "Today's Date" boxes on the front of the survey.
         B) If the "Today's Date" boxes are blank, use the date stamp to date the HIPAA form with the date stamped on the front page of the survey, and populate the field with this date.
      3) HIPAA form is unsigned – If the participant wrote a date in the "Today's Date" boxes on the front of the survey, populate with this date. Otherwise, populate with the date stamped on the front of the survey.
iv. If yes and the survey was returned without being completed, see the Senior Coordinator-Clinical Research Operations or CRA2 for direction.

B. **Date Survey Received** – Enter the date that is stamped on the front page of the survey.



C. **Survey Source** – Select 1-Paper.

D. Open the survey booklet, and turn to the **HIPAA Authorization Form**.

i. If the HIPAA is unsigned:

a. And the participant *did* write "Refused", "VOID", etc.

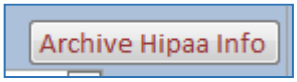
1) IF the **Date HIPAA Received**, **Date HIPAA Signed**, **HIPAA Source**, and/or **HIPAA Status** fields *are populated*, click the **Archive Hipaa Info** button, clear the data, and populate **HIPAA Status** with 2-Refused.

2) IF the **Date HIPAA Received**, **Date HIPAA Signed**, **HIPAA Source**, and/or **HIPAA Status** fields *are blank*, populate **HIPAA Status** with 2-Refused.

b. And the participant *did not* indicate "Refused", "VOID", etc., skip to the next step.

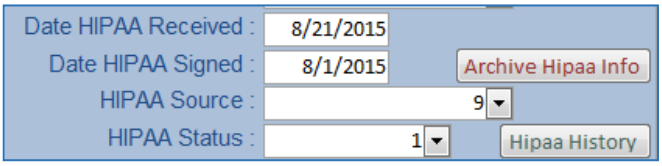
ii. If the HIPAA is signed by the participant or his/her legal representative:

a. IF the **Date HIPAA Received**, **Date HIPAA Signed**, **HIPAA Source**, and/or **HIPAA Status** fields *are populated*, click the **Archive Hipaa Info** button.



b. **Date HIPAA Received** – Enter the date that is stamped on the front of the survey.

c. **Date HIPAA Signed** – Enter the date the HIPAA was signed. If the participant did not date the HIPAA, date-stamp the Date blank with the date that is stamped on the front page of the survey, and populate the field with this date.



d. **HIPAA Source** – Populate with 18 | Follow-Up 6.

e. **HIPAA Status** – Populate with 1-Complete.

iii. If the HIPAA is signed by someone other than the participant or his/her legal representative, consult with the Senior Coordinator-Clinical Research Operations or CRA2 for a directive.

6. Navigate to the PARTICIPANT tab, and go to the contact information page of the survey.
NOTE: When someone other than the participant completes the survey (e.g. minor surveys), all steps to update contact information in the PARTICIPANT tab should be repeated in the ASSOCIATE tab record for the party that completed the survey.

A. If the participant provided an **email address**, determine whether the email address is already in the database.

i. If yes:

a. **Rank** – Select "1." If needed, adjust the **Rank** of other email addresses.

b. **Email Date** – Enter the date that is stamped on the front of the survey.

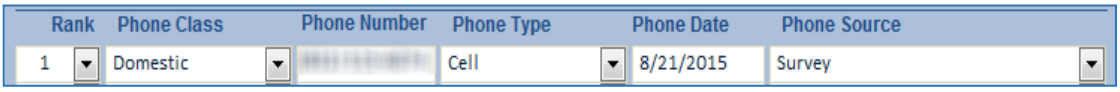
c. **Email Source** – Populate with "Survey."

ii. If no:

a. Enter the email address in the next available row.

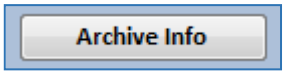
b. **Rank** – Select "1." If needed, adjust the **Rank** of other email addresses.
c. **Email Date** – Enter the date that is stamped on the front of the survey.
d. **Email Source** – Populate with "Survey."

B. If the participant indicated that the **survey contact information is correct**:
   i. Verify that the address information printed on the survey matches the address in the database.
      a. If yes:
         1) **Address Date** – Enter the date that is stamped on the front of the survey.
         2) **Address Source** – Populate with "Survey."
      b. If no, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.
   ii. Verify that the phone information printed on the survey matches one of the phone numbers in the database.
      a. If yes:
         1) Find the phone number in the database.
         2) **Phone Date** – Enter the date that is stamped on the front of the survey.
         3) **Phone Source** – Populate with "Survey."
         4) **Rank** – Adjust phone ranks as needed
      b. If no, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.
   iii. If additional phone numbers were provided and these ARE already in the database:
      a. **Rank** – Adjust, if needed.
      b. **Phone Type** – Select the appropriate option.
      c. **Phone Date** – Enter the date that is stamped on the front of the survey.
      d. **Phone Source** – Populate with "Survey."



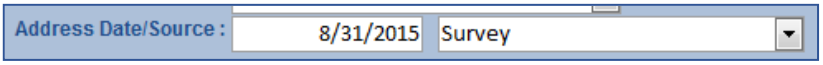
   iv. If additional phone numbers were provided and these ARE NOT in the database:
      a. Enter the first new phone number in the next available row.
      b. **Rank** – Rank the new number according to your best judgment. Adjust the rank of other numbers, if appropriate.
      c. **Phone Class** – Select either "Domestic" (for US numbers) or "International" (for non-US numbers).
      d. **Phone Type** – Select the appropriate option.
      e. **Phone Date** – Enter the date that is stamped on the front of the survey.
      f. **Phone Source** – Select "Survey."
      g. Repeat this process until all new numbers are recorded.

C. If the participant indicated that the **survey contact information is NOT correct**:
   i. Verify that the address information printed on the survey matches the address in the database.
      a. If yes:



1) Click the **Archive Info** button.
2) Update the address information.
3) **Address Date** – Enter the date that is stamped on the front of the survey.
4) **Address Source** – Select "Survey."

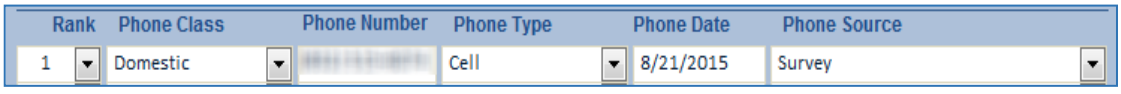
b. If no, compare the handwritten address to the address in the database.
   1) If they match:
      A) **Address Date** – Enter the date that is stamped on the front of the survey.
      B) **Address Source** – Select "Survey."



   2) If they do not match, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

ii. Verify that the phone information printed on the survey matches one of the phone numbers in the database.
   a. If yes and the participant DID NOT scratch through the number or write a note such as "Don't call this number," skip to the next step.
   b. If yes and the participant DID scratch through the number or write a note such as "Don't call this number":
      1) Find the phone number in the database.
      2) **Rank**
         A) If the participant specifically indicated we should NOT call the number, update to 37-Do Not Call.
         B) If the participant scratched through the number or otherwise indicated it is incorrect without specifically indicating that we should NOT call it, update to 11-Wrong Number.
      3) **Phone Date** – Enter the date that is stamped on the front of the survey.
      4) **Phone Source** – Select "Survey."
   c. If no, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

iii. If additional phone numbers were provided and these ARE already in the database:
   a. **Rank** – Adjust, if needed.
   b. **Phone Type** – Select the appropriate option.
   c. **Phone Date** – Enter the date that is stamped on the front of the survey.
   d. **Phone Source** – Select "Survey."



iv. If additional phone numbers were provided and these ARE NOT in the database:
   a. Enter the first new phone number in the next available row.
   b. **Rank** – Rank the new number according to your best judgment. Adjust the rank of other numbers, if appropriate.

c. **Phone Class** – Select either "Domestic" (for US numbers) or "International" (for non-US numbers).
d. **Phone Type** – Select the appropriate option.
e. **Phone Date** – Enter the date that is stamped on the front of the survey.
f. **Phone Source** – Select "Survey."
g. Repeat this process until all new numbers are recorded.

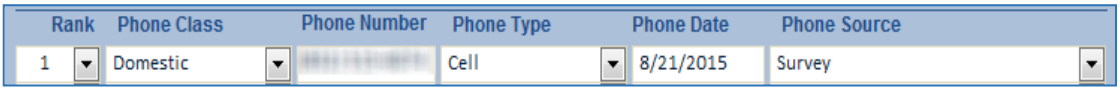
D. If the participant indicated that s/he is **moving**:

i. Verify that the address information printed on the survey matches the address in the database.
   a. If yes and the participant DID NOT provide an alternative address, skip to the next step.
   b. If yes and the participant DID provide an alternative address, make a copy of the contact information page and give the copy to the Senior Coordinator-Clinical Research Operations or CRA2.
   c. If no, compare the handwritten address to the address in the database.
      1) If they match:
         A) **Address Date** – Enter the date that is stamped on the front of the survey.
         B) **Address Source** – Select "Survey."
      2) If they do not match, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

ii. Verify that the phone information printed on the survey matches one of the phone numbers in the database.
   a. If yes and the participant DID NOT scratch through the number or write a note such as "Don't call this number," skip to the next step.
   b. If yes and the participant DID scratch through the number or write a note such as "Don't call this number":
      1) Find the phone number in the database.
      2) **Rank**
         A) If the participant specifically indicated we should NOT call the number, update to 37-Do Not Call.
         B) If the participant scratched through the number or otherwise indicated it is incorrect without specifically indicating that we should NOT call it, update to 11-Wrong Number.
      3) **Phone Date** – Enter the date that is stamped on the front of the survey.
      4) **Phone Source** – Select "Survey."
   c. If no, STOP and consult with the Senior Coordinator-Clinical Research Operations or CRA2.

iii. If additional phone numbers were provided and these ARE already in the database:
   a. **Rank** – Adjust, if needed.
   b. **Phone Type** – Select the appropriate option.
   c. **Phone Date** – Enter the date that is stamped on the front of the survey.

d. **Phone Source** – Select "Survey."



iv. If additional phone numbers were provided and these ARE NOT in the database:
   a. Enter the first new phone number in the next available row.
   b. **Rank** – Rank the new number according to your best judgment. Adjust the rank of other numbers, if appropriate.
   c. **Phone Class** – Select either "Domestic" (for US numbers) or "International" (for non-US numbers).
   d. **Phone Type** – Select the appropriate option.
   e. **Phone Date** – Enter the date that is stamped on the front of the survey.
   f. **Phone Source** – Select "Survey."
   g. Repeat this process until all new numbers are recorded.

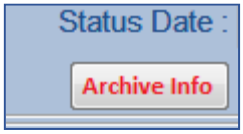
E. On the contact information page, review "Would you be willing to send/receive study-related texts?" item.
   i. If the participant provided a phone number, update the phone info per the instructions above.
   ii. If the participant indicated "Yes", "No", or "My phone is not text capable", then update the **Receive Study Text Messages** and **Date Text Messages** field (to the date stamps on the survey).

F. If the participant **neither confirmed nor corrected the survey contact information**:
   i. Determine if a return address was indicated on the envelope to confirm the mailing address. If so, use this to make the appropriate updates.
   ii. If the **Tracing Code** field is populated with an address-related tracing code AND **Address Source** is set to "Lexis Nexis":
      a. Clear or adjust the **Tracing Code** and **Tracing Date** fields, as appropriate, to remove the address-related tracing code.
      b. Record a dated note in the **Notes** field of the PARTICIPANT tab that the survey was returned via paper after mailing to the Lexis Nexis address and that the Lexis Nexis address is therefore presumed correct.
      c. **Address Date** – Enter the date that is stamped on the front of the survey.
      d. **Address Source** – Select "Survey."

7. Clear or adjust the **Tracing Code** and **Tracing Date** fields on the PARTICIPANT tab after updating the contact information. See the SOP titled **Outcome and Tracing Code Guidelines** or check with the Senior Coordinator-Clinical Research Operations or CRA2.

8. Review the **CCSS Study Outcome** and related **CCSS Outcome Date** fields in the header to determine if they should be cleared. When in doubt, consult with the Senior Coordinator-Clinical Research Operations or CRA2.

9. Navigate to the ASSOCIATES tab.
   A. If the participant DID NOT provide associate contact information, skip to the next step.
   B. If the participant DID provide associate contact information, determine whether the associate on the survey matches one of the associates in the database by comparing the name and relationship.
      i. If a full or partial match IS found:
         a. Compare the **associate names**.
            1) If they match, skip to the next step.
            2) If they do not match (e.g. last name change):
               A) **Notes** – Enter a dated note explaining the name change. *Example: 1/29/2016: Mother's name changed from Jane Doe to Jane Smith, per FU6 survey. [your initials]*
               B) **Name** – Update to the new name.
         b. Compare the **relationship**. This is the associate's relationship to the case or sibling participant.
            1) If they match, skip to the next step.
            2) If they do not match (e.g. ex-mother-in-law, ex-wife):
               A) **Notes** – Enter a dated note explaining the relationship change. *Example: 1/29/2016: Changed Jane Doe's relationship from Spouse to "Other" as she is now an ex-spouse per the FU6 survey. [your initials]*
               B) **Relationship** – Update the field.
         c. Compare the **associate address** on the survey to the information in the database.
            1) If they match:
               A) **Address Date** – Enter the date that is stamped on the front of the survey.
               B) **Address Source** – Select "Survey."
            2) If they do not match:
               A) Click the **Archive Info** button.
               B) Update the address information.
               C) **Address Date** – Enter the date that is stamped on the front of the survey.
               D) **Address Source** – Select "Survey."

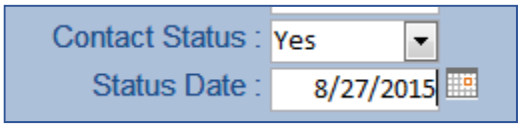


         d. Compare the **associate phone information** on the survey to the information in the database.
            1) For phone numbers provided on the survey that ARE already in the associate's record:
               A) **Rank** – Adjust, if needed.
               B) **Phone Type** – Select the appropriate option.
               C) **Phone Date** – Enter the date that is stamped on the front of the survey.
               D) **Phone Source** – Select "Survey."

2) For phone numbers provided on the survey that ARE NOT already in the associate's record:
   A) Enter the first new phone number in the next available row.
   B) **Rank** – Rank the new number according to your best judgment. Adjust the rank of other numbers, if appropriate.
   C) **Phone Class** – Select either "Domestic" (for US numbers) or "International" (for non-US numbers).
   D) **Phone Type** – Select the appropriate option.
   E) **Phone Date** – Enter the date that is stamped on the front of the survey.
   F) **Phone Source** – Select "Survey."
   G) Repeat this process until all new telephone numbers are recorded.

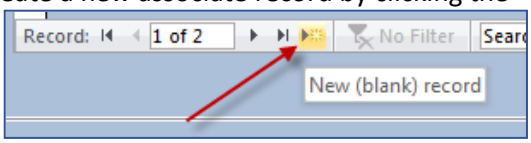
e. If the participant provided an **associate email address**, determine whether the email address is already in the associate's record.
   1) If yes:
      A) **Rank** – Select "1." If needed, adjust the rank of other email addresses.
      B) **Email Date** – Enter the date that is stamped on the front of the survey.
      C) **Email Source** – Select "Survey."
   2) If no:
      A) Enter the new email address in the next available row.
      B) **Rank** – Select "1." If needed, adjust the rank of other email addresses.
      C) **Email Date** – Enter the date that is stamped on the front of the survey.
      D) **Email Source** – Select "Survey."

f. Document the authorized **contact status**:



   1) **Contact Status** – Populate with or update to "Yes."
   2) **Status Date** – Enter the date that is stamped on the front of the survey.

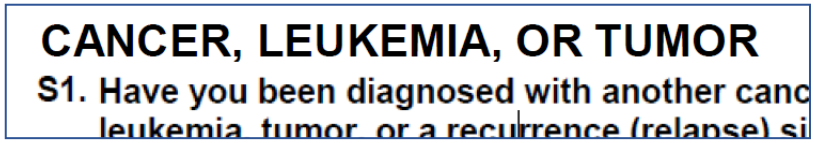
ii. If a full or partial match IS NOT found, create a new associate record by clicking the **New (blank) record** icon at the bottom of the screen.



a. **Relationship** – You MUST select a relationship. If one is not provided, select "Other," and enter a dated note explaining the "Other" value. *Example: 1/29/2016: Associate relationship not provided on FU6 survey. Entered Relationship = Other. [your initials]*
b. **Contact Status** – Select "Yes."
c. **Status Date** – Enter the date that is stamped on the front of the survey.
d. Enter all available contact information.

10. Turn to– **Cancer, Leukemia, or Tumor** section. If the participant responded "Yes", "Have you been diagnosed with another cancer…" OR provided any information in the section:

A. Make a copy of the page(s) and the HIPAA (if signed).



B. Give the copies to the SMN project coordinator (if s/he is in the office) or place the copies in the SMN project coordinator's hanging folder (if s/he is not in the office).

11. **Review Comments** – Review the participant's comments. If they include anything that requires or is suspected to require addressing, copy the page with the comments and give the copy to the Research Scientist for review.
12. **Initial and date** the **Edit** box on the paper survey cover page. Use purple ink, when possible.
13. **Route the survey booklet** for further processing.
    A. Give the in-processed survey to the Senior Coordinator-Clinical Research Operations.

Revision Record Printed 1/19/2018 10:15 AM

Current Filename:		Processing Returned FU6 Paper Surveys ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	9/12/2017	J. Ford	Initial Development
1.1	1/19/2018	A. McDonald	Adding information about no text capable phones

Processing Returned LTFU Recruitment Packets

Background

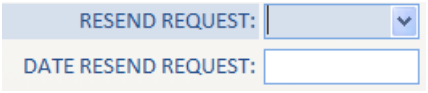
Handle recruitment study materials from participants *recruited by the Long Term Follow-Up Center* at St. Jude following these procedures. LTFU Recruitment packets contain study enrollment materials and (sometimes) surveys. The procedure first checks for HIPAA authorization and documents it in the Recruitment database. Then the CRA2 rolls over the records into the expansion database. When the packet contains a survey, processing continues with the Expansion Tracking database (procedure outlined in *Processing Expansion Questionnaires*).

Procedure

1. Date-stamp the blue BRE with date received.
2. Sort BRE's by recruiter source. (Those recruited by SJ will have the "STOP" label on the back). (Process the USC recruits in the usual manner.)

Logging the Return into the Recruitment Database

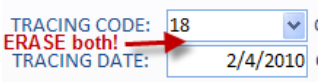
1. Open the envelope. Stamp the date the mail was received on the front of the packet, below the "The LTFU Center Staff" line. For Institutional HIPAAs, date stamp in upper right corner.
2. Discard the blue BRE; shred it if it contained a returned address. (If it contained a returned address, see whether it provides any new information, compared to the back of the booklet. If it DOES, then attach the new information in a post-it to the last page.)
3. Use the CCSSID to find the case in the Recruitment database. (Click in the CCSSID field, then use the Binoculars icon. In the Find dialog box, type in the CCSSID)
4. Double-check you have the correct case by checking name on packet with name on the database form.
    a. If the case has ALREADY ROLLED OVER into Expansion Tracking, review notes to determine whether a verbal HIPAA was obtained. *If a verbal HIPAA was obtained*, add "vH" after the date stamp on the survey booklet or institutional HIPAA. Set the material aside for STEP 2.
5. Go to the Tracking tab on the form
6. *If the packet was returned with a note indicating **refusal** to participate (and survey is blank)*
    a. Select OUTCOME CODE 4 (Refused)
    b. Enter date received in OUTCOME DATE
    c. Annotate as needed in RECRUIT NOTES
    d. File the returned booklet (if it was returned) with notation. A separate file cabinet drawer will be used for refusals.
    e. If note says refused, but survey was not blank, give this to CRA2 for decision.
7. CHECK to see if there is a "RESEND REQUEST" on file. If there is, remove it *and* DATE RESEND REQUEST. AND add a note in RECRUIT NOTES "*mm/dd/yy: Resend request*



CRA

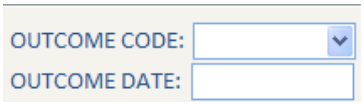
cancelled on receipt of packet [your initials]"

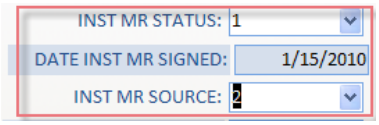
8. IF there is a value in TRACING CODE or TRACING DATE, delete (erase) them. (It's obvious that the survey got to the right party, and we no longer need to trace them.



9. Is the **Institution Medical Release (HIPAA) is properly signed?**
   a. *What makes a "properly signed" institutional HIPAA*? For adult participant, dated and signed by the participant. For minor participant, dated and signed by the minor's parent or guardian or personal representative.

   b. IF PROPERLY SIGNED, then
      i. Enter 1 for INST MR STATUS (Complete)
      ii. Type in the handwritten date from the Institutional HIPAA form into DATE INST MR SIGNED
      iii. Enter **2** for INST MR SOURCE (paper)
      iv. Enter **1** in OUTCOME CODE (Recruited), AND then enter the **date** we received the packet in the OUTCOME DATE field.



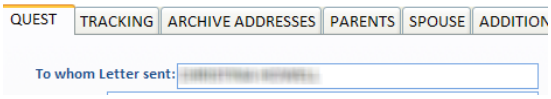


      v. In **red ink, print your initials to the right** of the date stamp on the front page. This signifies the survey was in-processed in the Recruiting database.

   c. IF NOT PROPERLY SIGNED, see below

10. If they **returned the Participant copy**, give it to the CRA2. Include a photocopy of the page showing name, address, and CCSSID. CRA2 will mail the copy back to the participant.

11. NAME changes:
    a. In **To Whom Letter Sent**, key in the new name.
    b. In Comments, annotate (e.g., "m/d/yy: name changed from ___ per (survey|HIPAA)")
    c. Photocopy the page showing the name change, and give it to the CRA2 who will update the name in the database.



12. Email the CRA2 to **request a Recruiting Rollover**, once you have in-processed your current batch of recruiting surveys. (The records will NOT appear in the Expansion Tracking database until they have been rolled over.)

13. In the Expansion database, after the records have rolled over, continue with the remainder of in processing.

CRA

Inst HIPAA NOT signed or not signed properly

1. For cases where **HIPAA was NOT signed** or not **properly** signed, check to see what WAS completed, and log those portions in appropriate fields on Recruitment Tracking tab. E.g.,
    a. LTFU Consent form
        i. A date is entered on consent signature page, enter it in DATE CONSENT SIGNED.
        ii. If *signed*, enter CONSENT STATUS "*Complete*"
        iii. If *not signed, but survey is completed*, enter CONSENT STATUS "*Implied*"
        iv. If *signed and survey is completed, but consent not dated*, enter date the form was stamped in DATE CONSENT SIGNED and then enter CONSENT STATUS "*Complete*"
        v. For minors, if minor signed, then code consent status as "Incomplete"
    b. SJ MR (HIPAA) form
        i. If a date entered on **LTFU** HIPAA Authorization Form page, enter it in DATE SJ MR SIGNED.
        ii. For SJ MR SOURCE, select 2 (Paper)
        iii. For SJ MR STATUS:
            1. If *signed*, select 1 (Complete)
            2. If *not signed, or signed by minor,* select 10 (Incomplete)
    c. Survey
        i. Enter DATE SURVEY COMPLETE, taken from the "Today's date" section on the first page of the survey itself.
            1. If the person did not write the date, then enter the date the packet was received (date stamp on front page).
        ii. Select SURVEY SOURCE: Paper (2)

    d. Address/Contact information updates
        i. Check for updated address, phone, email information on back of package.
        ii. If any corrections or additions were given:
            1. Go to the Quest Tab.
            2. Click the "**Archive Address**" button.
            3. Address/Phone/Email corrections
                a. Enter the corrected address information in the address area of the form.
                b. Enter any new phone numbers and /or email addresses in the next available phone/email space (several spaces are available).
                c. For each of these, also
                    i. Select the appropriate value for source (survey or paper)
                    ii. Enter the DATE the packet was received as the date
        iii. Click the **Update Print Table ADDRESS** button.

    e. NAME changes: Follow the NAME changes procedure outlined above.

CRA

2. Initial in red ink to right of date-stamp on front page to signify in-processed into recruitment.

3. **Put a post-it on front of survey explaining situation, then give survey to the CRA2** who will (1) send a letter and a blank HIPAA to the participant and (2) file document in the "UNSIGNED HIPAA" file cabinet, in order by CCSSID. We cannot move to Step 2 of the processing until we receive the signed and dated Institutional HIPAA.
    a. When the missing documents are returned to us, retrieve the packet and resume processing with Step 1 (Institutional HIPAA Information).

Processing recruited cases in Expansion Tracking database

Open the Expansion Tracking database, and process newly recruited cases in the same manner used for USC recruits. (See Procedure ***Processing Expansion Questionnaires*** for further detail.)

Revision Record Printed 7/6/2012 10:12 AM

Current Filename:		Processing Returned LTFU Recruitment Packets ver 1_6.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	1/25/10	J.Bates	Initial Development
1.1	2/4/10	J.Bates	Erase Tracing codes on INSTMR complete
1.2	2/5/10	J.Bates	Clear resend requests
1.3	2/24/10	J.Bates	Clarification on DATES
1.4	9/2/10	J.Bates	Clarifications-not fully recruited
1.5	9/8/10	J.Bates	Coding HIPAA incomplete, signed by minor
1.6	5/11/11	J.Bates	Adjust for recruit packets with no surveys

Processing Returned Saliva Samples

Background

As participants return saliva samples by mail, or we collect them from SJ Life participants at the TTU, we first record the sample collection, status, and consent in the database (expanded cohort, siblings, original cohort), and log it in the *CCSS Saliva Tracking Sheet*. Then the TTU technologist evaluates the sample, logs results, and ships to the Molecular Genetics Laboratory in Cincinnati, Ohio. Finally, we prepare a tracking sheet, forward it to the Cincinnati lab, and update the database about the shipment. For samples collected in TTU clinic, first see *St Jude Life CCSS Appointments*, then follow *Recording Collected Samples* (and all subsequent sections) (below).

Procedure: Samples Returned by Mail

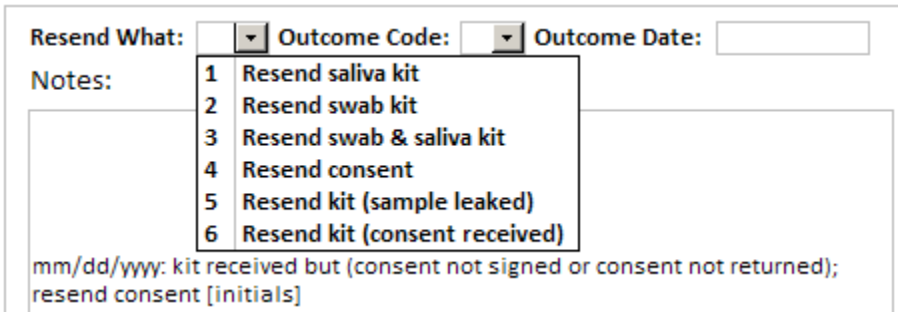
IMPORTANT: Date stamp each returned package with current date. Packages must be in-processed in the kit processing room within 24 hours of receipt. All saliva samples must be delivered to TTU within 24 hours of receipt. (For samples collected in TTU clinic, start first with the *St Jude Life CCSS Appointments* procedure.)

1. Open the exterior envelope to collect the consent form
    a. If the participant provided any contact information (e.g. wrote return address on outside of envelope; left a note the package with new phone number, etc.), update the appropriate database using standard CCSS procedures

2. If the packet is **an obvious refusal** (unused materials returned, note from participant, etc.) or there is notification that the participant deceased:
    a. Recycle non-PHI materials (kit, participant copy, biohazard bag, etc)
    b. If a refusal/deceased note was included, insert document into "Refusal/Deceased" folder in saliva consent file cabinet in CCSSID order
    c. Proceed to *Recording Collected Samples in Database*

3. If a **sample is provided** but the **consent is missing or not signed**:
    a. Determine if a consent form was previously signed by participant
        i. Open appropriate database, search by CCSSID, and view all records for participant
        ii. If a consent was signed within XX amount of days of receiving the current kit, process sample (see *Recording Collected Samples in Database*) using the previous record consent received date as the current record consent received date
    b. If a consent form was not previously signed by participant, update database (see *Recording Collected Samples in Database*) with a note "m/d/yy: Consent form not returned; send new consent to pt [initials]"
    c. Update ***CCSS Saliva Kit Tracking*** fields (see *Logging Obtained Sample in Saliva Tracking Sheet*): entering "N" in **Consent Received(Y/N)** and documenting in **Notes**: "m/d/yy: kit returned without consent [initials]"

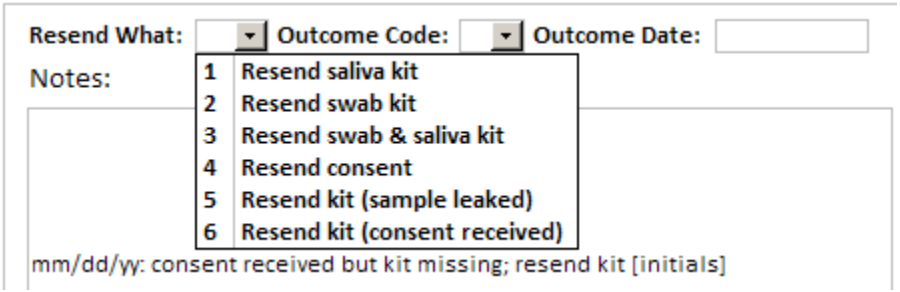
d. Open the **CCSS DNA Tracking** database:
   i. Search for CCSSID
   ii. Enter **4 Resend consent** in **Resend What:**
   iii. Document in **Notes**: "m/d/yy: kit received but [consent not signed or consent not returned]; resend consent [initials]"



e. Send kit to TTU lab and place in "Hold" bin
f. When the consent is returned, update database consent fields, update appropriate ***CCSS Saliva Kit Tracking*** fields (i.e. change consent to "Y"; add new note "m/d/yy: sample released to lab [inits]"; move record (i.e. row) from the **Hold** tab to the **Process** tab), and place kit in the appropriate processing bin at the TTU.

4. If **consent is signed but sample is missing**:

a. Insert consent into a manila file folder (attach CCSSID label)
b. File in saliva consent file cabinet (4th floor cabinet outside processing room)
c. Update database (see *Recording Collected Samples in Database*) with a note "m/d/yy: consent returned but kit missing; send new kit to pt [initials]"
d. Open the **CCSS DNA Tracking** database:
   i. Search for CCSSID
   ii. Enter **6 Resend kit (consent received)** in **Resend What:**
   iii. Document in **Notes**: "m/d/yy: consent received but kit missing; resend kit [initials]"



5. If **both sample and signed consent form are provided**:

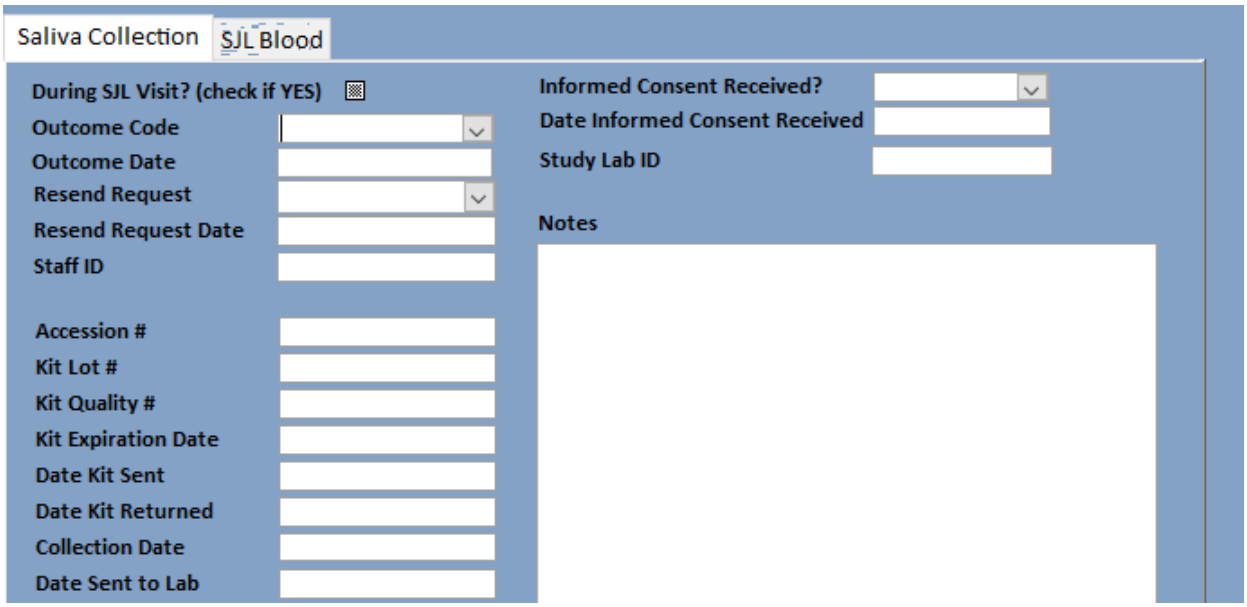
a. Give consent form to project CRA for scanning and filing
b. Proceed to *Recording Collected Samples in Database Samples*

Procedure: Recording Collected Samples in Database; Logging in Tracking Sheet

Use this and subsequent procedures for samples returned by mail and those collected in the TTU clinic.

RECORDING RETURNED SAMPLES IN DATABASE

1. Open the DNA Tracking database. In **CCSSID**, search for the case.
2. Select the **Saliva Collection** tab. On the **Saliva Collection** tab:
   a. For samples <u>obtained in clinic</u>: go to a blank record
   b. For samples <u>returned by mail</u>: open jiffy lite envelope to view kit info and find record with matching **Kit Lot#, Kit Quality #**, **Kit ExpirationDate**
      i. If a sample was not included in package, but refusal (unused kit or note) or deceased note was, go to *first* record (i.e. 1 of 2, 1 of 3, etc)



   c. Select appropriate **Outcome Code** from the dropdown list.
   d. Enter **Outcome Date**
      i. <u>In clinic</u>: use date the participant provides you with a signed consent form or date the participant refused
      ii. <u>Returned by mail</u>: use date package received
   e. Enter your initials in **Staff ID**
   f. Select code for **Informed Consent Received**
      - 1 Yes (use when consent signed)
      - 2 No (use when sample received but signed consent is missing)
   g. Enter **Date Informed Consent Received**: (date we received the signed consent). But leave BLANK if participant refused the study, is deceased, or the signed consent is missing.
   h. For samples <u>obtained in-clinic</u>, click the **During SJL Visit? (check if YES)** box and enter **Kit Lot#, Kit Quality#**, **Kit ExpirationDate**, **Date Kit Sent**, **Date Kit Returned**, and **Collection Date** from the *SJL In Clinic Saliva Tracking Sheet*.

i. For samples returned by mail, key in **Date Kit Returned**. Enter **Collection Date** as the date entered on the back of the jiffy lite envelope (if no date was provided, enter 11/11/1811). Leave these fields BLANK if the returned kit does not contain a saliva sample. *Be sure you use record with matching Kit Lot#, Kit Quality#, and Kit ExpirationDate.*

j. Enter ***any and all*** pertinent notes in the **Comments** section such as "Swab kit utilized [initials]; Received note that participant is [deceased, refused, etc.] [initials]; Unused kit/materials returned [initials]". As a rule of thumb, it is better to note any 'out of the ordinary' things than not. Doing so allows others who are unfamiliar with this study to understand the history of a case.

LOGGING OBTAINED SAMPLE IN SALIVA TRACKING SHEET

After a saliva sample is obtained (either during SJL/TTU visit or returned via mail), we update the Excel file *CCSS Saliva Tracking* so we can track *when* we deliver a specimen sample to the TTU for evaluation. The TTU lab updates this document as well.

1. Open *CCSS Saliva Kit Tracking* file **(\\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\TAS\TTU Saliva Tracking**)
2. Open appropriate sheet
   a. **Process** for samples with a signed consent
   b. **Hold** for samples without a signed consent or on hold for another reason
3. On the next available blank row, key in the following information about the kit, in the designated columns (CCSS Study Staff section): **CCSSID**, **Date Returned**, **Collected During SJL Visit (Y/N), Kit Lot#, Kit Quality#, Kit Expiration Date**, **Date Kit To TTU**, **Consent Received(Y/N), Date Sample Obtained**, and any pertinent **Notes**.

	A	B	C	D	E	F	G	H	I	J
1	*CCSS Study Staff*									
2	CCSSID	Date Returned	Collected During SJL Visit (Y/N)	Kit Lot #	Kit Quality #	Kit Expiration Date	Date Kit to TTU	Consent Received (Y/N)	Date Sample Obtained	Notes

4. Deliver the kit(s) to the TTU technologist.
   a. If the sample should be held and not processed, place the kit in the "Hold" bin

Procedure: (1) Sample Evaluation, (2) Cincinnati lab, (3) Updating Database

TTU Technologist Evaluates Sample and Ships to Cincinnati

TTU Lab Staff						
Date Kit Processed	Acceptable for Processing (Y/N)	Sample Weight (g)	Accession Number	Date Sent to CCSS Lab (CCHMC)	FedEx Tracking Number	Notes

The TTU technologist (1) evaluates the sample and disposes of invalid samples (i.e. leaked kits), (2) enters additional information in the TTU Lab Staff section of the *CCSS Saliva Tracking Sheet*, (3) removes the current label from valid kits and creates a new label (with barcoding system), (4) sends the valid kits via FedEx to the Cincinnati laboratory, and (5) emails the FedEx shipping information to the project CRA.

Notifying Cincinnati

When the TTU technologist emails the FedEx shipping information to the project CRA:

1. Check the TTU Lab Staff section of the *CCSS Saliva Tracking Sheet* (located at **\\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\TAS\TTU Saliva Tracking**) to identify CCSSIDs that are en route to Cincinnati.
   a. Refer to the email from TTU lab with FedEx Tracking # and shipment date.
   b. In Tracking Sheet, in TTU Lab Staff columns (see above), locate records with specified **FedEx Tracking Number** and **Date Sent to CCSS Lab (CCHMC).** Identify CCSSIDs (colA) belonging to this activity.
2. Create a new Excel file. Key in the **CCSSIDs** and **Accession Number** of the kits you just identified as being en route to Cincinnati.
3. Save the new Excel file as "Saliva Kit Batch [Current Date]"in: **Z:\SJShare\SJCOMMON\ECC\TAS\TTU Saliva Tracking\Sent to Cinn**
4. Email the new Excel file to the Cincinnati lab:
   a. Email to Bridget Litts (Bridget.Litts@cchmc.org).
   b. In email body, provide relevant FedEx Tracking # for the shipment.

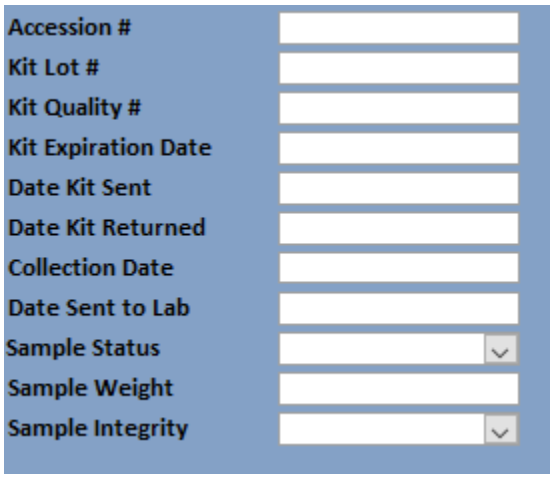
Updating Database (Samples sent to Cincinnati lab/Unacceptable Kits)

Reopen *CCSS Saliva Tracking Sheet.* Identify all CCSSIDs that are now en route to Cincinnati (same process as before) and/or unacceptable for processing. Open the CCSS DNA Tracking database, open Case or Sibling forms, and search for the CCSSID.

Samples sent to Cincinnati lab

1. If there is more than one Saliva Collection record for that CCSSID, page through them until you find the one that matches the **KitLot #**, **KitQuality #**, and **KitExpirationDate** for the record on the *CCSS Saliva Tracking Sheet* to the data entered in the database. You may have to scroll through multiple Saliva Collection records to find the right match.
2. When you locate the correct Saliva Collection record, enter:
   a. **Accession #**
   b. **Date Sent to Lab** (the date the kit was shipped to Cincinnati)

c. **Sample Status** (**Acceptable for Processing (Y/N)** from the tracking sheet)
   - Select 1 (Acceptable)



d. **Sample Weight**
e. Enter any and all pertinent **Notes** in the **Comments** section.

Unacceptable Kits

1. If there is more than one Saliva Collection record for that CCSSID, page through them until you find the one that matches the KitLot #, KitQuality #, and KitExpirationDate for the record on the CCSS Saliva Tracking Sheet to the data entered in the database. You may have to scroll through multiple Saliva Collection records to find the right match.
2. When you locate the correct Saliva Collection record, enter:
   a. **Sample Status** (**Acceptable for Processing (Y/N)** from the tracking sheet)
      - Select 2 (Unacceptable)
   b. Enter a value in the **Sample Integrity** field. Use the following:
      - 1= Container Broken
      - 2= Container Not Sealed
      - 3= Inadequate Amount
      - 4= Other: tracking sheet does not have a note *or* the note states a reason that does not match values 1 through 3 above
   c. Enter any and all pertinent Notes in the Comments section.
   d. Enter **5 Resend kit (sample leaked)** in **Resend What:** and current date
   e. Document in Notes: “mm/dd/yy: kit received on mm/dd/yyis unacceptable for processing; resend kit [initials]”

Revision Record Printed 8/20/2019 1:30 PM

Current Filename:		Processing Returned Saliva Samples ver 2_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	1/31/2012	J.Ford	Initial Development
1.1	2/10/12	J.Bates	Formatting
1.2	2/21/12	J.Ford	Integration
2.0	7/5/12	J.Ford	Revisions to actual practice
2.1	8/20/19	R. Vejandla, J. Ford	Network and database changes

Processing Returned Spanish Authorizations

Background

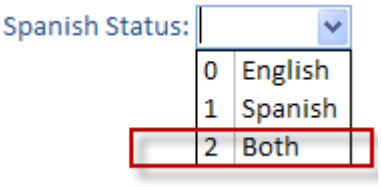
Materials sent to individuals thought to need a Spanish translation of the recruitment materials are inserted into the recruitment packet. The Spanish inserts include the cover letter and the institutional HIPAA. For the "full packet" recruitment process, the Spanish inserts also include translated LTFU consent and HIPAA. All forms are imprinted with name, date of birth, and CCSSID. There is no Spanish translation for the baseline survey.

Individuals who opt to use the Spanish insert can be expected to sign the authorization and consent documents and return them to the LTFU recruiting center. The cover letter advises them that a Spanish-speaking interviewer from the LTFU center will telephone them so they can complete the survey by phone.

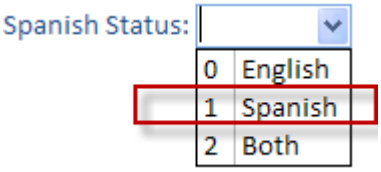
This procedure delineates how we in-process returned Spanish authorizations.

Procedure

1. Date-stamp the blue BRE with date received.
2. Date-stamp the returned signed document in the upper right corner. Add your initials to the right of the stamp.
3. Locate the individual in the database.
4. <u>If the individual returned a COMPLETED survey</u>,
    a. Document the fact in **Recruit notes**, indicating signed Spanish consents, but also completed survey.
    b. For **Spanish Status**, select "2" (Both) from the dropdown box.
    c. Place the Spanish documents inside the survey booklet.
    d. Process the survey *<u>in normal fashion</u>* (instead of steps below).



5. <u>If the individual only returned the signed Spanish documents</u>:
    a. If there is a return-address on the BRE with an address different from the database record, archive the current address and enter the new address. Indicate source as survey.
    b. Examine the signatures on the documents. Follow the guidelines in processing returned recruitment packets to determine whether the forms are appropriately signed.
    c. If you see a problem with the signatures, consult the CRA2 regarding appropriate action.
    d. If the signatures are in order,
        i. Enter "1" (Recruited) in **Outcome Code**
        ii. Enter today's date in **Outcome Date**
        iii. Select "1" (Complete) for **Inst MR Status**
        iv. Enter the **Date Inst MR Signed** (using date of signature)
        v. Enter "2" (paper) for **Inst MR Source**
        vi. In **Recruit Notes**, document "mm/dd/yy: Returned Spanish signed documents [inits]"
        vii. In **Spanish Status** (dropdown box), select "1" Spanish.
    e. File the document, by CCSSID, in the "Signed HIPAA for Expansion Baseline" file drawer.



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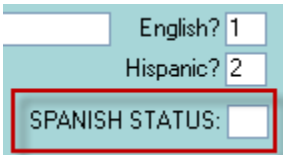
6. Send a courtesy email to the Survey Interviewer/team to alert them to the possible need to take a survey over the phone in Spanish.

Note: When the case rolls over into Expansion Tracking, the value you entered into Spanish Status displays on the Quest tab. (1=Spanish). Subsequently, the case will be identified by the survey interview team for follow-up. The follow-up entails telephone calls to complete the survey by phone. The survey interviewer enters the survey responses into the online system.



Revision Record Printed 7/6/2012 10:15 AM

Current Filename:		Processing Returned Spanish Authorizations ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	12/21/10	J.Bates	Initial Development
1.1	6/30/10	J.Bates	Courtesy email

Processing Sibling Baseline Paper Surveys

Background

Sibling Baseline survey data may be obtained online, over the phone assisted by a survey interviewer, or on paper using the printed survey mailed to the participant. Regardless of source, the survey completion must be documented in the tracking database. The CRA group processes the paper surveys. (The LeadSI team handles the documentation of online surveys.) Processing completed surveys involves recording return, consent, and HIPAA status, as well as updating contact information, identifying "additional" contact information, and flagging respondents with suicide ideation or reported malignancies. After a paper survey has been processed, it is put into the coding queue, then scanned and verified, QA'd and, finally, filed.

Procedures

Initial intake/processing


LTFU
Long-Term Follow-Up Study
Sibling Survey

St. Jude Children's Research Hospital
Ann & Robert H. Lurie Children's Hospital of Chicago
Children's Healthcare of Atlanta/Emory University
Children's Hospital at Stanford
Children's Hospital Colorado
Children's Hospital of Orange County
Children's Hospital of Philadelphia
Children's Hospital of Los Angeles
Children's Hospital of Pittsburgh
Children's Hospitals & Clinics of Minnesota, Minneapolis and St. Paul
Children's Medical Center of Dallas
Children's National Medical Center
City of Hope National Medical Center
Cook Children's Hematology-Oncology Center
Dana-Farber Cancer Institute/ Children's Hospital Boston
Methel Children's Hospital at UCLA
Mayo Clinic
Memorial Sloan-Kettering Cancer Center
Miller Children's Hospital
Nationwide Children's Hospital
Riley Hospital for Children – Indiana University
Roswell Park Cancer Institute
Seattle Children's Hospital

St. Jude Children's Research Hospital

Thank you for participating in the Long-Term Follow-Up study as a brother or sister of an individual treated for childhood cancer, leukemia, tumor or a similar illness. Your participation helps to provide us with valuable information in the fight against these serious illnesses of childhood and adolescence.

You can be assured that we will respect your privacy at all times. Your name or other identifiers will not be used in any report of our findings, or released to any person or agency, except study investigators.

Your generosity in participating is greatly appreciated.

Sincerely,

Date Stamp with Date Received HERE

The LTFU study staff

The questions in this booklet relate to:

1. Date-stamp the front of the survey with the date received. A paper survey must be recorded in the database within 24 hours of its receipt.
2. If the questionnaire is blank, see the CCSS CRA2 for guidance.
3. Check to see if the "Keep for your files" consent documents (participant copy) were returned to us.
   a. If they were returned, we need to mail these back to them. Did they sign the participant copies? If so, check to see that the actual consent/HIPAA forms in the bound questionnaire are signed.
   b. Then consult the CCSS CRA2 for further action.
4. NOTE: Do NOT use the Permission tab for data entry related to having obtained a Sibling Baseline survey!

Updating Sibling Gender, Spanish Status, Date of Birth

Check the following information from the survey and update as needed. To edit, use the **Edit Header** button to open the **Edit Sibling Info** form. After entering the changes, use the **Save and Close** button to close the form.

1. **Gender.** Refer to the "What is your sex" question on the survey. If this question was answered, record it (1=Male; 2=Female)

2. **Spanish Status**. If a paper survey was returned in English, record "0" for Spanish Status.

3. **Date of Birth.** Refer to the What is your date of birth question (A1). Compare this to the date of birth in the database. *In the event of a discrepancy*,
   a. First document the source of the information in the **Comments** area of the **SibInfo** tab and include date of birth the database *currently* has, as well as the corrected date. Then and only then:
   b. Change the date of birth on the **Update Header** screen.
   c. On the **Sib Info** tab, use the **Update Sibling Print Table** button.

CRA

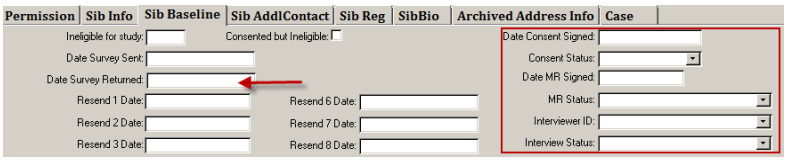
Data Entry on the Sib Info tab

1. **Send Q-aire To**
   a. For Over 18 Questionnaires, most likely use "1 = sibling" from drop down menu. There may be exceptions if participant's legal guardian or parent completed the questionnaire (use 6 or 7)
   b. For Under 18 Questionnaires, use of the following options: 2=Mother (sib under 18); 3=Father (sib under 28); 4=Both (sib under 18). Determine answer based on contact information/comments provided on the back of survey as well as information on first page (person completing).
   c. If the survey was completed by a LAR, use 7=LAR.
   d. For Deceased questionnaires, use 5=Parents (sib has died).
2. **Tracing Status** – remove anything listed unless it is "Resend Newsletter" (also clear **Tracing Date**).
3. **Sib CCSS Hold** – remove anything listed in the **Sib CCSS Hold** field AND the value in **Sib Hold Date**.
4. **Name Change**. If participant indicated name change anywhere on survey (check signature pages too):
   a. In **Comments** on **Sib Info** tab, thoroughly document information source, the name as the database currently has it, and then the new name. Explain the reason (if known or can be easily deduced from the source). For name changes that may be due to marriage or divorce, sometimes comparing the names with the last name(s) of the parent(s) (on the Sib Reg tab) can be helpful.
   b. Change the name in the **Sibling Name** field. This is the full name (using pattern Firstname Lastname).
   c. Click the **Save Record** icon, then click the update **Print Sibling Print Table** button
   d. Then use the **Edit Header** button to open the form where you will change the **FirstName** and **LastName** fields. If a name change is due to marriage, the maiden name will be preserved in the last name parenthetically as in "(maiden) married". Check with the CRA2 in case of questions.
5. **Address/phone/email information updates**. Look at the back page of the questionnaire. Compare with information on **Sib Info** tab. IMPORTANT! *Be sure you are using **Sib Info** tab (NOT Permission tab!)*
   a. If Sib Info tab address/phone information is the SAME as survey information, and participant indicated that the address presented by the survey is correct (on back page of survey), enter the date the survey was received (date stamped on front) for **Addr Date** and "Survey" as **Addr Source** (which indicates the address was confirmed).
   b. However, *if changes indicated on survey*:
      i. Click the **Archive Information** button *before* you make the changes.
      ii. Update/Enter **Address**, **City**, **State**, and/or **Zip** if changes were indicated. NOTE: Use the **Country/Region** field ONLY if address is outside the USA.
      iii. Enter the date the survey was returned in the **Addr Date** field (return date will be stamped on the front of the booklet).
      iv. In **Addr Source** field select "Survey" from drop-down list.
      v. *After* changing *address*, click the **Save record** icon, then click **Update Sibling Print Table** button.

6. Update/Enter **PhoneNumber** field if indicated on the survey (update/enter all phone numbers provided).
   a. If a new phone number is provided on the survey, enter it in an available phone number field.
   b. Use the date survey returned for **Phone Date** and "Survey" as **Phone Source** for all phone numbers added or confirmed by the survey.
   c. Select appropriate **Phone Rank** (e.g., 1 or 2)
7. Update/Enter **Email** as indicated on the survey.
   a. In **Email Date** enter the date the survey was returned.
   b. In **Email Source** field use the drop-down to choose "Survey."
   c. Select "1" for the **email RANK** for any email address obtained from the survey.

Data Entry on the Sib Baseline Tab

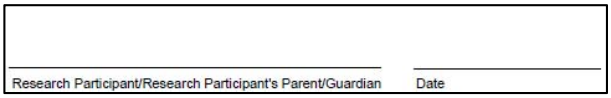
Survey completion information is recorded on the **Sib Baseline** tab of the CCSS SIBLING TRACKING Data form.



1. **Date Survey Sent:** This should not be empty, indicating we mailed a survey. If this field is blank, notify Lead CRA.

2. **Date Survey Returned**: key in the date we actually obtained the survey (should be same as date stamp on front). NOTE: STOP if this date is already filled in! Do not change it. Document in notes that a second survey had been received and then present the second survey to the **Lead CRA** who will determine which data set will be used.

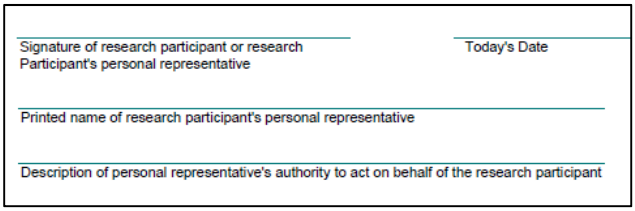
3. **CONSENT**
   a. Locate the **LTFU Consent form signature page** in the survey. Check to see if the Consent Form has been signed and dated **properly**. A *properly completed consent* will have the signature of *either* the adult research participant *or* the legally authorized representative (parent) for minor participant. A date should also be written (make sure the date is not participant's birth date).



   b. **Date Consent Signed** and **Consent Status**: Find information for these entries on paper surveys at the bottom of the consent form. Use the following chart to determine the appropriate entry based on signature status and signature date. NOTE: For consent discrepancies, consult with CRA2 (and see **Handling LTFU Consent Discrepancies**).

CONSENT SIGNATURE	SIGNATURE DT	For Date CONSENT Signed, do this:	For CONSENT Status, enter
Signed properly	Dated	Enter date from the form	1 (complete)
Signed properly	NOT dated	Date stamp when received. Enter date received	1 (complete)
NOT signed	Dated	Enter date from the form	2 (implied)
NOT signed	NOT dated	Do NOT use a date stamper. Enter date received	2 (implied)
MINOR participant OR PARENT of adult participant signed		Leave blank. See **Handling LTFU Consent Discrepancies** and consult with CRA2	Leave blank

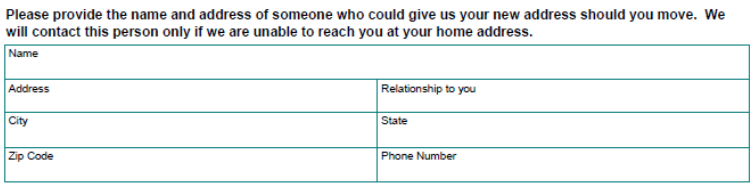
4. **HIPAA Authorization** (**Date MR Signed** and **MR Status**)
   a. Locate HIPAA Authorization Page.
   b. Check to see if the HIPAA form has been signed and dated correctly. Use the following chart to determine the appropriate data entry:



MR (HIPAA) Situation	For Date MR Signed, do this:	For MR Status, enter
1. MINOR signed MR	Leave blank. Add tracking comment:"Minor signed MR"	10 (incomplete)
2. Signature and date are correct	The date on the form	1 (complete)
3. Signed, but NOT dated	Date stamp when received and enter that date	1 (complete)
4. NOT signed, but dated	Leave blank	10 (incomplete)
5. NOT signed and NOT dated	Leave blank	3 (No Medical Release)
6. Wrote "refused" or similar notation	See CRA2 for guidance, and Leave blank	7 (Refused medical Release)

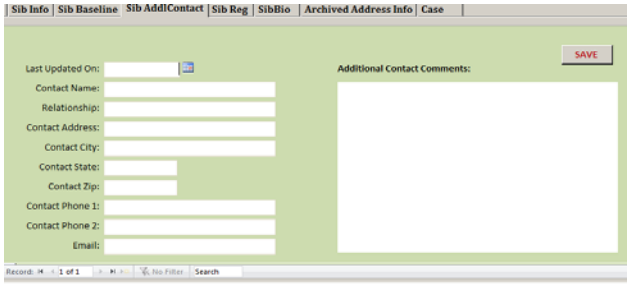
Data Entry on the Sib AddlContact Tab

(Additional Contact Information provided by Participant) The survey asks the sibling to provide name and address of a person we may contact in the event we are unable to reach the participant. The participant also indicates the contact's relationship.


Please provide the name and address of someone who could give us your new address should you move. We will contact this person only if we are unable to reach you at your home address.

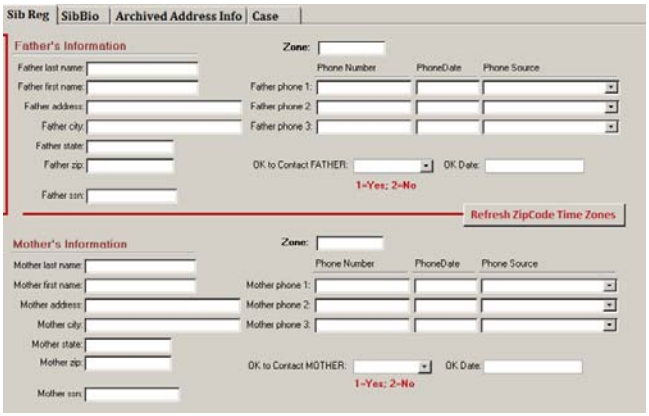
Name	
Address	Relationship to you
City	State
Zip Code	Phone Number

1. ***If the Additional Contact IS NOT the father or the mother***, use the **AddlContact** tab to record the additional contact. This form allows multiple entries.
   a. If the initial AddlContact screen is empty, complete it with the additional contact information. Be sure to enter the current date in **Last Updated On**.
   b. If the first screen already contains the person the survey gives as an Additional Contact, check to see if the address is the same. If it has CHANGED, document the existing address in the **Additional Contact Comments** box, then update the record, including **Last Updated On**.



   c. If there is somebody else in the initial screen, page through the forms to see if the person from the survey is listed on another card. If so, update the information as needed, documenting the old information as above and updating the **Last Updated On**.
   d. If the additional contact is not already on file, go to the next available record and enter all information for the new Additional contact, making sure to enter the **Last Updated On**.
   e. In every case, be sure to specify the **Relationship** that the participant indicated.

2. If the ***Relationship of the Additional Contact IS Mother or Father***, enter the information on the **Sib Reg** tab instead of Sib AddlContact tab.
   a. If the information provided on the survey is *different* from the information already in the specific parent's section, document the existing information in the Parent Comments field before updating the database.
   b. Fill in (or update after documenting previous information) the specified parent's **name**, **address**, and **phone** information.



   c. Since the participant is giving us permission to contact the parent, be sure to select 1=Yes in the **OK to Contact XXXX** box. In addition, record the current date in the **OK Date** box.
   d. If we already have name/address information in the database for the specified parent, and the information is the same, simply enter the OK to Contact code and OK Date.

Handling changes in Sibling Survival Status, Death Data

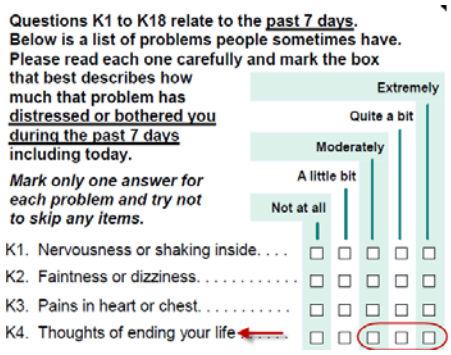
Occasionally we discover from a paper survey that a participant we thought was alive is in fact deceased. Complete the processing of the survey, and then follow the procedure to update the participant's vital status. (i.e., Document the source of the information on the **Comments** area of the **Sib Info** tab. Use the **Death Data Form** button on the **Sib Info** tab to change the **Alive/Dead Status** (1=Alive; 2=Deceased), and enter the **Date of Death** if known. Use the **SAVE** button to save the date, and then close the death data form.)

Handling Suicide Ideation

For Adult surveys, check question K4 (Thoughts of ending your life). If the participant marked Moderately, Quite a Bit, or Extremely, photocopy the following:

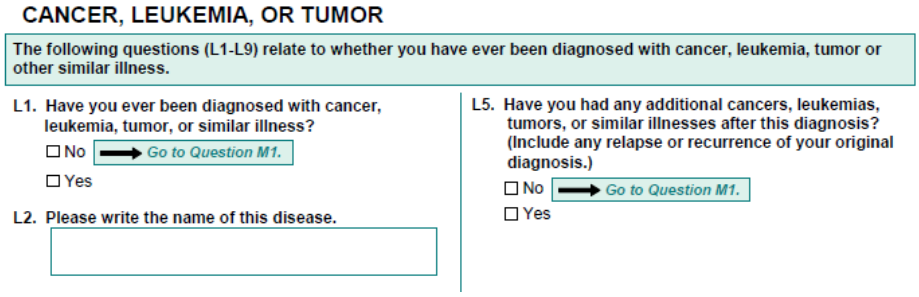
- K4 survey page
- The survey page that identifies who completed the questionnaire
- The HIPAA page
- Contact Info Page

Staple these together and take them to the LeadSI responsible for handling the suicide ideation situations.



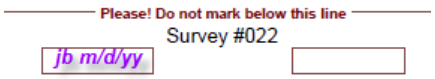
Handling a Sibling Reported Malignancy

Check Section L in the survey. If the participant indicated "yes" on item L1 (or checked No but wrote *any other information on that page)*, then PHOTOCOPY the page, and the HIPAA form (if signed). Paper-clip the 2 documents and give them to the CRA2 responsible for processing Malignancy reports.



Signing off on the processing Sibling Baseline

After the paper survey is completely processed, carefully initial and date the survey on the first page in purple ink staying within the bottom left box. Place survey in designated location for the coding queue.



Revision Record Printed 5/9/2013 9:48 AM

[236] Current Filename:		Processing Sibling Baseline Paper Surveys ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	5/7/13	J.Bates	Initial Development

Processing St Jude Life In-Hospital Recruits

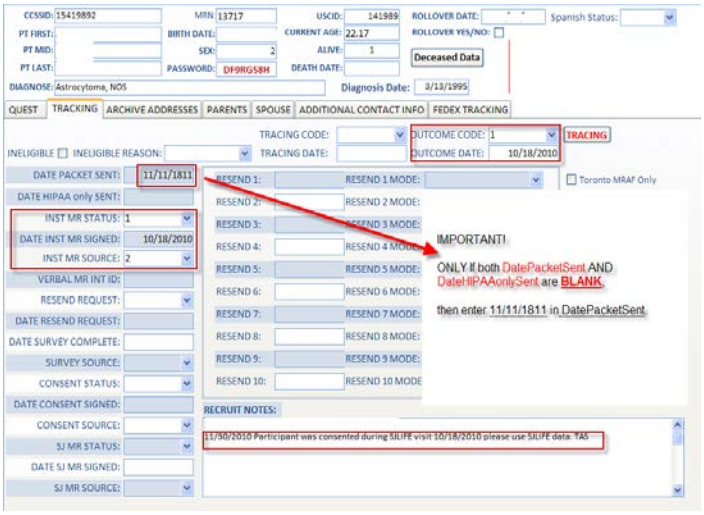
Background

Former St. Jude patients who are returning to St. Jude for their St. Jude Life study visit may be recruited to the Long Term Follow Up study if they are eligible for the expanded cohort. A LTFU CRA explains the study to them, reads the St. Jude HIPAA, LTFU informed consent, and LTFU HIPAA forms, and asks if they would like to participate (see *SJL CCSS Appointments*). If so, the case signs the forms along with a contact information update sheet. This procedure details the processing of these cases in the Recruitment and Expansion Tracking databases. Data entry in recruitment database is expected to be completed within 24 hours of recruiting the case during the SJLife visit.

Procedures

1. Determine if participant is in the CCSS Expansion Tracking database
    a. Open CCSS Expansion Tracking and search by CCSSID
        i. If pt is in the database, then proceed to Step #4
        ii. If pt is not in the database, then open the CCSS Recruitment Database and proceed to Step #2
2. **Update information in the Recruitment database** using the contact information update sheet as a source document (within 24 hours of recruiting the SJL individual for LTFU):
    a. On **TRACKING** tab, if **TRACING CODE** is not blank, remove the code and the **TRACING DATE**
    b. On **QUEST** tab, if you have ***any corrected name or address information***, click the **Archive Address** button
    c. If the participant indicated a **Name** or **DOB** change, notify the appropriate CRA2
    d. Enter any corrected or new name, address, phone, and email information
    e. Enter appropriate **ADDRESS DATE/SOURCE**, **Phone Type**, **Relationship**, **Date**, **Source**, and **EMAIL DATE/SOURCE**
3. Enter appropriate phone **Rank** info (e.g. 1 is preferred, 9 is disconnected/inactive, 37 is do not call/use)

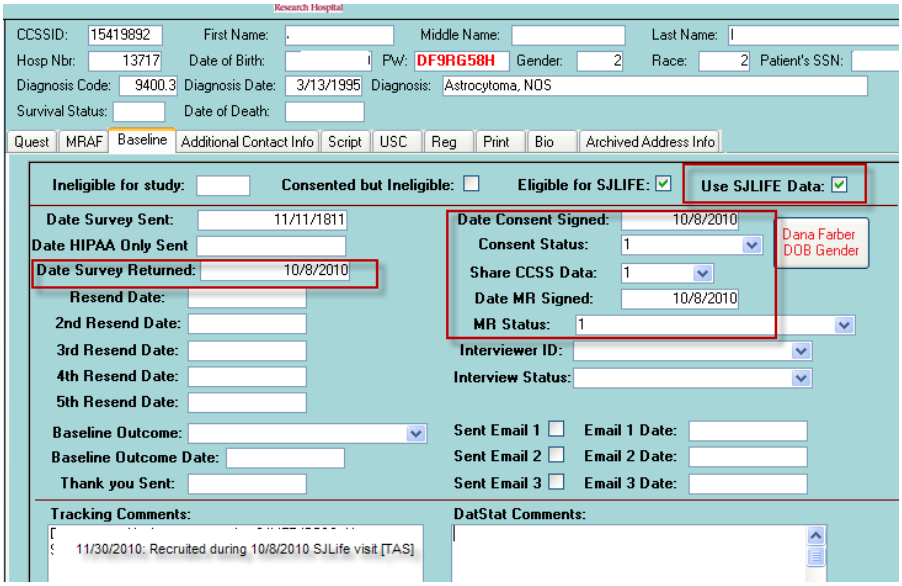
    Post the recruiting information:
    a. Enter "1" in **OutcomeCode**
    b. Enter the date you consented the person in **OutcomeDate**
    c. IF BOTH **DatePacketSent** and **DateHIPAAonlySent** fields are BLANK, then code **DatePacketSent** with 11/11/1811. (If either of those fields has a date in it, then do NOT enter 11/11/1811 in DatePacketSent.)
    d. Enter 1 in **InstMRStatus** (Complete)
    e. Enter date they signed the forms in **DateInstMRsigned**
    f. Enter 2 in **InstMRsource** (paper)



CRA

g. Type a note in **Recruitnotes** indicating pt was recruited during SJL visit. For example: **mm/dd/yyyy: Recruited during m/d/yy SJLife visit [inits].**

4. *Within 24 hours of the record rolling over to the Expansion Tracking database*, update the information in the **Expansion Tracking database**:
   a. On the **Baseline** tab:
      i. Enter the date recruited viaSJLife in **DateSurveyReturned**
      ii. Check the box for **Use SJL Data**
      iii. Type a note in **Tracking Comments**: e.g.: **mm/dd/yy: Recruited during mm/dd/yy SJLife visit [inits]**
      iv. Date Survey Sent rolls over from recruitment. But if DateSurveySent is blank, then enter 11/11/1811 in **Date Survey Sent**
      v. Enter the date they signed the consent in **Date Consent Signed**
      vi. Enter 1 in **Consent Status**
      vii. For **Share CCSS Data**, enter 1=Yes
      viii. Enter 1 in **MR Status**
      ix. Enter the date they signed the LTFU HIPAA in **Date MR Signed**



   b. Update **Additional Contact info** tab if applicable

   c. Review (and CLEAR) the **Tracing Status** and **Tracing Date** values from the Quest tab.

5. Scan CCSS consent form and St. Jude HIPAA (if applicable) to PDF and save here:
   a. **\\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Consents - CCSS exp\SignedForms-pdfs**
6. File CCSS consent form and St. Jude HIPAA (if applicable) by CCSSID in the CCSS consents: Recruited during SJLife visit cabinet.

Revision Record — Printed 8/21/2019 8:45 AM

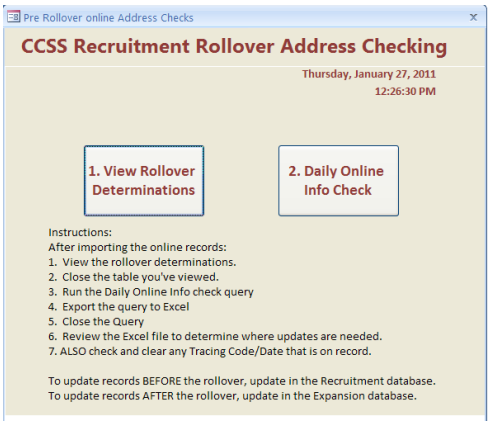
29 Current Filename:		Processing St Jude Life InHospitalRecruits ver 2_6.docx	
Revision No.	Date	Responsible Author	Change Description
1	6/15/2010	J.Bates	Initial Development
2	11/22/10	J.Bates	Edit USC involvement: major procedural change
2.1	11/29/10	A. McDonald	Revisions to process
2.2	5/10/11	J.Bates	Clearing '82'
2.3	6/16/11	J.Bates	Clarification re 11/11/1811
2.4	12/15/11	J.Bates	11/11/1811 for blank date survey sent in expansion tracking
2.5	1/8/13	J.Ford	Additional specificity
2.6	8/21/19	J.Ford	Added more detail and updated network paths

Processing Updated Online Recruitment Name and Contact Information

Background

As individuals complete the recruitment process online, they can update name and contact information. We update the database manually since this information is not automatically updated during the import process. This procedure outlines capturing the online contact information and comparing it to the information in the database. Update the information in the Recruitment database *before* the rollover procedure.

Procedure



1. After importing the online recruits into the recruitment database, but BEFORE rolling the records over to the expansion database:
   a. Open the form **frmAdmin_JBx_PreRollover**
   b. View the rollover determinations (use button 1)
      i. Close the table you've viewed.
   c. Run the **Daily Online Info Check** (use button 2)
      i. If the number of records does NOT match the number in the imported Excel file, investigate & correct before proceeding.
   d. Export the **qry_JBx_dailyOnlineInfo_beforeRollover** query to Excel and save here: \\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Jerry\PreRollover_addressChecks
      i. Close the query
   e. Review the Excel file to determine where updates are needed (see below).
   f. Rename the Excel file (add date to end of file name) after reviewing it.

Columns in the dailyOnlineInfo_beforeRollover Excel file (and source query)

RolloverDate		first_name	phone1
InstMRSource		last_name Check for name changes when Relationship is SELF	phone2
Ov18	Identifies minors/deceased, for whom the Relationship code is likely legal guardian or custodial parent.	**R_PTfirst**	**R_contphone**
BirthDate		**R_PTlast**	**R_CONTPHONE2**
Vital_Status		address	**R_PHONENUM**
Relationship code	(see description)	city	**R_PHONE4**
Description	(for relationship code)	state	**R_phone5**
CCSSID		Zip, country	email
TRACINGCODE	(Be sure to CLEAR these in the recruitment database before rollover)	**R_add1**	**R_EMail_1**
TRACINGDATE		**R_city_1**	**R_EMail_2**
Interviewerid	(Responsible for vHIPAA data entry)	**R_State_1**	**R_EMail_3**
id		**R_Zip5, R_Country**	*append_date*
		time_stamp	

2. Review each record in the Excel file **DailyOnlineInfo_beforeRollover** Excel file, highlighting fields that need database attention:
   a. Check Description field. If the text is anything other than "self" for adults (i.e. 18 or older), go to the participants' record in Recruitment, add a note to the Quest and Tracking tab stating who completed the HIPAA and their relationship to the participant (e.g. 1/1/2016: *inst HIPAA completed by legal guardian, John Smith [initials]*), update LAR/Proxy fields, Care Of field, Parents tab, and/or Associates tab (if applicable).

b. Check for **Tracing Code** and **Tracing Date.** If either one is not null, be sure to CLEAR it in the recruitment database.
c. Compare first_name/last_name to **R_PTfirst/R_PTlast**. When the respondent was self, these should be the same. Highlight if they are not; they may need to be updated (and documented) in the database.
d. Compare address/City/state/zip/country to R**_Add1/R_city_1/R_State_1/R_Zip5/R_country**. Highlight differences. Pay attention to possible typographical errors. Will need to update database.
e. Compare phone1/phone2 to **R_contphone/R_CONTPHONE2/R_PHONENUM/R_PHONE4/R_phone5**. If either phone1 or phone2 is NOT in the other phone entries, highlight it so you can add it to the database.
f. Compare email to **R_Email_1/R_Email_2/R_Email3**. If email is not in any of the other email fields, highlight so you can add it to the database.

3. For records posted by a survey interviewer which did NOT have the database updated, provide Dayton with a list for possible follow-up with the interviewer.
4. BEFORE the rollover, update the Recruitment database with any necessary changes. Find the record by CCSSID and follow standard updating procedures. Data source is HIPAA.
5. Proceed to *Rolling Over Recruited Cases* procedure.

Updating in Expansion (After Rollover if not done before)

Use the QUEST tab in Expansion tracking to update records. Locate record by CCSSID and then:

1. Document the change in **Comment** field (e.g., "{name|address|phone|email } change per online HIPAA")
2. For **NAME** changes:
   a. Enter in **To Whom Letter Sent**
   b. *Save the changes and move to the next record*
   c. Open tblCCSSExpansionTrackingMain to enter name change (use **PTFirst** or **PTlast**, as needed). *Save* the record. *Close* the table.
   d. Return to the QUEST tab and go back to the record you are updating.
      1. Verify that the name was changed in the top part of the form.
      2. Use the **Update Print Table NAMES** button to update the print table.
3. For **ADDRESS** changes:
   a. Use **Archive Contact Info** to archive existing contact information
   b. Enter the new address information (Address, City, State, Zip Code)
   c. Enter **Addr date** (current date) and **Addr Source** (HIPAA)
   d. If living, use **Update Print Table ADDRESS** button to update the print table.
4. For **PHONE** and/or **EMAIL** changes, use the next available phone/email field (do NOT erase existing phone/email information)
   a. Enter phone number, date (current date), and source (HIPAA)
   b. Enter Email address, date (current date), and source (HIPAA)

Revision Record Last printed 5/16/2018 3:28 PM

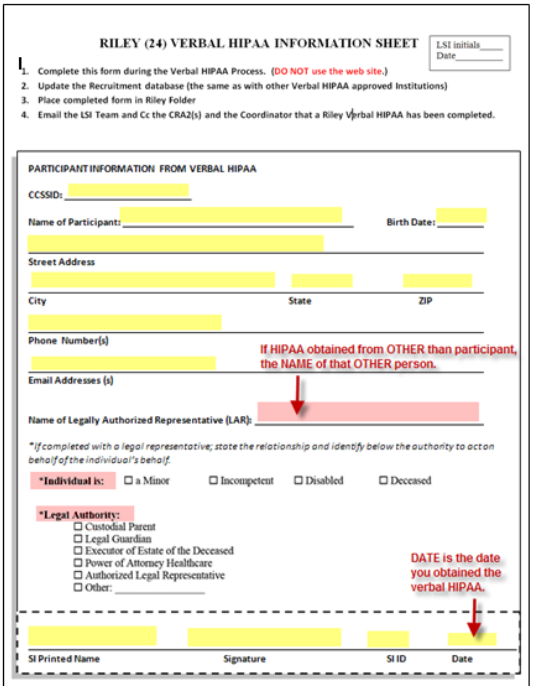
Current Filename:		Processing Updated Online Recruitment Name and Contact Information ver 1_6.doc	
Revision No.	Date	Responsible Author	Change Description
1	1/2/2011	J.Bates	Initial Development
1.1	1/4/2011	J.Bates	Form automation
1.2	1/27/2011	J.Bates	Check tracing codes
1.3	7/20/2011	J.Bates	Update BeforeRollover field list; evaluation tips
1.4	4/13/12	J.Bates	Add DO ROLLOVER; checking number of records
1.5	8/3/15	J.Ford	Added location to save prerollover file; minor changes to flow
1.6	5/16/18	J.Ford	Added Description field info; updated server path

Processing Verbal HIPAA Riley Forms

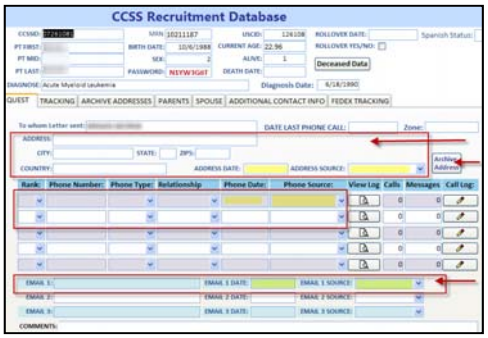
Background

After the Survey Interviewer (SI) has completed the Riley Verbal HIPAA process, the completed forms and the database entry must be inspected for accuracy and the forms delivered to the CRA2.

Procedure



1. Retrieve the Riley Verbal HIPAA forms from the file folder, labeled "Riley Verbal HIPAAs."
2. Using the CCSSID as a guide, place the forms in numeric order.
3. Inspect the forms and ensure all fields are complete.
4. Open the Expansion Recruitment database and search for the first CCSSID in the stack of forms.
5. Perform a quality assurance inspection of the data entry, referring to the SOP, **Verbal HIPAA Authorization Process for Riley**, located in the SOP Library.)
   a. If no errors are found, initial and date the form at the top right-hand corner, indicating inspection complete.
   b. If errors are found, log them in the LSI Excel workbook, **SI Training Opportunities**, located at: *Z… Interviewers\LSI\QA Audits,* review the procedure with the SI, instruct them to correct the error and inspect the correction before initialing the form.



6. Once a week, the LSI team or their designee will deliver the completed forms to the CRA2 on the 5th floor.

Revision Record
Printed 6/4/2013 3:39 PM

[246] Current Filename:		Processing Verbal HIPAA Riley Forms v1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	6/3/2013	B. Carson, R, Massey, D. Rinehart	Initial Development

Providing Institutional HIPAA Copies to Data Managers

Background

When recruiting for an institution is completed, we will provide each institution's data manager with a pdf copy of the signed institutional HIPAA for each person recruited for their institution. A data manager may request the copies in advance of that time. Facsimile HIPAAs for medical releases obtained online are provided only as requested. We use the database to keep track of HIPAAs prepared and sent to data managers. (USC also recruited cases for the expansion cohort. USC already provided the medical releases of those cases to the respective institutions. Archive boxes of recruitment materials obtained by USC are stored offsite in the Bruner building.)

Procedures

Location of harvested pdf/ imaged HIPAA documents

We file the pdf HIPAAs for each institution in a designated folder in the individual institution's recruitment folder.

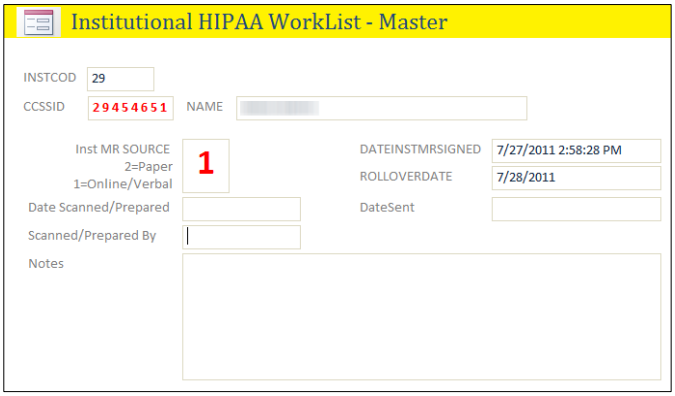
1. The file folder name is **!Inst_XX_SIGNED HIPAAS**, where "XX" is the instcod.
2. E.g., for 01, University of Minnesota, the folder is named !INST_01_SIGNED HIPAAS, and it is located in Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\1-University of Minnesota\.

ADDING records to the table used to log status of the institutional HIPAA preparation

1. We use a local table (tbl_PaperInstHIPAAlist-Z) in the recruitment database to keep track of when we prepare the HIPAA copy as well as when we send it to the data manager. *[NOTE: you may wish to have this table converted to a SQL table, to protect it from loss during database crashes.]*
2. As new cases are recruited, records for the new cases need to be added to this table. *This should be done on a regular basis.*
3. Run **qry_ID_newInstHIPAAs** to determine if there are recruited cases that need to be added to the table
4. If this ID query displays any records, then run these 2 queries to append the new records to the table:
   a. **qapp_NewPaperInstHIPAAs** appends records for paper HIPAAs
   b. **qapp_NewOnlineInstHIPAAs** appends records for online (verbal) HIPAAs

Responding to *individual* requests for HIPAA copies

1. Determine whether a copy of the HIPAA has already been prepared.
   a. Look in the institution's SIGNED HIPAAs folder
   b. Look up the CCSSID in the database using **frm_ALL_InstHIPAA_WorkLog**
2. If the copy has NOT already been prepared, prepare, file, and log it (see below).
3. Locate the copy in institution's SIGNED HIPAA folder
4. Send to data manager in the manner requested (see below).
5. In the database, log that the files were sent to the data manager (DateSent and Notes) using the form (see below).



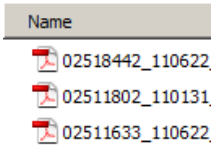
Lead CRA

PREPARING Data Manager HIPAA Copies

1. The field **InstMRSource** identifies the HIPAA type (1=Online; 2=Paper). Code 3 (verbal) is defunct.
2. **Paper HIPAAs** (InstMRSource 2)
   a. Locate the signed institutional HIPAA. Look BOTH in the signed institutional HIPAA file (for those who returned the HIPAA-only document) and in the full survey booklet file.
   b. Use Adobe Acrobat at the scanner to make a pdf copy of full institutional HIPAA. (Some institutions have multi-page HIPAAs; others are a single page).
   c. Save the file in the institution's designated SIGNED HIPAAs folder
   d. NAME the file with the CCSSID of the individual.
   e. Refile the original signed documents in the location where you found them, by CCSSID.

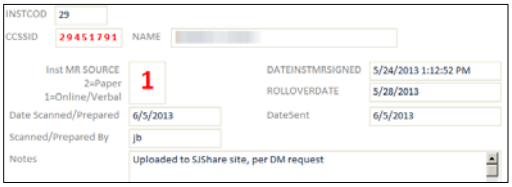
3. **Online (verbal) HIPAAs** (InstMRSource 1)
   a. Locate the pdf facsimile for the individual on the server. See **Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Recruitment Database\Daily website PDFs**
   b. These files are named with USCid followed by the date submitted (as yymmdd).
   c. COPY those you need into the institution's designated SIGNED HIPAAs folder. (Do NOT move them!)

   d. RENAME the copied file, changing the USCID portion of the file name to the full CCSSID, leaving the _99999 (date) portion.



   e. In Adobe Acrobat, on each facsimile, add text in the top right corner (using the Typewriter Tool) for the CCSSID, name, and date of birth. Use **red** text. (TIP: The query **qry_PaperInstHPAAs_SentStatus** displays USCID, CCSSID, Birthdate, and Name.) Resave the pdf.

3. **Log the fact that copies were prepared (and sent, if applicable)**
   a. Before attempting to document the completed work, make sure the table is up to date. (See **ADDING records to the table used to log status of the institutional HIPAA preparation** (above)
   b. Open **frm_ALL_InstHIPAA_Worklog**
      i. Search for the CCSSID
      ii. Record the date **scanned/prepared** and **initials** of person doing so.
   c. If also sending the copies at this time, while the form is open:
      i. Record the **DateSent** (to data manager)
      ii. Add applicable notes (e.g., "***m/d/y: {Uploaded to SJSharesite, per DM request| Sent via Encrypted email |Sent via FedEx} [inits]***") Do not replace existing notes!



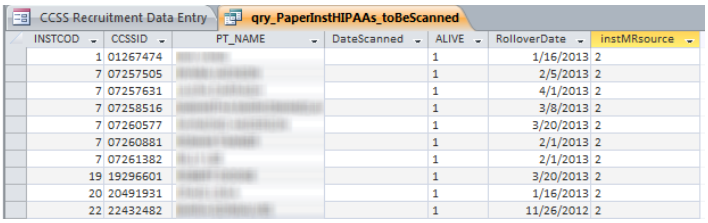
   d. If handling a large number of files at one time, you may prefer an adhoc posting query.
   e. NOTE that if the production team is assigned to harvest batches of HIPAAs (see below), they should be logging their own work as they complete it.

Lead CRA

BATCH HARVESTING PAPER HIPAAs

Harvesting batches of paper HIPAAs can be assigned to the production team. You may use the database to prepare the assignment files. The production team prepares files and logs their completed work in the database.

1. Run query to identify paper HIPAAs that need to be scanned (**qry_PaperInstHIPAAs_toBeScanned**). Export to Excel. This becomes the photocopy "work list."


CCSS Recruitment Data Entry | qry_PaperInstHIPAAs_toBeScanned

INSTCOD	CCSSID	PT_NAME	DateScanned	ALIVE	RolloverDate	instMRsource
1	01267474			1	1/16/2013	2
7	07257505			1	2/5/2013	2
7	07257631			1	4/1/2013	2
7	07258516			1	3/8/2013	2
7	07260577			1	3/20/2013	2
7	07260881			1	2/1/2013	2
7	07261382			1	2/1/2013	2
19	19296601			1	3/20/2013	2
20	20491931			1	1/16/2013	2
22	22432482			1	11/26/2012	2

2. Assign and distribute the assignments to the production team
3. Production team then follows ***Scanning and Logging Institutional HIPAAs for Data Managers*** to locate, scan, file, and log the assigned HIPAAs.
4. CRA2 QA's the completed scanned paper HIPAAs (are the CCSSID pdf files filed correctly, is the image legible, does the filename match the CCSSID on the pdf) and verifies that the scanning has been logged.

Dealing with Paper HIPAAs Obtained After Online/Verbal HIPAA

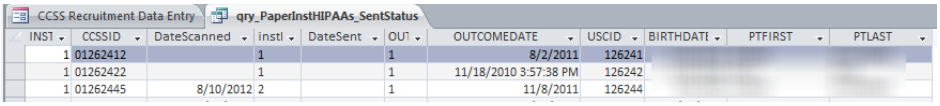
If a paper HIPAA is obtained for a case previously obtained verbally or online, we DO image the paper HIPAA, as it is preferable to send an image of the signed paper document. The project manager will need to capture the paper HIPAA *at the point it arrives*, image and store the file, and then find and document the record for the case in the worklist:

1. Use the HIPAA Work List (log) form to locate the case in the HIPAA log table.
2. If the data manager's copy of the online/verbal HIPAA is already logged as having been prepared, update the date prepped/scanned with the current date, Scanned/Prepared By with your initials.
3. In **Notes**, document that a signed paper HIPAA was subsequently obtained for the case that was originally recruited by verbal (or online) HIPAA. (E.g., ***8/31/2012: received signed paper inst HIPAA dated 8/15/2012; originally recruited by verbal HIPAA on 7/15/12. Both copies are available. [jb]***)

SENDING Files to the Data Manager

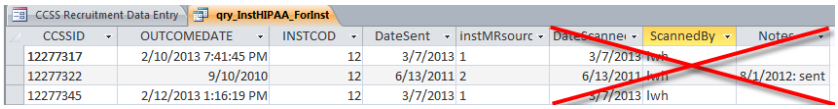
1. The actual HIPAA pdf files contain PHI. They can be sent by email *as long as the [Encrypt] option is used*. Alternatively, individual files (or a zipped batch) could be uploaded to the St. Jude Share site.

2. If sending a large number of files, you may use the database to generate a tick list of the CCSSIDs being sent. Several queries may be useful (in each case, set the InstCod criteria):
   a. **qry_PaperInstHIPAAs_SentStatus** indicates both the scan and sent status of the cases. Includes all records, whether scanned or sent or not. Includes USCID, DOB, birthdate, and name.


CCSS Recruitment Data Entry | qry_PaperInstHIPAAs_SentStatus

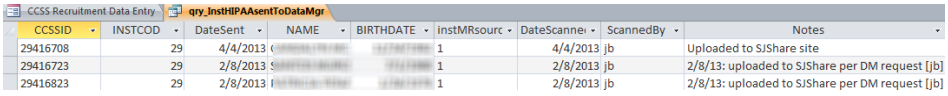
INST	CCSSID	DateScanned	instl	DateSent	OUT	OUTCOMEDATE	USCID	BIRTHDATE	PTFIRST	PTLAST
1	01262412		1		1	8/2/2011	126241			
1	01262422		1		1	11/18/2010 3:57:38 PM	126242			
1	01262445	8/10/2012	2		1	11/8/2011	126244			

   b. **qry_InstHIPAA_ForInst** gives all records for Inst, whether scanned or sent or not.


CCSS Recruitment Data Entry | qry_InstHIPAA_ForInst

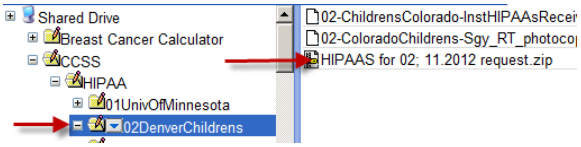
CCSSID	OUTCOMEDATE	INSTCOD	DateSent	instMRsourc	DateScanne	ScannedBy	Notes
12277317	2/10/2013 7:41:45 PM	12	3/7/2013	1	3/7/2013	lwh	
12277322	9/10/2010	12	6/13/2011	2	6/13/2011	lwh	8/1/2012: sent
12277345	2/12/2013 1:16:19 PM	12	3/7/2013	1	3/7/2013	lwh	

   c. **Qry_InstHIPAAsentToDataMgr** lists only records with a value in DateSent.


CCSS Recruitment Data Entry | qry_InstHIPAAsentToDataMgr

CCSSID	INSTCOD	DateSent	NAME	BIRTHDATE	instMRsourc	DateScanne	ScannedBy	Notes
29416708	29	4/4/2013			1	4/4/2013	jb	Uploaded to SJShare site
29416723	29	2/8/2013			1	2/8/2013	jb	2/8/13: uploaded to SJShare per DM request [jb]
29416823	29	2/8/2013			1	2/8/2013	jb	2/8/13: uploaded to SJShare per DM request [jb]

3. SEND, using one of these methods:
    a. Attach to an **ENCRYPTED** email. (Start the subject line with [ENCRYPT] to force the email to be encrypted.)
    b. Upload individual files or a zipped group of files to the institution's CCSS\HIPAA folder on the St Jude Share Site.



4. Alert the data manager.
    a. If uploading the files to the Share Site, notify the data manager and provide a list of the CCSSIDs uploaded.
    b. If the group contains online HIPAAs, be sure the data manager understands what the online facsimiles are. A note such as "We have no physical signature for individuals who completed the HIPAA online. We are sending the date-stamped facsimile, to which we have added CCSSID, pt name and date of birth."

LOG files sent to the Data Manager

1. Either before or after sending a batch of pdf institutional HIPAAs to the data manager, document which records have been sent. Log this fact in the database tbl_PaperInstHIPAAlist-Z
2. You may do this for individual records using the form, or in an ad hoc query.
3. Record the following:
    a. The date sent (**DateSent**)
    b. Use **Notes** field to add other documentation. Sample notes:
        m/d/yy: Uploaded to SJSharesite, per DM request [inits]
        m/d/yy: Sent via Encrypted email [inits]
        m/d/yy: Sent via FedEx [inits]
4. If using an update query, be sure you do NOT overwrite any existing data in the **Notes** field.

Revision Record — Printed 7/11/2013 12:36 PM

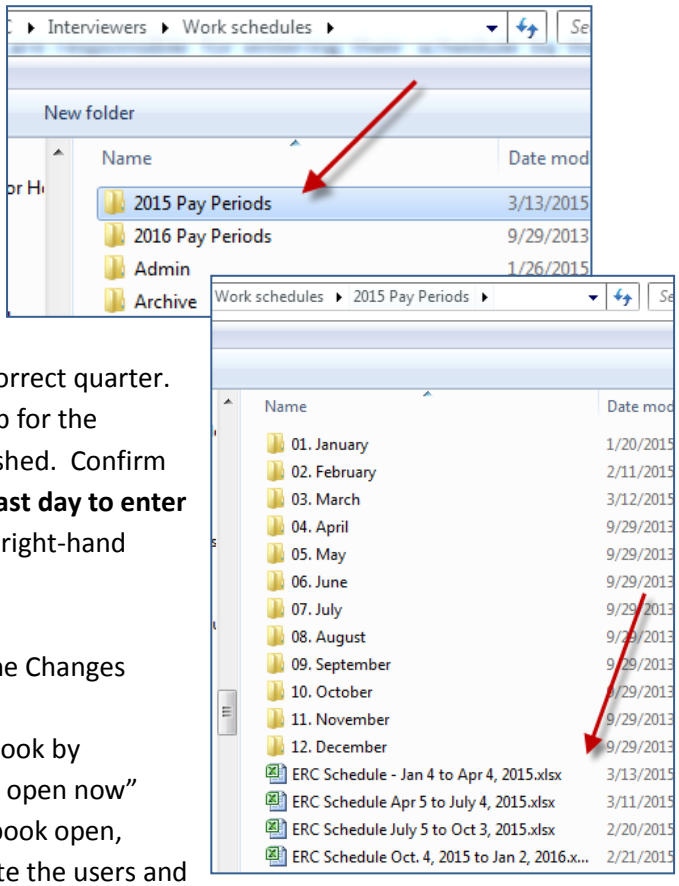
130 Current Filename:		Institutional HIPAAs for Data Managers ver 3_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/3/11	J.Bates	Initial Development
2.0	12/5/12	J.Bates	New filing location; delete excel register; add db
2.1	1/9/13	J.Bates	Rev sequencing
2.2	2/8/13	J.Bates	SentStatus query assist; remove "SENT" addition to filename option and ONLINE filename addition
2.3	6/5/13	J.Bates	Appending new HIPAAs to log file; update query reference
3.0	7/11/13	J.Bates	Incorporate maintaining HIPAA worklist (retired as separate SOP)

Publishing the Call Center Schedule

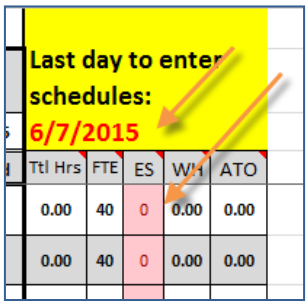
Background

All Survey Interviewers (SIs) are responsible for entering their schedule by the designated weekly deadline per the SOP titled **Survey Interviewer Self Scheduling**. After the designated deadline, the Coordinator or Lead Survey Interviewer (LSI) will publish the schedule according to the below procedures.

Procedures



1. Open the schedule for the quarter in question.
    a. Go to *Z:\SJShare\SJCOMMON\ECC \Interviewers\Work schedules*.
    b. Double-click on the folder for the correct year.
    c. Open the MS Excel workbook for the correct quarter.
2. At the bottom of the workbook, click on the tab for the worksheet containing the schedule to be published. Confirm that the deadline has passed by checking the **Last day to enter schedules** value in the yellow box in the upper right-hand corner of the worksheet.
3. Remove the workbook from shared use.
    a. Click on the **Share Workbook** icon in the Changes group of the Ribbon's Review tab.
    b. Ensure no other users are in the workbook by reviewing the "Who has this workbook open now" window. If other users have the workbook open, work with the Call Center team to locate the users and ask them to close the workbook.
    c. Once the workbook has been closed by all other users, unshare the workbook by unchecking the **Allow changes by more than one user at the same time** checkbox, then clicking **OK**. An Excel window will appear explaining that the action will remove the workbook from shared use. Click the **Yes** button.
4. Review the schedule for appropriate entries.
    a. If the schedule being published includes an SI new to self-scheduling, confirm the SI has selected standard shift start and stop times.
    b. Ensure all interviewers have at least one night shift scheduled by checking the **ES** ("Evening Shift") column. The cell in the **ES** column will be red-filled if there are zero



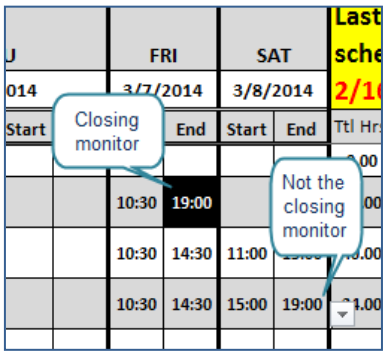
evening shifts scheduled in that interviewer's row. Determine if the SI in question has approval for this policy deviation.

c. Ensure all interviewers have scheduled the appropriate number of hours by comparing the **Ttl Hrs** column (indicating the total number of scheduled hours for the week) to the **FTE** column (indicating the number of weekly hours the SI was hired to work). These fields should match in every row unless the SI has received approval from the Call Center Coordinator.

d. Ensure all shifts have a minimum of two SIs scheduled to work by checking the **Total Staff** row at the bottom of the schedule. The cell in this row for any shift with less than two scheduled SIs will be red-filled.

e. If the schedule being published contains the last weekend day of the month, review all previously published schedules containing days for the same month to ensure each SI has met the minimum weekend hours for his/her weekly FTE status. See the SOP titled **CCSS Call Center Scheduling Policy** for details regarding the required weekend hours for each FTE status.

5. After all concerns noted in the previous step have been resolved, unprotect the worksheet.
   a. Click the **Unprotect Sheet** icon in the Changes group of the Ribbon's Review tab.
   b. Enter the password.
6. Select a closing monitor for each day of the week. Indicate the closing monitor status by changing the cell with the closing time to have black fill and white font in the appropriate row and column.



7. Set the print area.
   a. Highlight the area to be printed (cells B1 through Y26).
   b. Click the **Print Area** icon in the Page Setup group of Ribbon's Page Layout tab, then click **Set Print Area**.
8. Print the schedule to the PDFCreator printer.
   a. Go to the File tab on the MS Excel Ribbon. Click the **Print** option.
   b. Select the PDFCreator printer.
   c. Use the margins setting to properly center the schedule using the preview provided. Rows or columns may need to be resized to fit the schedule onto a single page.
   d. Click the **Print** button.
   e. In the PDFCreator screen, change the document title to properly reflect the dates of the schedule being published. Use the suffix _r1 for the first revision, _r2 for the second revision, and so on.
   f. Click the **Save** button.
   g. Save the schedule to *Z:\SJShare\SJCOMMON\ECC\Interviewers\Work schedules\20xx Pay Periods\##. Month*, selecting the appropriate year and month folders.
9. Clear the print area by clicking on the **Print Area** icon in the Page Setup group of the Ribbon's Page Layout tab and then clicking on **Clear Print Area**.
10. Protect the worksheet:

a. Click the **Protect Sheet** icon in the Changes group of the Ribbon's Review tab.
b. Enter the password. Confirm the password by entering it again.

11. Share the scheduling workbook:
    a. Click the **Share Workbook** icon in the Changes group of the Ribbon's Review tab.
    b. Check the **Allow changes by more than one user** checkbox, then click the **OK** button.
    c. Click the **OK** button to save the workbook.
12. If the newly published schedule is a revision to a previous publication, go to *Z:\SJShare\SJCOMMON\ECC\Interviewers\Work schedules\20xx Pay Periods\##. Month* and archive any previous versions of the schedule by dragging the outdated schedule to the Archive folder.
13. For an original or revised schedule publication, attach the newly published schedule to an email and send it to the Research Scientist, the appropriate administrative staff member, and the list "CCSS Interviewers".

Revision Record Printed 3/18/2015 4:09 PM

Current Filename [267]:		Publishing the Call Center Schedule ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	2/19/2014	R. Massey, D. Rinehart	Initial Development
1.1	3/13/2015	R. Massey	Content Revision

Pursuing Subsequent Neoplasm Pathology Records

Background

The subsequent neoplasm (SN) project seeks to track SNs with which Long-Term Follow-Up (LTFU) Study participants are diagnosed. When a participant or his/her proxy reports one or more subsequent cancers, leukemias, tumors, or similar illnesses during their participation, study staff members review these reports to screen out conditions that are not true SNs. If the report may be a true SN, the study team will pursue a pathology report and/or other medical records from the diagnosing entity to verify the condition.

This procedure outlines the process for pursuing pathology reports and other medical records for reported SN conditions. For information about the initial review process, which precedes this procedure, see the SOP titled **Initial Review of Reported Subsequent Neoplasms**. For information about the process of verifying the SNs, which follows this procedure, see the SOP titled **Subsequent Neoplasm Pathology Report Reviews**.

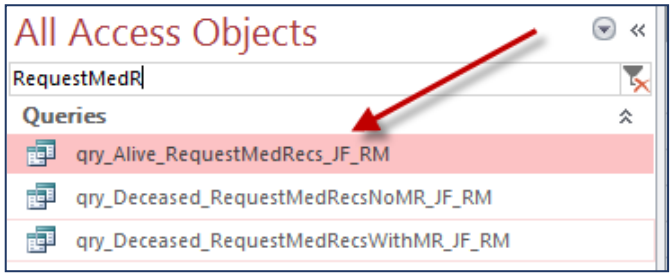
Procedure

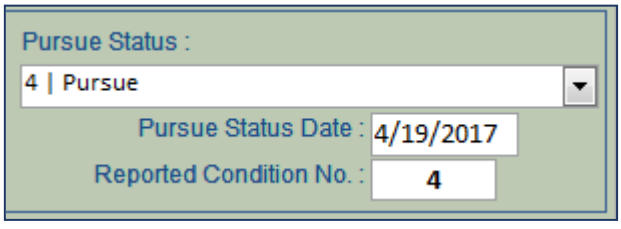
Pursuing Pathology Reports – Alive Participants

If the initial reviewer determines that a reported condition may be a true SN, pathology reports and/or other medical records will be requested from the reported diagnosing entity in order to verify the condition.

Sending Pathology Report Requests

1. Open the SNT, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Minimize the search screen, and open the Access Navigation pane.
3. Run the query **qry_Alive_RequestMedRecs_JF_RM**. This query reports all conditions for alive participants where:
   A. **Request Status** is not set to 5-Suspended or 6-Complete AND
   B. The project either never needed a new MR OR
   C. The project needed and obtained a new MR AND
   D. The maximum **Request Date** for **Request Type** = Medical Record is either <null> or is less than the date we received an institutional MR AND
   E. **Pursue Status** is either 3-Condition-Level Project Mgr Action Required or 4-Pursue.





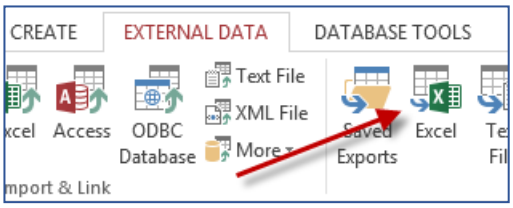
4. For any condition where project mgr action is requested, review the action requested to determine if the path report should be requested.

5. For institution 15 cases, determine if the path report or other needed records can be obtained from MILLI. (NOTE: Survivorship Care Plans will have accurate dates for any reports in MILLI.) If the needed medical records are obtained through MILLI, document as such in the condition record, then rerun the query to refresh the results.
6. Review the query results.
   A. If the **facility information is missing**:
      i. Open the SNT database record for the condition.
      ii. If the participant reported the diagnosing facility and/or doctor, use the participant's self-report to populate the **Request Condition** and facility information in the Facilities Group. These are both needed to create a request.
      iii. If the participant did not report adequate information to locate the facility:
         a. **Pursue Status** – Update from 4-Pursue to 6-Pursue, Need Info from Pt.
         b. **Pursue Status Date** – Update to the current date
         c. **Condition Notes** – Enter a dated note explicitly indicating to the SIs what information is needed from the participant (diagnosing facility info) and documenting the changes to the **Pursue Status** and **Pursue Status Date** fields.
   B. If the **facility information is present but the fax number is missing**:
      i. Open the SNT database record for the condition, and locate the facility in question.
      ii. **Request Status** – Update to 1-Need Info From Facility if this field is not already set thus.
      iii. **Request Status Date** – Update to the current date if the **Request Status** field was updated.
      iv. **Facility Notes** – If changes were made to the **Request Status** and **Request Status Date** fields, enter a dated note explicitly advising the SIs about what information is needed and documenting changes made to the **Request Status** and **Request Status Date** fields.
   C. Review the **ReconsentNeeded** field. If the value is set to NO, no action is required. If the field value is set to YES, review the **ReconsentOutcome** and **ReconsentDate** fields.
      i. If there is no **ReconsentOutcome**:
         a. Original Cohort – The participant does not need to be reconsented. See the Research Scientist or Senior Coordinator for guidance.
         b. Expansion Cohort
            1) Open the condition record in the SNT database.
            2) **Pursue Status** – Update from 4-Pursue to 5-Pursue, Pending Reconsent.
            3) **Pursue Status Date** – Update to the current date
            4) **Condition Notes** – Enter a dated note documenting the changes to the **Pursue Status** and **Pursue Status Date** fields.
      ii. If reconsent has been completed (or confirmed to be inapplicable), confirm that the date of the LTFU HIPAA is equal to or later than the reconsent date.
         a. If yes, no action is needed.
         b. If no:
            1) Open the condition record in the SNT database.
            2) **Pursue Status** – Update from 4-Pursue to 7-Pursue, Pending First MR.
            3) **Pursue Status Date** – Update to the current date.
            4) **Condition Notes** - Enter a dated note documenting the changes to the **Pursue Status** and **Pursue Status Date** fields.

iii. If the reconsent resulted in refusal, ensure the correct study outcome is recorded and seek guidance from the Research Scientist or Senior Coordinator on whether or not the condition should be closed to further pursuit.

D. Review the **OutcomeID** field. If an outcome is indicated, determine whether the pathology report can be pursued.
   i. If yes, no action is required.
   ii. If no:
      a. Open the condition record in the SNT database.
      b. **Pursue Status** – Enter an appropriate code to indicate the condition is closed.
      c. **Pursue Status Date** – Enter the current date.
      d. **Condition Notes** – Enter a dated note documenting the changes to the **Pursue Status** and **Pursue Status Date** fields and indicate the reason for closing the condition's pursuit.

7. Close the query results, and run the query **qry_Alive_RequestMedRecs_JF_RM** again.
8. **Export the query results** as an Excel workbook. Seek assistance, if needed.
   A. Save the file at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
   B. Add the current date to the file name: **qry_Alive_RequestMedRecs_JF_RM 100917**.



9. Resave the worksheet adding the suffix "-REVISED" to the file name: **qry_Alive_RequestMedRecs_JF_RM 100917-REVISED**.
10. **Delete**
   A. Any requests for University Health Network (UHN), Toronto General, Toronto Western, Princess Margaret, or Sick Kids – These facilities require a prohibitive prepayment for records, but the CCSS has a contact that can often obtain records at no charge. For any rows that are deleted for these facilities:
      i. Also add these conditions to the invoice tracking sheet if they are not already logged there.
      ii. Be sure the medical release form on file is valid!! It will be required by the CCSS contact in order to release records. If the MR is not valid, take action to obtain an updated medical release.
   B. Any requests where a fax# is still missing.
   C. Any rows that should not be requested for other reasons (e.g. pending project manager action).
11. **Collect copies of the LTFU HIPAA forms** for each unique CCSSID in the revised worksheet. See the guidance document titled **Locating HIPAAs** found at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
    NOTE: It may be useful to ensure there are no HIPAA forms pending scanning.
12. Create a **fax cover sheet** for each request using mail merge and the revised query results.
   A. Breast Cancers (identified by reviewing the **RequestCondition** field of the query results)
      i. If the study is requesting records related to a breast cancer, merge the information from the revised sheet with the following documents, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Breast Cancer Medical Records*, adding the date in the appropriate document locations:
         a. **Breast Cancer Recs – ALIVE pts – Fax TEMPLATE –Merged**

1) NOTE: If there is a qualifying male participant, make the appropriate updates to the pronouns in the letter.
2) NOTE: If the facility is flagged with a "*FEE*" prefix, the facility is known to send records with an invoice. Add the following statement to the fax cover page: "All fees must be APPROVED by our facility before they are incurred. If provision of records is associated with a fee, please contact us BEFORE sending the records."

b. **First Request for BC Records – ALIVE pts - 3-12-15rev merged MA signature – MERGED** – NOTE: If there is a qualifying male participant, make the appropriate updates to the pronouns in the letter.

ii. Print the merged documents.

B. Non-Breast Cancers (identified by reviewing the **RequestCondition** field of the query results)

i. If the study is requesting records related to a cancer other than breast cancer, merge the information from the revised sheet with **TEMPLATE, Request Path Rpt for ALIVE pts –merged**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Fax Templates*, adding the date in the appropriate document location.

ii. Edit individual documents as necessary.

a. Correct verbiage for missing dates, add verbiage to include MRI reports and/or clinical notes (e.g. for meningiomas or other brain tumors), and adjust the number of pages being sent (e.g. for multi-page HIPAA forms), as appropriate.

b. NOTE: If the facility is flagged with a "*FEE*" prefix, the facility is known to send records with an invoice. Add the following statement to the fax cover page: "All fees must be APPROVED by our facility before they are incurred. If provision of records is associated with a fee, please contact us BEFORE sending the records."

iii. Print the merged documents.

13. **Scan** the documents for each condition.
    A. Stack the printed fax cover page followed by the request letter (for breast cancers only) and then by the signed HIPAA.
    B. Scan the documents for the condition using Adobe Acrobat.
    C. Save the scanned document as a PDF file.
        i. Save the PDF file at *Z:\Departments\ECC\common\Interviewers\SMN and Blood and Tissue\Faxes\SMN Pathology Requests*
        ii. Save the file as **CCSSID_FacilityName_mmddyy**.
14. **Fax the requests** to the treating institution.
15. **Run the resend request query** (**qry_Alive_ResendMedRecReq_RM**) to determine if any requests need to be resent. If yes, follow the same preparatory steps described above. This query reports all conditions for alive participants where:
    A. **Request Status** is not set to 5-Suspended or 6-Complete AND
    B. **Resend Request** in the facility record is set to 1-Med Rec Request.
    C. The project either never needed a new MR OR
    D. The project needed and obtained a new MR AND
    E. **Pursue Status** is either 3-Condition-Level Project Mgr Action Required or 4-Pursue.
16. When confirmation of the faxes' successful transmission is received:
    A. Resave the **qry_Alive_RequestMedRecs_JF_RM 100917-REVISED** or **qry_Alive_ResendMedRecReq_RM-REVISED** worksheet with a "2" suffix (e.g. **qry_Alive_RequestMedRecs_JF_RM 100917-REVISED2**).
    B. **Create a new tab** in the –Revised2 worksheet named _TEMPSNNewRecReqs.

C. Copy tab qry_Alive_Request_MedRecs_JF_RM (or qry_Alive_ResendMedRecReq_RM) to the new tab.
D. In the new sheet, delete any row where:
    i. The fax was unsuccessful.
    ii. The facility requires a MAILED request.
    iii. The request was not faxed for other reasons.
E. Also in the new sheet:
    i. Delete all columns except ParticipantID, FacilityID, ConsecutiveSNT, SNT_Facilities_Consecutive.
    ii. Rename ConsecutiveSNT to be ConsecutiveSNT_Facilities.
    iii. Rename the SNT_Facilities_Consecutive column to be SNTFacilitiesConsecutive.
    iv. Add a column titled RequestDate, and populate it with the current date.
    v. Add a column titled RequestType, and populate it with the number 1.
    vi. Add a column titled CreatedByUser, and populate it with your username.
    vii. Add a column titled CreatedDate, and populate it with the date and time with format mm/dd/yyyy hh:mm:ss AM (e.g. 6/7/2017 12:24:00 PM). NOTE: The displayed format may vary from what is entered, but enter it as described.
F. Import the data in _TEMPSNNewRecReqs into the SNT database to update the **Request Date** and **Request Type** fields.
    i. Choose the radio button for Append a copy of the records to the table.
    ii. Choose table tblRequests.
G. Import the data in _TEMPSNNewRecReqs into the SNT database again to update the **Request Status**, **Request Status Date**, and **Facility Notes** fields.
    i. Choose the radio button for Import the source data into a new table in the current database and follow the prompts.
    ii. Overwrite the existing table, if prompted.
    iii. See the Senior Coordinator or Research Scientist for guidance, if needed.
H. Use **qry_ReqMedRecs_UpdFacRec_RM** to update the **Request Status**, **Request Status Date**, and **Facility Notes** fields. NOTE: Also clear the **Resend Request** (=1) and **Resend Request Date** fields for fulfilled resend requests, and document this in the notes.
    i. Run the query as a Select query to confirm the results to be updated.
    ii. Be aware of facilities that already have a value in the **Request Status** and **Request Status Date** fields.
    iii. If the results are correct, change the query to an Update query with appropriate values.
    iv. Run the query once for FacilityNotes is not null (first) and once for FacilityNotes is null (second). Build an appropriate, dated note for each query.
    v. DO NOT save the changes to the query.
I. **Mail requests** to facilities that require mailing.
    i. Make a copy of the LTFU HIPAA or facility medical release form. NOTE: DO NOT send an original, signed form to the institution. Originals should stay at the CCSS Coordinating Center.
    ii. Modify the appropriate letter to mail, and print the document onto St. Jude letterhead.
        a. Breast Cancers – **First Request for BC Records - ALIVE pts - NO merge - MA signature 3-12-15rev 032816** found at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Breast Cancer Medical Records*

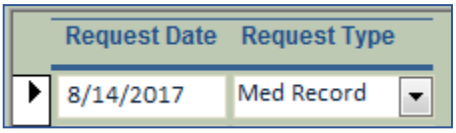
b. Non-Breast Cancers - **Request for Path Report 110916** found at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Letters to Institutions*

iii. Modify **Envelope_NoMerge**, found at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Letters to Institutions*, and print the document onto an LTFU Study envelope.

iv. Stack the letter atop the appropriate medical release form. Fold the stack into thirds, and insert into the printed envelope.

v. Seal and mail.

J. **Manually document mailed requests** using data from the –revised worksheet (not the –revised2 worksheet).



i. **Request Date** – Enter the date of the mailed request.

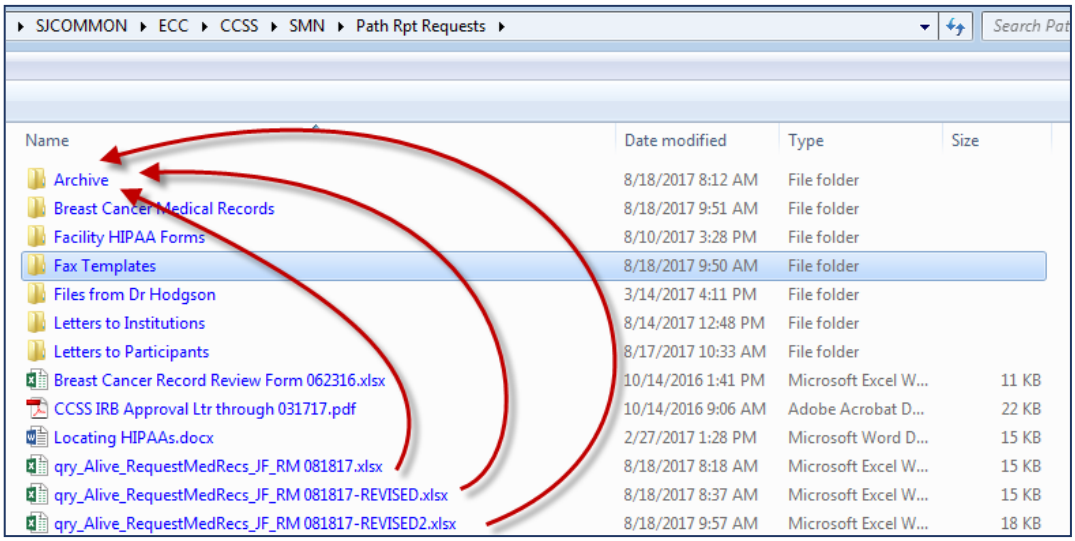
ii. **Request Type** – Choose "Med Record" from the drop-down menu.

iii. **Request Status** – Update, if appropriate.

iv. **Request Status Date** – Enter the current date if any change was made to the **Request Status** field.

v. **Facility Notes** – Enter a dated note documenting the mailed request and the changes to the **Request Status** and **Request Status Date** fields, if applicable.

K. **Archive** the saved query results once all faxes and mailings are documented.



L. **File faxed requests**.

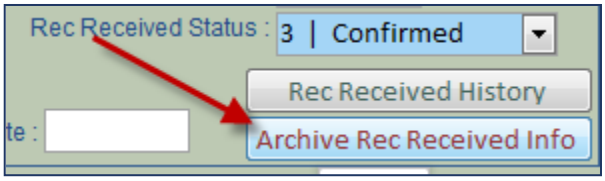
<u>Documenting Medical Records Received</u>

When medical records are received:

1. Print the CCSSID and date received at the bottom of the page.
   a. Records Received Via eFax – Before printing the PDF file, add a footer by choosing Document -> Header & Footer -> Add. Change the Size from 8 to 10, and type the data into the **Center Footer Text** field. (e.g. CCSSID 12345678, Received Via Fax 11/29/2017)

b. Records Received Via US Mail – Create a blank MS Word document, and type the data into the footer (e.g. CCSSID 12345678, Received Via US Mail 11/29/2017). Print X copies of the document where X is the number of pages received, feeding the received records through the printer to receive the printed footer.

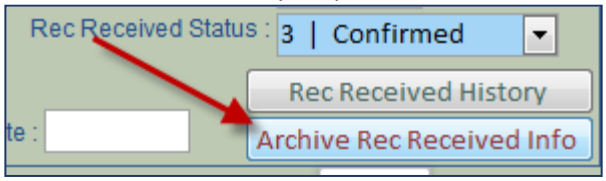
2. Open the SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
3. Use the Search form to locate the participant in question. In the participant's record, locate the condition and facility in question. NOTE: There may be more than one condition covered by the facility in question.
4. Document receipt of the records as soon as possible after receipt. This ensures the SI team will not lose time calling a facility that has already responded to our request.
   a. **Archive Rec Received Info** – If there is data in the **Record Status Date** and **Rec Received Status** fields, click this button to archive the data.
   b. **Record Status Date** – Enter the date the records were received.
   c. **Rec Received Status** – Enter 1-Unreviewed.
   d. **Request Status** – Update to be 4-Project Mgr Action Required.
   e. **Request Status Date** – Update to the current date.
   f. **Facility Notes** – Enter a dated note documenting that records were received and documenting the changes to the **Request Status** and **Request Status Date** fields.



When the received medical records are reviewed:

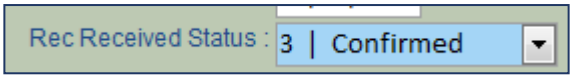
1. Open the SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Use the Search form to locate the participant in question. In the participant's record, locate the condition and facility in question.
3. If the received records are determined to be INCOMPLETE for the facility in question:
   A. **Archive Rec Received Info** – Click this button to archive the data in the **Record Status Date** and **Rec Received Status** fields.
   B. **Record Status Date** – Enter the current date.
   C. **Rec Received Status** – Update the field to be 2-Incomplete.
   D. **Request Status** – Update the field from 4-Project Mgr Action Required to the most appropriate value. Note that if pursuit with the facility will be closed, the Project Manager should ensure there are still active facilities being pursued or update the condition-level **Pursue Status** and **Pursue Status Date** accordingly.

   E. **Request Status Date** – Enter the current date.
   F. **Facility Notes** – Enter a dated note describing what was received, what was missing, what action is needed from the SI, etc. Document the above changes to the **Request Status** and **Request Status Date** fields in the note.
4. If the received records are determined to be COMPLETE for the facility in question:
   A. **Archive Rec Received Info** – Click this button to archive the data in the **Record Status Date** and **Rec Received Status** fields.



B. **Record Status Date** – Enter the current Date.

C. **Rec Received Status** – Update the field to be 3-Confirmed.



D. **Request Status** – Update the field from 4-Project Mgr Action Required to 6-Complete.

E. **Request Status Date** – Update the field to the current date.

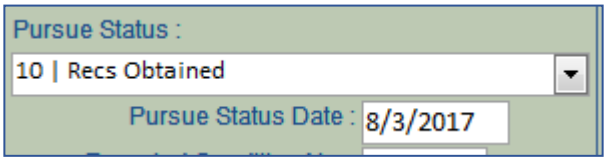
F. **Facility Notes** – Enter a dated note documenting what was received and the above changes to the **Request Status** and **Request Status Date** fields.

G. If the records are determined to be COMPLETE FOR THE CONDITION:

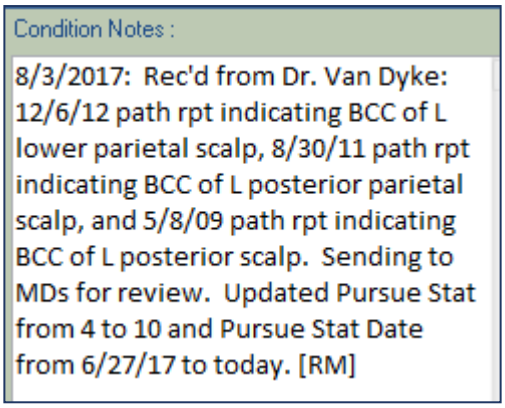
i. Suspend pursuit of all other facilities currently being pursued using the **Request Status**, **Request Status Date**, and **Facility Notes** fields.

ii. **Pursue Status** – Update to 10-Recs Obtained.

iii. **Pursue Status Date** – Update to the current date.



iv. **Condition Notes** – Enter a dated, condition-level note explaining how and why record pursuit has ended. Document the above changes to the **Pursue Status** and **Pursue Status Date** fields.



v. Remove the faxed request from the pending faxes.
   a. Locate all unique copies of medical release forms and set aside.
   b. Discard/shred any other documents that don't need to be sent to the MDs for review.

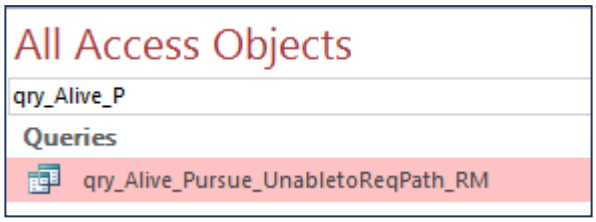
vi. Set the complete packet of records aside to be batched for review by the CCSS pathologist.

vii. Determine if a copy of each unique HIPAA form has previously been scanned and saved at *Z:\SJShare\SJCOMMON\ECC\CCSS\HIPAA Forms*.
   a. If yes, file the HIPAA numerically in the appropriate cabinet and hanging folder.
   b. If no:
      1) Scan the HIPAA.
   c. Save the copy in the appropriate facility folder at *Z:\SJShare\SJCOMMON\ECC\CCSS\HIPAA Forms*.
   d. Name the saved copy using the format CCSSID_mmmyyyy where "mmm" is the first 3 letters of the signature month and "yyyy" is the signature year. NOTE: Non-LTFU HIPAA copies can be saved at the same location with the facility name as a suffix (*e.g. 12345678_Jan2017_MayoClinic*).

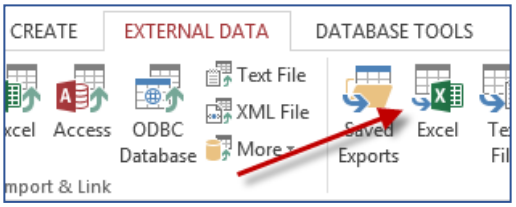
Unable to Pursue Pathology Report – Alive Participants

In circumstances where there is not a valid LTFU HIPAA on file, where the institution requires their own medical release form to be signed, where additional information is needed, and/or where reconsent is needed, additional work is required before a pathology report can be requested. Once monthly:

1. Open the SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Open the Access Navigation Pane.
3. Run the query **qry_Alive_Pursue_UnabletoReqPath_RM**. This query reports all alive cases where:
   A. The initial review resulted in a "pursue" decision AND
   B. There is not a valid LTFU HIPAA on file OR
   C. An institutional medical release is needed OR
   D. Additional information is needed OR
   E. The case needs to be reconsented.



4. **For institution 15 cases, determine if needed records can be obtained through MILLI**. (Check also the SJL Survivorship Care Plan research report.) If so, make the necessary documentation in the SNT database to indicate records have been obtained, then re-run the query before exporting the results, below. If not, document what dates were researched in the condition record. Recheck once or twice annually.
5. **Export the query results** as an Excel workbook. Seek assistance from the Senior Coordinator or Research Scientist, if needed.
   A. Save the file at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
   B. Add the current date to the file name: **qry_Alive_Pursue_UnabletoReqPath_RM mmddyy**.



6. **Request authorization to contact the ALIVE participants** from the Senior Coordinator by sending him/her the list of CCSSIDs that qualified for the query. Coordinate with the Blood and Tissue (B&T) project manager to seek contact authorization for both projects at once.
7. **Update the SNT database with the authorization decision**. NOTE: This automated process should be used for ALIVE participants only; deceased participant contact is evaluated on a case-by-case basis.
   A. Save a copy of the authorization list at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*, and add the current date to the file name.
   B. Created a new sheet in the Excel workbook. Name the new sheet _TEMPAuthtoContactSN.
   C. Copy the data from the authorization to the new sheet.
   D. Use the Excel filter to delete all non-SN rows in the new sheet.
   E. Ensure the columns in the worksheet are labeled exactly as follows: CCSSID, Purpose, Note.
   F. Import the data into the SNT database into temporary table _TEMPAuthtoContactSN. Overwrite the existing file if prompted.
   G. Open the query **qry_UpdateSNContactAuth_RM** in Design View.
      i. For **Notes** (in tblSNT) criteria = Is Not Null:
         a. Update the criteria for **Note** in _TEMPAuthToContactSN to the first value in the contact authorization list.

b. Set the **HoldID** and **HoldDate** values appropriately.
   1) If the **Note** criteria indicates the participant the participant CAN be contacted for the SN project, update the **HoldID** "Update To" value to be Null and the **HoldDate** "Update To" value to Null.
   2) If the **Note** criteria indicates the participant CANNOT be contacted for the SN project, update the **HoldID** "Update To" value to be 1-No Pt Contact and the **HoldDate** "Update To" value to the current date.
c. Zoom the **Notes** (in tblsNT) field "Update To" value. Enter the current note date and an appropriate note based on the **Note** value from the temporary table.
d. Run the query.
e. Repeat this process for each **Note** value in the contact authorization list.

ii. Update the **Notes** (in tblSNT) criteria to be Is Null.
   a. Update the **Note** criteria from _TEMPAuthToContactSN to the first value in the contact authorization list.
   b. Set the **HoldID** and **HoldDate** values appropriately.
      1) If the **Note** criteria indicates the participant the participant CAN be contacted for the SN project, update the **HoldID** "Update To" value to be Null and the **HoldDate** "Update To" value to Null.
      2) If the **Note** criteria indicates the participant CANNOT be contacted for the SN project, update the **HoldID** "Update To" value to be 1-No Pt Contact and the **HoldDate** "Update To" value to the current date.
   c. Zoom the **Notes** field "Update To" value.
      1) Delete the characters "[tblSNT]![Notes] &".
      2) Delete the hard return after the first quotation marks.
      3) Enter the current note date and an appropriate note based on the **Note** value from the temporary table.
   d. Run the query.
   e. Repeat this process for each **Note** value in the contact authorization list.
   f. Do NOT save the changes to the query.

8. **Run the stand-alone queries for alive participants**: **qry_Alive_Need1stLTFUHIPAA_RM**, **qry_Alive_Need1stLTFUHIPAA_ResendReq_RM**, **qry_Alive_NeedCurrentHIPAA_RM**, **qry_Alive_NeedAddlInfo_RM**, **qry_Alive_NeedFacilityMR_RM**, **qry_Alive_NeedReconsent_PermLtr_RM**, and **qry_Alive_NeedReconsent_RM**.
   A. Exclude participants who are on hold by specifying the criteria "Is Null" in the SNHold field.
   B. Export the results of each query as an Excel file.
   C. Save the Excel file to *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
   D. Save each file with the current date appended to the file name.
   E. Do NOT save the changes to the query.
9. **Update CCSS SI Assignments database**.
   A. Notify the Call Center Coordinator, LSI team, and SN project Survey Interviewers (SIs) that work is being done in the SI Assignments db. Ask that all stakeholders avoid any process that accesses the participant call assignments table (e.g. accessing participant call lists, running macros for this table, etc.). Working in the facility lists is okay.
   B. Open the CCSS SI Assignments database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
   C. Run the SN participant call macro, mcrSNTParticipants, in the SI Assignments db. Respond Y to each prompt.

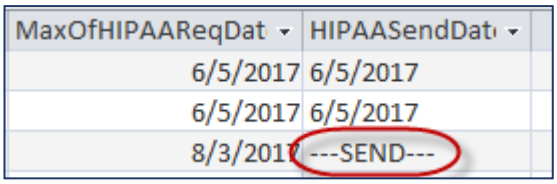
D. Add a column titled "OK" to worksheet _TEMPAuthtoContactSN in the Senior Coordinator's authorization response.
E. Filter the _TEMPAuthtoContactSN worksheet so that all "OK to call" types of authorization decisions are displayed, and populate the OK column with Y.
F. Filter the _TEMPAuthtoContactSN worksheet so that all "Do Not Call" types of authorization decisions are displayed, and populate the OK column with N.
G. Import _TEMPAuthtoContactSN into a temporary table in the CCSS SI Assignments database. Overwrite the existing table, if prompted.
H. Export a copy of the tblAssignments_SNTParticipants table to *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests* to have a record of the table prior to the update. Add "Before Update" and the date to the file name.
I. Run the query **qupd_SN_UpdateBurdenHold_RM**.
J. Run the SN participant call macro, mcrSNTParticipants, in the SI Assignments db. Respond Y to each prompt.
K. Export a copy of the tblAssignments_SNTParticipants table to *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests* to have a record of the table after the update and to check the update. Add "After Update" and the date to the file name.
L. Use the query **qry_SN_Deceased_SNTBurdenHoldCheck_RM** to identify all participants in tblAssignments_SNTParticipants that are deceased and that have open conditions.
    i. Note the participant's date of birth and date of death. No contact should be authorized in these months nor in May (Mother's Day), June (Father's Day), November (Thanksgiving), and December (Christmas).
    ii. Check the participant's CCSS and SN hold status in the query results.
    iii. In the CCSS LTFU Participants database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx, review each participant's Notes window and call log history.
    iv. In the SNT database, review each participant's SN records.
    v. If appropriate upon consideration of reviewed materials, manually update the BurdenHoldCheck field in tblAssignments_SNTParticipants to be Y, which indicates the participant's representatives (family, executor, etc.) can be called.
    vi. Also make a note in the SNT database documenting the decision in the **Condition Notes** field of each open condition.

10. Notify the Call Center Coordinator, LSI team, and SN project SIs that work in the participant call assignments table is complete. Notify the SIs that they can resume work in the participant call lists.
11. **Take action on each issue**, as outlined below. Note that if a participant falls into more than one of the below categories, a holistic approach should be taken to address the mailing so as to avoid unnecessary contact and participant burden. See the Senior Coordinator-Clinical Research Operations or Research Scientist if guidance is needed.

Need LTFU HIPAA or Updated HIPAA

For those participants from whom a signed LTFU HIPAA form is required, as indicated by a Y in the **Needs1stLTFUHIPAA** field of the **qry_Alive_Pursue_UnabletoReqPath_RM** query results, or from whom an *updated* LTFU HIPAA form is needed, as indicated by a Y in the **NeedsNewHIPAA** field of the **qry_Alive_Pursue_UnabletoReqPath_RM** query results:

1. **Review the stand-alone query results** (**qry_Alive_Need1stLTFUHIPAA_RM**, **qry_Alive_Need1stLTFUHIPAA_ResendReq_RM**, and **qry_SN_Pursue_Alive_NeedCurrentHIPAA_RM**) to confirm they do not contain "on SN hold" participants and to confirm the participant is not in tracing for a bad address, is not on CCSS hold, and does not have a study outcome code that indicates an LTFU HIPAA should not be pursued. For participants falling into one of these categories:
   A. Do not pursue an LTFU HIPAA at this time.
   B. If appropriate, update the **Pursue Status** and **Pursue Status Date** fields for the condition(s) in question.
   C. For conditions that will remain open to future pursuit, make a note in the **Condition Notes** field of the SN record documenting the reason no HIPAA is being mailed to the participant.
2. If mailing to a LN address, ensure the query results show the **most current LN address**.
3. Determine if **Spanish materials** are needed.
4. Determine if **project manager action** is required by reviewing the **PursueOutcomeDesc** column. If so, review required action prior to creating mail run.
5. Determine if a HIPAA-bearing survey (e.g. FU6) is currently being pursued from the pt. If yes, consider whether a separate HIPAA request should be mailed.
6. For those needing a first-time (not updated/current) HIPAA, confirm there is no indication that the HIPAA was previously received (e.g. DateHipaaReceived or DateHipaaSigned is populated).
7. For those needing an updated HIPAA:
   A. Review the date of the HIPAA on file (DateHipaaSigned column) to ensure the HIPAA was not received without the receipt being fully or properly documented.
   B. Review the PursueOutcomeDesc column to confirm the condition is currently being pursued.
8. **Check to see if an MR was previously sent** to the participant. If so, subsequent requests should be sent once per quarter unless the verbiage "---SEND---" displays in the **HIPAASendDate** field to indicate a resend request.



9. For all other participants:
   A. **Produce materials needed to mail the request**. All needed documents are located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Letters to Participants*.
      i. Use mail merge and the results of queries **qry_Alive_Need1stLTFUHIPAA_RM**, **qry_Alive_Need1stLTFUHIPAA_ResendReq_RM**, and **qry_SN_Pursue_Alive_NeedCurrentHIPAA_RM** to personalize the following documents. NOTE that if a participant appears in the stand-alone query results more than once (e.g. for more than one condition), each document should only be printed once.
         a. **Need LTFU HIPAA - New or Updated – ALIVE – AJM approved 063017 rev**
         b. **CCSS HIPAA Amend 20_0 IRB-Appr 3-25-14**
         c. **Envelope_Merged - ALIVE**
      ii. For each request being mailed, print the following non-personalized documents:
         a. **Form Requesting Treating Information – ALIVE – AJM approved 063017**
         b. **LTFU HIPAA_Participant Copy**
   B. **Produce the mailing**:
      i. Staple the **Form Requesting Treating Information – ALIVE – AJM approved 063017** to the back of the **CCSS HIPAA Amend 20_0 IRB-Appr 3-25-14**.

ii. Stack the **Need LTFU HIPAA - New or Updated – ALIVE – AJM approved 063017 rev** on top of the **CCSS HIPAA Amend 20_0 IRB-Appr 3-25-14** followed by the **LTFU HIPAA_Participant Copy**.

iii. Fold the document stack into thirds and insert into the personalized envelope.

iv. Insert a postage-paid return envelope.

v. Before sealing the envelopes:

a. Determine if any other document or information (e.g. institutional HIPAA, reconsent) is needed from the case by reviewing the **qry_Alive_Pursue_UnabletoReqPath_RM** query results. Take the appropriate action based on the query results. Consult the Senior Coordinator or Research Scientist for guidance, if needed.

b. Determine if the participant is also on the B&T list. If so, coordinate the mailings.

c. Perform a quality check on the mailing materials to ensure:

1) The name on the envelope matches the name on the letter and the name on the HIPAA.
2) The participant copy is included.
3) The return envelope is included.

vi. Seal the envelopes and place them in outgoing mail.

C. **Document**

i. Resend Requests – *Need 1st LTFU HIPAA*

a. In the query results from **qry_Alive_Need1stLTFUHIPAA_RM**, create a new worksheet named _TEMPNeed1stLTFUHIPAAResends.

b. Copy the query results to the new sheet.

c. Delete:

1) All non-resend rows (i.e. those rows where HIPAASendDate does not have the value "---SEND---")
2) Resend rows that are being held to combine with other documentation
3) Resend rows that were not mailed for any other reason

d. Import _TEMPNeed1stLTFUHIPAAResends into a new table in the database. Overwrite the existing table, if applicable.

e. Run **qry_Alive_Need1stLTFUHIPAA_FulfillResendReq_RM** to confirm the results to be updated.

f. Change the query to an Update query.

g. For HIPAAReqDate Is Not Null and HIPAASendDate Is Null, update the **HIPAASendDate** field to the current date.

h. Close the query, but do NOT save the changes.

i. Import the query results from **qry_Alive_Need1stLTFUHIPAA_ResendReq_RM** into a new table named _TEMPNeed1stLTFUHIPAAResends. Overwrite the existing table, if applicable.

j. Run **qry_Alive_Need1stLTFUHIPAA_FulfillResendReq_RM** to confirm the results to be updated.

k. Change the query to an Update query.

l. For HIPAAReqDate Is Not Null and HIPAASendDate Is Null, update the **HIPAASendDate** field to the current date.

m. Close the query, but do NOT save the changes.

ii. Routine Mailings – *Need 1st LTFU HIPAA*

a. Use **qry_Alive_Need1stLTFUHIPAA_RoutineMail_RM** to locate the participants that received mailings. NOTE 1: This query groups by CCSSID, so the total may be less than the total from the originating query. NOTE 2: This runs query qry_**Alive_Need1stLTFUHIPAA_RM** anew, so a delay from the original run may cause mismatched results.
b. Export the results as an Excel file.
   1) Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
   2) Append the current date to the file name.
c. Create a new worksheet named _TEMPSNTUpdate_LTFURoutineMail.
d. Copy the data from the export to the new worksheet.
e. In the new worksheet
   1) Delete all rows for participants that had HIPAASendDate = "---SEND---" in the **qry_Alive_Need1stLTFUHIPAA_RM** results used for the mailing.
   2) Delete all rows for which SNHold = "No Pt Contact."
   3) Delete all rows for which no LTFU HIPAA was sent due to tracing (or other) issues.
   4) Delete all rows that were added after contact authorization was obtained.
   5) Delete all rows for which documents are being held to combine with other documentation.
   6) Delete the FirstName, LastName, and SNHold columns.
f. Use conditional formatting to confirm there are no duplicates in the ParticipantID column.
g. Clear all values in the HIPAAReqDate and HIPAASendDate columns.
h. Populate the HIPAAReqDate and HIPAASendDate columns with the current date for all rows.
i. Import the data in _TEMPSNTUpdate_LTFURoutineMail into the SNT database.
   1) Choose the radio button for Append a copy of the records to the table.
   2) Choose table tblHipaaPursue.

iii. Add Note that LTFU HIPAA and add'l info sheet have been mailed. – *Need 1st LTFU HIPAA*
a. Open **qry_Alive_Need1stLTFUHIPAA_Note_RM** in Design View.
b. Update HIPAASendDate criteria to the date the HIPAAs were mailed, and clear the Notes criteria.
c. Confirm results to be updated.
d. Change the query to an Update query.
e. Create an appropriate note to document the mailing in the Update To cell of tblSNT's Notes field.
f. Run the query once for Notes in tblSNT Is Not Null (first) and once for Notes Is Null (second).
g. Close the query, but DO NOT save the changes.
h. Review results of **qry_Alive_Need1stLTFUHIPAA_ResendReq_RM**, and manually add a note for the participants listed. If appropriate, also update **Pursue Status** and **Pursue Status Date**.

iv. Resend Requests – *Need Updated LTFU HIPAA*
a. In the query results from **qry_Alive_NeedCurrentHIPAA_RM**, create a new worksheet named _TEMPNeedCurrentHIPAAResends.
b. Copy the query results to the new sheet.

c. Delete all non-resend rows (i.e. rows where HIPAASendDate does not have the value "---SEND---")
d. Delete resend rows that are being held to combine with other documentation.
e. Import _TEMPNeedCurrentHIPAAResends into a new table in the database. Overwrite the existing table, if applicable.
f. Run **qry_Alive_NeedCurrentHIPAA_FulfillResendReq_RM** to confirm the results to be updated.
g. Change the query to an Update query.
h. For HIPAAReqDate Is Not Null and HIPAASendDate Is Null, update the **HIPAASendDate** field to the current date.
i. Close the query, but do NOT save the changes.

v. Routine Mailings – *Need Updated LTFU HIPAA*
a. Use **qry_Alive_NeedCurrentHIPAA_RoutineMail_RM** to locate the participants that received mailings. NOTE 1: This query groups by CCSSID, so the total may be less than the total from the originating query. NOTE 2: This query runs **qry_Alive_NeedCurrentHIPAA_RM** anew, so a delay from the original run may cause mismatched results.
b. Export the results as an Excel file.
   1) Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
   2) Append the current date to the file name.
c. Create a new worksheet named _TEMPSNTUpdate_LTFURoutineMail.
d. Copy the data from the export to the new worksheet.
e. In the new worksheet
   1) Delete all rows for participants that had HIPAASendDate = "---SEND---" in the **qry_Alive_NeedCurrentLTFUHIPAA_RM** results used for the mailing.
   2) Delete all rows for which SNHold = "No Pt Contact."
   3) Delete all rows for which no LTFU HIPAA was sent due to tracing or other issues.
   4) Delete all rows that were added after contact authorization was obtained.
   5) Delete all rows for which documents are being held to combine with other documentation.
   6) Delete the FirstName, LastName, and SNHold columns.
f. Use conditional formatting to confirm there are no duplicates in the ParticipantID column.
g. Clear all values in the HIPAAReqDate and HIPAASendDate columns.
h. Populate the HIPAAReqDate and HIPAASendDate columns with the current date.
i. Import the data in _TEMPSNTUpdate_LTFURoutineMail into the SNT database.
   1) Choose the radio button for Append a copy of the records to the table.
   2) Choose table tblHipaaPursue.

vi. Add Note that LTFU HIPAA and add'l info sheet have been mailed – *Need Updated LTFU HIPAA*
   1) Open **qry_Alive_NeedCurrentHIPAA_UpdFacNote_RM** in Design View.
   2) Update the criteria in HIPAASendDate to specify the date of the HIPAA mailing.
   3) Run the query to confirm the results to be updated.
   4) Change the query to an Update query.

5) Update the **FacilityNotes** field to include a dated note that the updated LTFU HIPAA needed for the facility in question and an additional information sheet has been mailed. Run this once for **FacilityNotes** field IS NOT null (first) and once for **FacilityNotes** field IS null (second).
6) Close the query, but DO NOT SAVE the changes.
7) If needed, update the **Request Status** from 4-Project Mgr Action Req'd to 3-Need New MR and the **Request Status** from the current value to the current date.

Documenting HIPAAs/Medical Release Forms Received

When **a properly signed and dated HIPAA/medical release form is received**:

1. Open the CCSS LTFU Participants database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
   A. If the participant confirmed any contact information on the HIPAA form, update the LTFU Participants database to reflect this confirmation. See the SOP titled **LTFU Participant Database Data Entry** for details on this process.
   B. If **the signed form is an LTFU HIPAA form**, review the HIPAA-Participation History tab's HIPAA Tracking group.
      i. If there is data in any field, click the **Archive Hipaa Info** button.
      ii. **Date HIPAA Received** – Enter the date the form was received at the Coordinating Center.
      iii. **Date HIPAA Signed** – Enter the date the participant wrote on the form as his/her signature date. NOTE: If this date was omitted or if the DOB was written in error, use a date stamp to stamp the date the HIPAA was received.
      iv. **HIPAA Source** – Choose "SMN."
      v. **HIPAA Status** – Choose "Complete."
2. Open the SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
   A. Locate the participant's record, then locate the first condition pending the form in question.
      i. Pending 1st LTFU HIPAA
         a. **Pursue Status** – Update the Pursue Status to the new status (either 4-Pursue or 6-Pursue, Need Info from Pt.
         b. **Pursue Status Date** – Update to the current date.
         c. **Condition Notes** – Enter a dated note documenting receipt of the signed HIPAA, the additional information provided, and the changes made to the **Pursue Status** and **Pursue Status Date** fields.
      ii. Pending Updated LTFU HIPAA or Facility MR
         a. Locate the facility that required the updated LTFU HIPAA form.
         b. **MR Received Date** – Enter the date the updated LTFU HIPAA or institution-specific medical release form was received.
         c. **Request Status** – Update from 3-Need New MR to the most appropriate new code.
         d. **Request Status Date** – Update to the current date.
         e. **Facility Notes** – Enter dated note documenting receipt of the signed form and changes to the **Request Status** and **Request Status Date** fields. If the participant provided additional information, document it in the **Condition Notes** field, as this is not facility-specific.

B. Navigate through remaining conditions to determine if any other condition is pending the form in question. If yes, repeat the documentation process.

Need Institution-Specific Medical Release Form

Some institutions require their own HIPAA/medical release (MR) form to be signed in order to release medical records to the study team. For those participants from whom a signed institution-specific form is required, as indicated by a Y in the **NeedsFacilityMR** field of the **qry_Alive_Pursue_UnabletoReqPath_RM** query results:

1. **Review the stand-alone query results** from **qry_Alive_NeedFacilityMR_RM** to confirm they do not contain "on SN hold" participants and to confirm the participant is not in tracing for a bad address, is not on CCSS hold, and does not have a study outcome code that indicates an institution-specific medical release form should not be pursued. For participants falling into one of these categories:
   A. Do not pursue an institution-specific HIPAA at this time.
   B. If appropriate, update the **Pursue Status** and **Pursue Status Date** fields for the condition(s) in question.
   C. For conditions that are not being closed to further pursuit, make a note in the **Condition Notes** field of the SN record documenting why no mailing occurred.
2. If **mailing to a LN address**, ensure the most current address is in the query results.
3. Determine if **Spanish** materials are needed.
4. Check to see if we have **a prior signed MR for this facility** in the network file. If so, review for an expiration date and any diagnosis restrictions to determine if a new MR should be requested.
5. Determine if **project manager action is required** (condition-level or facility-level) by reviewing the **PursueOutcomeDesc** and **RequestStatusName** columns. If so, review required action prior to creating mail run.
6. Decide whether to send an MR.
   A. Check the **LastFacilityMRReqDate** column to see if a facility MR was previously sent. If so, subsequent mailings should be sent once per quarter.
   B. Check the ResendReq column for those requiring a sooner resend.
7. For all other participants:
   A. **Produce materials needed to mail the request**. All needed documents (except the institution-specific HIPAA form) are located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Letters to Participants*. The institution-specific form must be obtained directly from the institution or from its website.
      i. Use mail merge and the query **qry_Alive_NeedFacilityMR_RM** to personalize the following documents. NOTE that if a participant appears in the stand-alone query results more than once (e.g. for more than one condition), each document only needs to be printed once.
         a. **Need Facility MR - New or Updated - ALIVE - AJM approved 063017**
         b. **Envelope_Merged**
         c. **CCSS HIPAA amend 20 0 irb appr 3-25-14** – This document is only needed if the participant has not signed an LTFU HIPAA form or if the signature date is greater than 6 months old.
      ii. For each request being mailed, print or obtain the following non-personalized documents:
         a. Institution's required HIPAA form

b. **LTFU HIPAA_Participant Copy** – If **CCSS HIPAA amend 20 0 irb appr 3-25-14** is being sent (see above), this document must be sent as well.
c. **Form Requesting Treating Information – ALIVE – AJM approved 063017** – If additional information is also needed, as indicated by a "Y" in the **NeedsAdd'lInfo** column of **qry_Alive_Pursue_UnabletoReqPath_RM** query results, print this document.

B. **Fill out the institutional HIPAA form for the participant** using Adobe's Typewriter feature, but leave any address and/or phone number fields blank. Type the CCSSID in the lower left-hand corner. Make a copy for him/her to keep, and keep a copy here in case a resend is needed. Highlight the fields that need his/her attention, including signature field, signature date field, and address and/or phone number fields.
C. If an LTFU HIPAA is being included, staple the participant's copy of the institutional HIPAA to the back of the participant's copy of the LTFU HIPAA.
D. If **Form Requesting Treating Information – ALIVE – AJM approved 063017** is being included, staple it to the back of either the institutional HIPAA or the LTFU HIPAA.
E. **Produce the mailing**:
   i. Stack the **Need Facility MR - New or Updated - ALIVE - AJM approved 063017** on top of the institution-specific HIPAA followed by the LTFU HIPAA (if being sent) and finally the participant copy of the institution-specific HIPAA (and participant copy of the LTFU HIPAA, if being sent).
   ii. Fold the document stack into thirds and insert into the printed envelope.
   iii. Insert a postage-paid return envelope.
   iv. Before sealing the envelope:
      a. Determine if any other document or information (e.g. reconsent) is needed from the case by reviewing the **qry_Alive_Pursue_UnabletoReqPath_RM** query results. Take the appropriate action based on the query results. Consult the Senior Coordinator or Research Scientist for guidance, if needed.
      b. Determine if the participant is being contacted for the B&T project. If possible, coordinate mailings.
      c. Perform a quality check on the mailing materials to ensure:
         1) The name on the letter matches the name on the envelope.
         2) The correct institution-specific HIPAA form is included, and the name matches the envelope.
         3) The participant copy of the institution-specific HIPAA form is included, and the name matches the envelope.
         4) If the LTFU HIPAA is included, the name matches the envelope, and a participant copy is included.
         5) The return envelope is included.
   v. Seal the envelopes and place them in outgoing mail.
F. **Document** the mailing in the **Request Date**, **Request Type**, and **Facility Notes** fields of the appropriate Facilities group record.
   i. Run **qry_Alive_NeedFacMR_UpdFacRec_RM** to locate the participants that received mailings.
      a. Export the results as an Excel file.
         1) Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
         2) Append the current date to the file name.
      b. Create a new worksheet named _TEMPSNTUpdate_FacMRMailed.

c. Copy the data from the export to the new worksheet.
d. In the new worksheet
    1) Delete all rows for which SNHold = "No Pt Contact."
    2) Delete all rows for which no facility MR was sent due to tracing or other issues.
    3) Delete all rows that were added after contact authorization was obtained.
    4) Delete the FirstName, LastName, ConditionID, SNHold, RequestStatus, RequestStatusName, RequestStatusDate, NewMRName, and FacilityNotes columns.
    5) Rename ConsecutiveSNT to be ConsecutiveSNT_Facilities.
    6) Rename the SNT_Facilities_Consecutive column to be SNTFacilitiesConsecutive.
    7) Add a column titled RequestDate, and populate it with the current date.
    8) Add a column titled RequestType, and populate it with the number 2.
    9) Add a column titled CreatedByUser, and populate it with your username.
    10) Add a column titled CreatedDate, and populate it with the date and time with format mm/dd/yyyy hh:mm:ss AM (e.g. 6/7/2017 12:24:00 PM).
e. Import the data in _TEMPSNTUpdate_FacMRMailed into the SNT database.
    1) Choose the radio button for Append a copy of the records to the table.
    2) Choose table tblRequests.

ii. Add Note that facility MR have been mailed.
    a. Open **qry_Alive_NeedFacMR_UpdFacRec_RM** in Design View.
    b. Either include the appropriate CCSSIDs or exclude the CCSSIDs that are on hold/no mailing due to tracing/documents being held to combine with other mailings – depends on whether the months' mailing is a full-mail month or a select-mail month.
    c. Run the query to confirm the results to be updated.
    d. Change the query to an Update query.
    e. Update the **FacilityNotes** field to include a dated note that the needed facility MR has been mailed. Run this once for Facility Notes field IS NOT null (first) and once for **FacilityNotes** field IS null (second).
    f. Close the query, but DO NOT SAVE the changes.
iii. If needed, update the **RequestStatus** from 4-Project Mgr Action Req'd to 3-Need New MR.
iv. If needed, update the **RequestStatusDate** to the current date.
v. If needed, clear requests for resends (in **Resend Request** and **Resend Request Date** fields) that have been fulfilled.
vi. If mailings for 1st or updated LTFU HIPAAs were included for any participant, manually make the appropriate documentation for these mailings, too.

NOTE: When the requested institutional HIPAA is received, see the section of this document titled *Documenting HIPAAs/Medical Release Forms Received*, above, for additional directives.

Need Additional Information

There are occasions when the LTFU Study does not have enough information to pursue medical records for an SN report (e.g. the diagnosing entity may not have been reported). These participants are indicated by a Y in the **NeedsAdd'lInfo** field of the **qry_Alive_Pursue_UnabletoReqPath_RM** query

results. If contact authorization is received from the Senior Coordinator, Survey Interviewers call the participant to obtain the needed information.

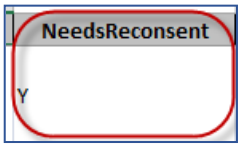
Missing Information Received

When all **needed missing information is obtained**:

1. Open the SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Locate the participant and condition record in question.
3. Update the database with the data obtained.
4. **Pursue Status**
   A. If currently set to 6-Pursue, Need Info from Pt, update to 4-Pursue.
   B. If currently set to 8-Pursue, Need 1st MR & Info from Pt, update to 4-Pursue or 7-Pursue, Pending First MR, as appropriate.
5. **Pursue Status Date** – Update to the current date.
6. **Condition Notes** – Enter a dated note with initials indicating what data was obtained and documenting the changes to the **Pursue Status** and **Pursue Status Date** fields.

Need Reconsent

When a participant turns 18 years old, the consent to participate given by her/his legal guardian expires, and s/he must be reconsented to participate in the study. For participants that need to be reconsented to the study, as indicated by a Y in the **NeedsReconsent** field of the **qry_Alive_Pursue_UnabletoReqPath_RM** query results:



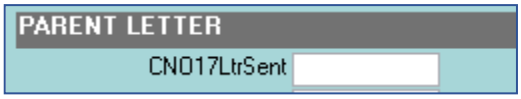
1. If the participant is in the **original cohort**, reconsent is not needed. All participants have been sent a letter with the essential components of consent, and her/his continued participation in the study implies consent. See the Senior Coordinator or Research Scientist for guidance on how to proceed.
2. If the participant is in the **expansion cohort**, check the **NeedsPermLetter** field in the **qry_Alive_Pursue_UnabletoReqPath_RM** query results.
   A. If the **NeedsPermLetter** field displays Y, a letter must first be sent to the now-adult participant's family requesting permission to contact the now-adult case or sibling for continued participation in the LTFU Study. This procedure has been approved by the IRB and must be followed.
      i. Determine if the participant is in tracing (If using an LN address, be sure it's up-to-date *for the parents* and included in the query results.), if the participant's parents have already refused, if the participant has an outcome that prevents pursuit, or if Spanish materials are needed.
      ii. Determine if project manager action is required by reviewing the **PursueOutcomeDesc** column of the **qry_Alive_NeedReconsent_PermLtr_RM** query results. If so, review required action prior to creating the mail run.
      iii. **Print** the following documents, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Letters to Participants*, for each qualifying participant using mail merge and the query results from **qry_Alive_NeedReconsent_PermLtr_RM**.
         a. **AOM Parent Permission Letter_Merged**
         b. **AOM Perm Envelope_Merged**

iv. Fold **AOM Parent Permission Letter_Merged** in thirds, and insert it with a postage-paid return envelope into the **AOM Perm Envelope_Merged**.

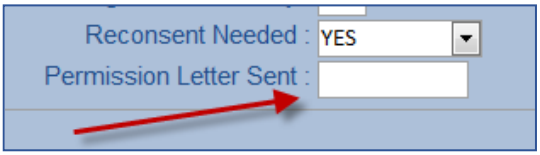
v. Perform a quality check to confirm:
   a. The name on the permission letter matches the name on the envelope.
   b. The postage-paid return envelope is included.

vi. Seal, and place in outgoing mail.

vii. **Document** the permission letter sent.
   a. CCSS Expansion Tracking database – If the participant has not rolled over from the Expansion Tracking database to the LTFU Participants database:
      1) **CNO17LtrSent** (AgeofMajority tab) – Enter the current date.
      2) **Comments** (Quest tab) – Enter a dated note that the AOM permission letter has been sent to the participant's parents.



   b. CCSS LTFU Participants database – If the participant has rolled over from the Expansion Tracking database to the LTFU Participants database:
      1) **Permission Letter Sent** (HIPAA-Participation History tab) – Enter the current date.
      2) **Notes** (Participant tab) – Enter a dated note that the AOM permission letter has been sent to the participant's parents.



viii. Set an Outlook **reminder to follow up in 2 weeks**. At that time, review the participant record in the CCSS LTFU Participants database to determine the outcome of the request for permission.
   a. If the parent or guardian refuses permission, the reconsent process stops and no further contact with the participant occurs.
      1) Document the reconsent outcome. See the SOP titled **Age of Majority Reconsenting** for details.
      2) Update the CCSS outcome. See the SOP titled **Processing Refusals: Participants, Proxies, and Associates.**
      3) Determine what outcome, if any, should be recorded in the outstanding SN conditions. See the Research Scientist or Senior Coordinator for guidance, if needed.
   b. If the **parent or guardian identifies himself or herself as the legally authorized representative** (LAR) of the now-adult participant, the reconsent process stops.
      1) Document the reconsent outcome as directed in the SOP titled **Age of Majority Reconsenting**.
      2) Determine if outstanding SN conditions need to have the **Pursue Status** field updated (e.g. from 5-Pursue, Pending Reconsent).
      3) The participant will be re-evaluated for requesting the appropriate medical records the next time the procedure is completed.

c. If the parent or guardian has not responded to the permission letter after 2 weeks, proceed with the reconsent process, as described below.

B. If the **NeedsPermLetter** field does not display "Y", determine if the AOM letter with HIPAA request has already been mailed by reviewing the notes and AOM fields, described below, for the participant.

i. If yes:
   a. Research whether the participant is in call rotation by the SI team.
   b. Continue to send reconsent requests quarterly, using the steps below.

ii. If no, **proceed with the reconsent process**. Note that the parent or guardian can still refuse permission at this stage until the participant responds.
   a. Determine if the participant is in tracing (If using an LN address, be sure it's up-to-date and included in the query results), if the participant's parents have already refused, if the participant has an outcome that prevents pursuit, or if Spanish materials are needed.
   b. Determine if project manager action is required by reviewing the **PursueOutcomeDesc** column of the **qry_Alive_NeedReconsent_RM** results. If so, review required action prior to creating mail run.
   c. Using mail merge and the results of **qry_Alive_NeedReconsent_RM**, print the following documents, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests\Letters to Participants*:
      1) **AgeofMajority HIPAA Only Letter - merged**
      2) **CCSS HIPAA amend 20 0 irb appr 3-25-14**
      3) **Form Requesting Treating Information – ALIVE – AJM approved 063017**
      4) **LTFU HIPAA_Participant Copy**
      5) **Envelope_Merged** (to use mail merge with query **qry_SN_Pursue_Alive_NeedReconsent_RM**) or **Envelope_NoMerge** (to type the data directly into the document)
   d. Staple the **Form Requesting Treating Information** to the back of **CCSS HIPAA amend 20 0 irb appr 3-25-14**.
   e. Stack the documents with **AgeofMajority HIPAA Only Letter - merged** on top followed by **CCSS HIPAA amend 20 0 irb appr 3-25-14** and finally the **LTFU HIPAA_Participant Copy**.
   f. Fold the document stack into thirds and insert it with a postage-paid return envelope into the personalized envelope.
   g. Before sealing the envelopes:
      1) Determine if any other document or information (e.g. institutional HIPAA) is needed from the case by reviewing the **qry_Alive_Pursue_UnabletoReqPath_RM** query results. Take the appropriate action based on the query results. Consult the Senior Coordinator or Research Scientist for guidance, if needed.
      2) Determine if the participant is also being contacted for the B&T project. If so, coordinate the mailings.
      3) Perform a quality check on the mailing materials to ensure:
         A) The name on the envelope matches the name on the letter and the name on the HIPAA.
         B) The participant copy of the HIPAA is included.
         C) The return envelope is included.

h. Seal envelopes and place in outgoing mail.
i. **Document** that the reconsent letter has been sent.
   1) Expansion Tracking database – If the participant has not rolled over from the Expansion Tracking database to the LTFU Participants database:
      A) **AOMSent** (AgeofMajority tab) – Enter the current date.
      B) **Comments** (Quest tab) – Enter a dated note that the AOM letter with HIPAA request has been sent to the case.

   2) LTFU Participants database – If the participant has rolled over from the Expansion Tracking database to the LTFU Participants database, enter a dated note in the **Notes** field of the Participant tab that the AOM letter with HIPAA request has been sent to the participant.
   3) SNT database
      A) Enter a dated note in the **Condition Notes** field for all open conditions that an AOM letter with LTFU HIPAA was mailed to pt.
      B) Populate the **Request Date** and **Send Date** fields in the LTFU HIPAA Pursuit group with the date of the mailing.

Pursuing Pathology Reports – Deceased Participants

Sending Pathology Report Requests

1. Run the query **qry_Deceased_RequestMedRecsWithMR_JF_RM**. This query reports all conditions for deceased participants where:
   A. The **Purse Outcome** is 3-Condition-Level Project Mgr Action Req'd or 4-Pursue AND
   B. The **Request Status** is not 5-Suspended or 6-Complete AND
   C. The most recent **Request Date** for medical records is either <null> or earlier than the receipt of a facility or updated MR AND
   D. The participant or his/her representative has signed an LTFU HIPAA, AND
   E. There is no indication that an institutional medical release is needed.
2. Export the results as an Excel file. Seek assistance, if needed.
   A. Save the file to *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
   B. Add the date to the file name.
3. Use the results to request pathology reports WITH an MR. Use the above procedure for alive participants with the following changes:
   A. When creating the fax cover sheets, use **Breast Cancer Recs - DECEASED pts, Have HIPAA - Fax TEMPLATE - Merged** and **First Request for BC Records - DECEASED pts - MERGED - MA signature** for breast cancers and **TEMPLATE, Request Path Rpt for DECEASED pts WITH HIPAA - merged** for non-breast cancers.
   B. Use **qry_Deceased_ResendMedRecReq_WithMR_RM** to identify resend requests.
4. Run the query **qry_Deceased_RequestMedRecsNoMR_JF_RM**.
5. Export the results as an Excel file. Seek assistance if needed.
   A. Save the file to *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Path Rpt Requests*.
   B. Add the date to the file name.

6. Use the results to request pathology reports WITHOUT an MR. Use the above procedure for alive participants with the following changes:
   A. When creating the fax cover sheets, use **Breast Cancer Recs - DECEASED pts, NO HIPAA - Fax TEMPLATE - Merged 080116** and **First Request for BC Records - DECEASED pts - MERGED - MA signature** for breast cancers and **TEMPLATE, Request Path Rpt for DECEASED pts with NO HIPAA - merged 062716** for non-breast cancers.
   B. Use **qry_Deceased_ResendMedRecReq_NoMR_RM** to identify resend requests.

Unable to Pursue Pathology Report – Deceased Participants

In circumstances where a valid LTFU HIPAA is needed, where the institution requires their own medical release form to be signed, and/or where additional information is needed, additional work is required before a pathology report can be requested.

1. Run the query **qry_Deceased_NeedReconsent_RM**. Any participant on this list should have the **Pursue Status** field updated to a new value, since reconsent is not applicable to deceased participants.
2. Work **"no path request" queries** using the above procedures for alive participants with the following changes:
   A. NOTE that we should NOT mail anything near the participant's birthday, the participant's death date, Mother's Day (May), Father's Day (June), or major holidays (November and December). Except for those with related birth or death dates, standard mailings can be in January, April, July, and October.
   B. Use **qry_Deceased_Pursue_UnabletoReqPath_RM** in place of **qry_Alive_Pursue_UnabletoReqPath_RM**.
   C. Rather than requesting contact authorization from the Senior Coordinator, review each participant individually to determine if contact is appropriate. Consult the Research Scientist or Senior Coordinator if guidance is needed.
   D. Do not use an automated process to denote contact authorization. Update each participant manually.
   E. The "stand-alone" queries are **qry_Deceased_Need1stLTFUHIPAA_RM**, **qry_Deceased_Need1stLTFUHIPAA_ResendReq_RM**, **qry_Deceased_NeedAddlInfo_RM, qry_Deceased_NeedCurrentHIPAA_RM**, and **qry_Deceased_NeedFacilityMR_RM**. The reconsent process does not apply to deceased participants.
   F. For all documents, use the corresponding "Deceased" version, if there is one available.
   G. Update the database manually to document mailings.

Revision Record
Printed 10/24/2017 3:57 PM

[301]Current Filename:		Pursuing Subsequent Neoplasm Pathology Records ver2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	7/1/15	L. Harrison	Initial Development; overhaul of SMN Confirmation Process
2.0	10/24/17	R. Massey	Completely rework SOP for new procedures, new database.

Quality Assurance Review of Ready to Send Questionnaire Packets

Background

Questionnaire packets are reviewed before they are sealed and mailed to the participants. A general process is provided below. It is important to note that some questionnaires/ packet mail outs will have additional or different items to review.

Procedure

1. In general, *at least* 10% of the packets should be reviewed.
2. Open the selected envelope and remove all contents. Common review items are as follows.
    a. Check that all materials are present:
        i. Questionnaire
        ii. Cover letter
        iii. Blue business return envelope with indicia for US residents or with stamps for Canadian residents
        iv. HIPAA and consent forms (with Expansion Baseline Questionnaire)
    b. Compare address of participant on the envelope mailing label and cover letter.
        i. If international address, make sure the country name is spelled out on the last line of the mailing label
    c. Compare the CCSSID on envelope, cover letter, and questionnaire
    d. Compare the participant name on cover letter, mailing label, and questionnaire
    e. Review the questionnaire to make sure no pages or items are missing (e.g., no print errors).
    f. Review cover letter to see if the mail merge appeared to work correctly (e.g., password, institution name, participant name and address).
3. Insert materials back into envelope
4. Seal.

Revision Record

Printed 7/6/2012 12:15 PM

Current filename:		QA of Questionnaire Packets ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/25/09	A. McDonald	Initial Development

Questionnaire Comments that Need to be Addressed

Background

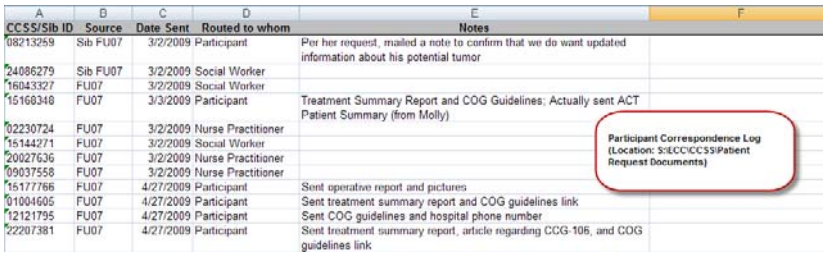
All questionnaire comments are reviewed. Based on the content of the comments, they may be routed to one of the following persons for follow-up with the participant:

- Routine/informational requests: **CCSS Coordinating Center Staff**
- Director of Social Work (**Fran Greeson** via Aaron) for insurance questions, etc.
- Medical-related questions (**Dr Green** via his admin assistant) (See additional notes on page 2)
- Mental-health related questions (to **Aaron** to route to appropriate party)

Procedure

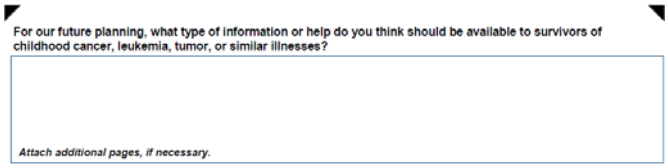
1. Generate a hard copy of the comments.
    a. Photocopy the paper-based questionnaire comments. (All comments are photocopied as part of in-processing.)
    b. Download Online comments via query (to be developed)

2. CRAII reviews comments to determine what further action is warranted. For those warranting further action:
    a. Update ***_Participant Correspondence Log*** (…\ECC\CCSS\Patient Request Documents)
    b. If applicable, save a copy of any correspondence sent directly to the participant in the above path. Start the file name with the CCSSID.
    c. Note that the wording on the expansion baseline survey makes knowing whether a comment requires a response less straightforward than with FU7002.



3. Remember to periodically review the online comments to be sure nothing is missed.

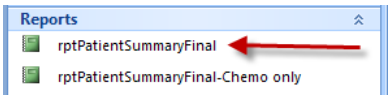
4. Comments related to *study information requests*, etc. are handled by Coordinating Center staff on a case-by-case basis
    a. Address the comment as applicable (i.e., mail information to participant; send an email, etc. See sample email)
    b. Remember to update the *_Participant Correspondence Log*



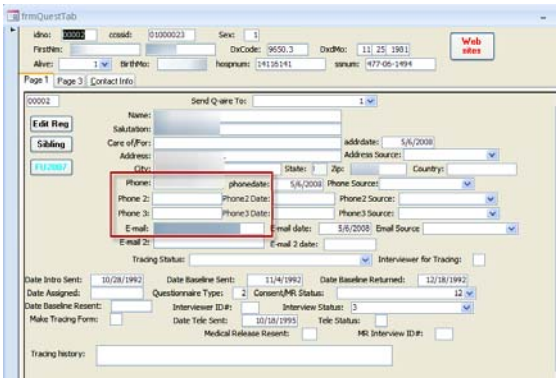
    c. *Medical related questions* are routed to admin support to give to Dr. Green; *Social Work related questions* are sent to Fran Greeson by way of Aaron; and *Mental Health questions* are routed to Aaron for forwarding to the appropriate party. (See section on process for Medical Related Questions.)

General Process for Medical Related Questions

1. Generate the Patient Summary Report:
    a. Open Reg database (Expansion does not yet have a Patient Summary Report)
    b. Open Reports list in the Objects Menu (hint: minimize the switchboard)
    c. Print *Patient Summary Report*
        i. Open rptPatientSummaryFinal
        ii. At the prompt, enter CCSSID
        iii. Print report



    d. If Patient Summary Report is incomplete, print the MRAF from Alchemy.
2. Assemble the documents:
    a. Patient Summary Report
    b. Actual comments
    c. Contact information (As applicable, on the summary report, write patient email address from the database OR make a screen print of the database page, highlighting phone and email contact information.)



3. Prepare a brief explanatory note/cover memo for the packet.
4. Send the material (questionnaire comment, participant treatment summary, participant contact information and cover memo) to Dr. Green's administrative assistant, who will determine with Dr. Green whether or not an appointment should be made.
    a. If yes, then the assistant sets up an appointment with the participant. Appointments can be made by phone, letter, or email.
    b. If no, comment page and treatment summary are shredded by the admin.
5. If admin works with Dr. Green to schedule a phone call appointment time,
    a. He/she also provides Dr. Green with a copy of the comment and treatment summary in advance of the appointment.
    b. Sample appointment letter/email (for Dr. Green's admin to use): Thank you for completing the Long Term Follow-Up (LTFU) Questionnaire. In your questionnaire comments, you asked about a medical-related condition. If you would like to schedule a time to speak with a doctor at St. Jude Children's Research Hospital, please call 1-800-775-2167 or (901) 595-5914. Thank you again for your participation in the LTFU study.

Revision Record — Printed 7/9/2012 10:32 AM

Current Filename:		Questionnaire Comments that need to be Addressed ver1_4.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/3/09	A. McDonald	Initial Development for manual
1.1	11/4/09	J.Bates	Expansion baseline annotations
1.2	11/17/09	J.Bates	Participant Correspondence Log
1.3	2/16/10	J.Bates	Update Social Work contact
1.4	7/5/11	J.Bates	Update contact; refine language

Quick Reference Sheet for Recruitment Interviewers

Background

This document is designed to provide a brief reminder to interviewers working on the Expansion Recruitment project and to provide guidance about where to find detailed instructions. This is an at-a-glance reference and not a complete procedure. Find the full procedures in the SOP library.

Procedures

Outcome	SI Action	Files/Resources	Related SOP
SI obtains updated contact information for the case or his/her associates	update the CCSS Recruitment database	Database link: *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*	**Expansion Recruitment Process for Survey Interviewers**
potential participant requests a resend of the recruitment materials	log the request in the CCSS Recruitment database's Tracking tab	Database link: *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*	**Expansion Recruitment Process for Survey Interviewers**
potential participant requests enrollment link	send link via email using approved template	Templates: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Email Requests\To Enroll*	**Emailing LTFU Internet Links to Expanded Cohort Participants**
participant needs a participant copy of the HIPAA form after completing the Verbal HIPAA	enter the request in the Excel workbook titled **HIPAA Participant Copy Request Form**	**HIPAA Participant Copy Request Form**: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Verbal HIPAA*	**Requesting Participant Copies of Recruitment HIPAA**
participant completes the Verbal HIPAA and requests to complete the baseline survey on paper	NONE: As long as the participant qualifies for a paper survey (not deceased, not Spanish-only), the paper survey will be mailed automatically.	N/A	**Expansion Recruitment Process for Survey Interviewers**
participant completes the verbal HIPAA and requests to complete the baseline survey online	send link via email using approved template	Templates: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Email Requests\To COMPLETE SURVEY*	**Emailing LTFU Internet Links to Expanded Cohort Participants**
all telephone numbers recorded for potential participant and his/her associates are invalid	add the case to Tracing	Database link: *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*	**Expansion Recruitment Process for Survey Interviewers**
potential participant REFUSES participation	document refusal in call notes, update Outcome in CCSS Recruitment database, log refusal in **Call Outcomes Log**	Database link: *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx* **Call Outcomes Log**: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls*	**Expansion Recruitment Process for Survey Interviewers**
SI finds the case's DOB, gender, or vital status needs to be changed	document information and source in call notes, complete **Expired Pt Info Sheet** if appropriate, update **Call Outcomes Log**	**Expired Pt Info Sheet**: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools* **Call Outcomes Log**: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls*	**Expansion Recruitment Process for Survey Interviewers**
case believed to be INELIGIBLE	log suspected ineligibility circumstances in **Call Outcomes Log** for a determination	**Call Outcomes Log**: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls*	**Expansion Recruitment Process for Survey Interviewers**

Revision Record Printed 3/5/2014 9:59 AM

[201] Current Filename:		Quick Reference Sheet For Recruitment Interviewers ver2_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	7/6/12	B. Carson/M. Jackson	Initial Development
1.1	7/10/2012	B. Carson/M. Jackson	Formatting, Addition of Background
2.0	2/28/2014	R. Massey	Content Update, Expanded Content

Race Codes

Background

A procedure manual describes race coding for the Reg database thus:

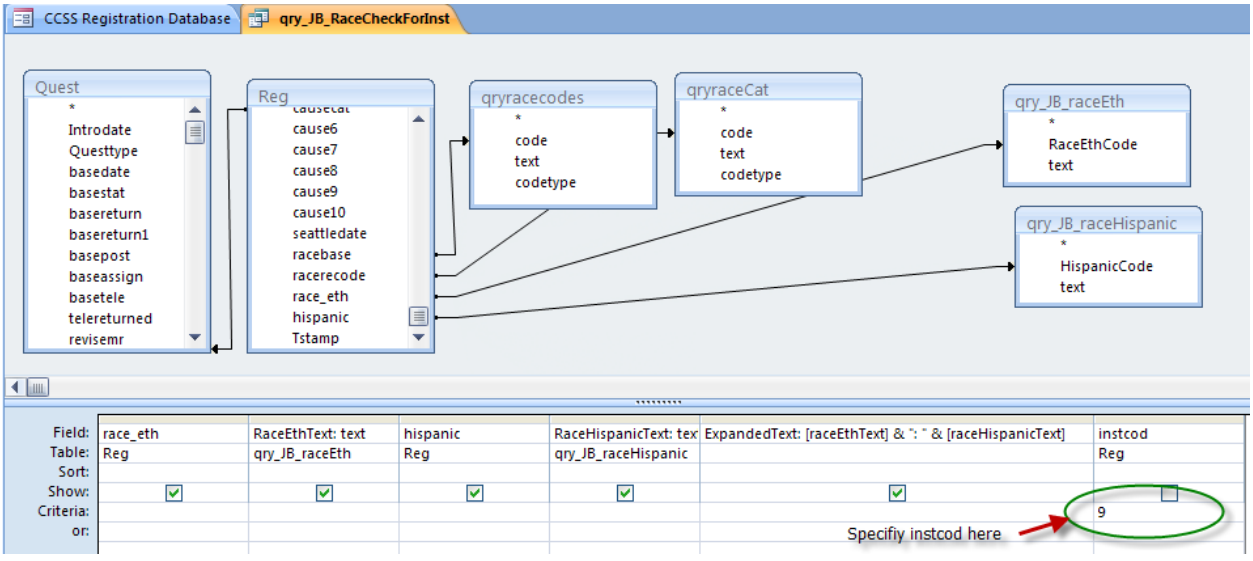
> "**Racebase** is what the respondent reported in the baseline questionnaire. These were recoded into **major categories**: Hispanic, white non-hispanic, black non-hispanic, american indian/alaskan, asian/pacific islander, other/mixed, missing. The variable **race_recode** holds this recoded information. Recently, however, hispanic has been viewed as an ethnicity rather than race, so we have re-created the race values based on ethnicity. The variable **hispanic** has the format 1=hispanic, 2=not hispanic, 7=unknown. **Race_eth** is recoded to exclude hispanic status: 1=white, 3=black, 4=american indian/alaskan, 5= asian/pacific islander, 6=other/mixed, 7=missing. Unless mixed race, a person who indicated him/herself as mexican, spanish or other hispanic-type ethnicity is coded as white. A person with any part black was coded as black, all other mixed races were coded other/mixed."

Each record in the Reg table (original cohort database) contains FOUR FIELDS related to race:

Racebase, raceRecode, Race_eth, and Hispanic. The definitions for the first 2 are located in the table Codes, as "race" and "raceCat" respectively.

We built a new table (tbl_JB_RaceExpanded) to hold text values for the codes Race_Eth and Hispanic, based on the information from the procedure manual.

A query (qry_JB_RaceCheckForInst) now display the 4 coded race fields and their respective text values, for an individual institution. The query builds an expanded text field to display race_eth: Hispanic.



Revision Record

Printed 7/10/2012 2:24 PM

Current Filename:		RaceCodes ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/11/11	J.Bates	Initial Development

Reconsenting Calls

The Long-Term Follow-Up (LTFU) Study informed consent for a minor recruited to the LTFU study is provided by the parent or other legally authorized representative. This agreement expires on the birthday when the individual turns 18. Before we collect any new information, living individuals not having a legal guardian must be reconsented upon turning 18.

Survey Interviewers (SIs) should determine if a participant has reached the age of majority during pre-call profile building and should complete the required database data entry following reconsent attempts.

Note: The **Age of Majority** fields are located on both the **HIPAA-PARTICIPATION HISTORY** tab of the **CCSS LTFU Participants Database** and also the **FU# TRACKING** tabs of the **CCSS Follow-Up Survey Tracking** database. Updating the fields on the **HIPAA-PARTICIPATION HISTORY** tab will also update the fields on the **FU# TRACKING** tab (see "After the Call" section below). Please consult with an LSI or the Coordinator if you have any questions.

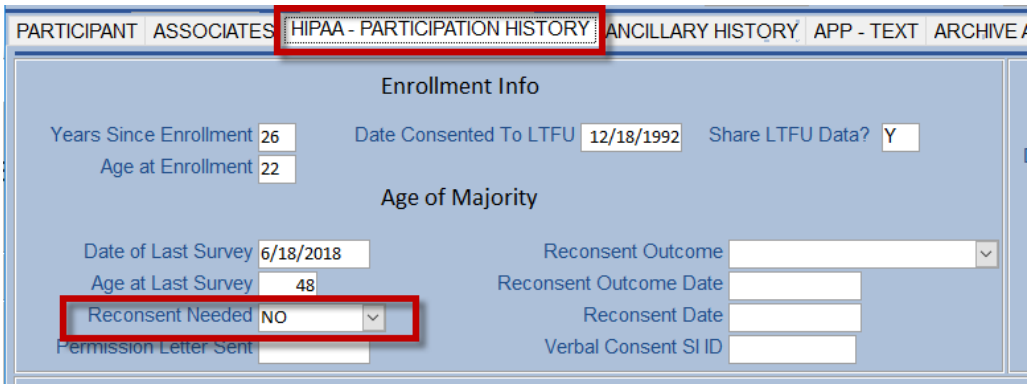
Tools Needed:

1. **Age of Majority Reconsent Script jf**, located at *Z:…Interviewers\FU7\Scripts*
2. **LTFU Study Age of Majority Reconsent Form_r1am**, located at located at *Z:…Interviewers\FU7\Scripts*
3. The **CCSS LTFU Participants Database**

Procedures

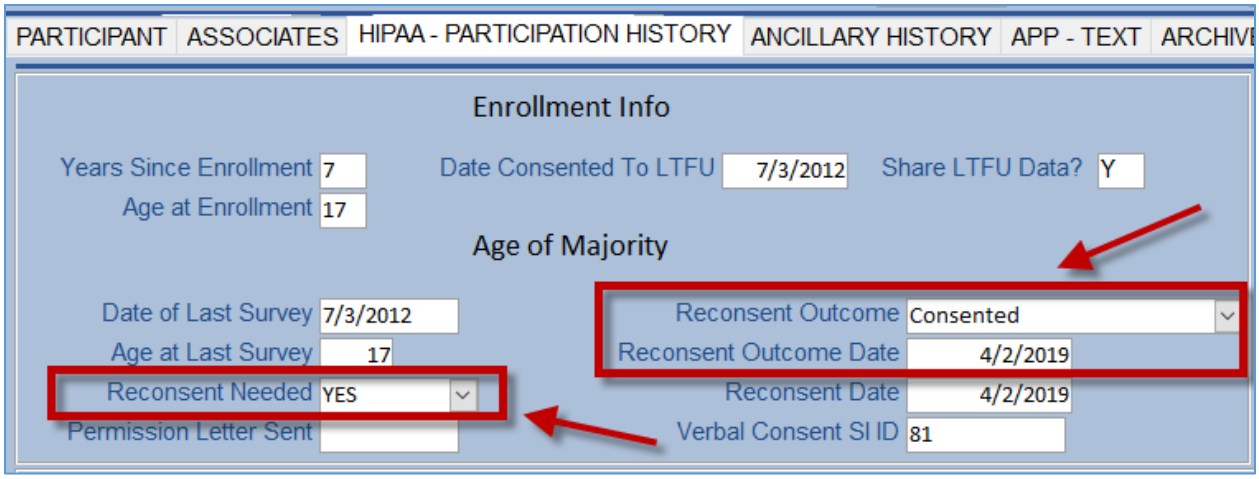
Before the Call:

Determine whether the participant needs to be reconsented. In the participant's record in the **LTFU Participant database**, go to the **HIPAA-PARTICIPATION HISTORY** tab and review the Age of Majority fields.

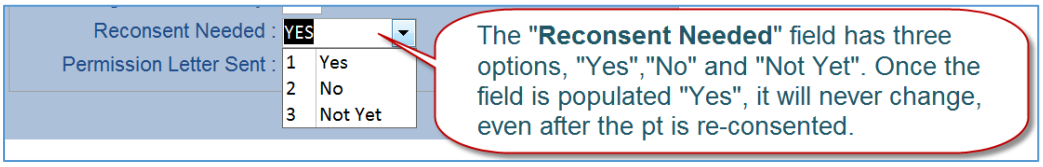


1. **No reconsent needed**:
   A. If the **Reconsent Needed** field is populated with "**NO**", the participant does *NOT* need to be reconsented.

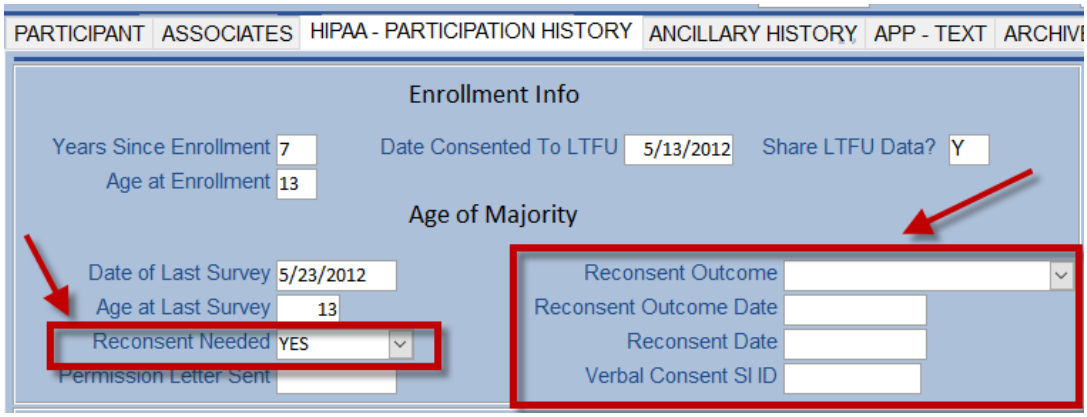
B. If the **Reconsent Needed** field is populated with "**YES**" *AND* the fields **Reconsent Outcome**/**Reconsent Outcome Date** *ARE* populated, "**Consented**" or "**LAR**", the participant does *NOT* need to be reconsented.



NOTE: *Once the **Reconsent Needed** field is populated YES, it does NOT change, even after the participant has been reconsented. Reports are tied to this field.*



2. **Reconsent Needed** – If the **Reconsent Needed** field is populated, "**YES**" and the fields **Reconsent Outcome**, **Reconsent Outcome Date**, and **Reconsent Date** are *NOT* populated, the participant *MUST* be reconsented (give consent to be in the LTFU Study).



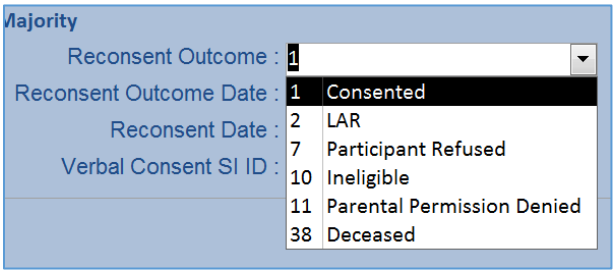
During the Call

Use the **Age of Majority Reconsent Script** to address the reconsent issue with the participant. Note that participants who ARE familiar with the study and do not directly refuse participation during the script are providing implied consent, and the database should be updated accordingly.

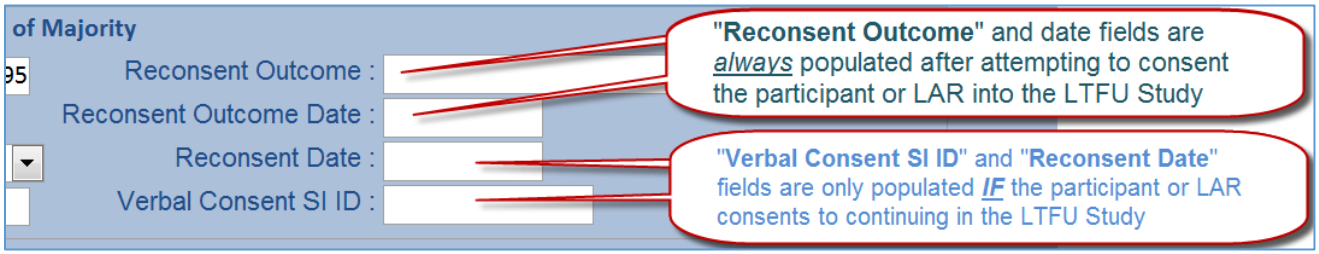
After the Call

After the reconsent attempt, update the LTFU Participant database with the appropriate outcome:

1. Update the **HIPAA-PARTICIPATION HISTORY** tab:
   A. **Reconsent Outcome** – Populate with the appropriate outcome from the drop-down menu.



No:	Outcome	When to Use
1	Consented	Use 1-Consented if the now-adult participant agrees to stay in the study.
2	LAR	Use 2-LAR if the now-adult participant has an LAR. NOTE: The LAR may/may not be the same person who completed the baseline survey when the participant was a minor.
7	Participant Refused	Use 7-Participant Refused when the now-adult participant refuses during the reconsent call. *Also update the database with the "Refused All Else" outcome. See the SOP titled **LTFU Participant Database Data Entry** for details.*
10	Ineligible	The 10-Ineligible outcome is not used by the SIs. Use the **DB Changes** field of the contact or trace log to alert the Coordinator and Lead Survey Interviewers (LSIs) if the participant is suspected to be ineligible.
11	Parental Permission Denied	Use 11-Parental Permission Denied when the parent refuses to release the participant's contact information in order to consent the participant. *This is equivalent to a "Refused All Else" outcome, and the database should be updated accordingly. See the SOP titled **LTFU Participant Database Data Entry** for details.*
38	Deceased	Use 38-Deceased when the reconsent attempt reveals that the participant is now deceased. *Also complete all other steps required for documenting and communicating a vital status update (i.e., **Expired Participant Information Sheet**, **DB Changes** field in contact or trace log, etc.). See the SOP titled **LTFU Participant Database Data Entry** for details.*



   B. **Reconsent Outcome Date** - Populate with the current date.
   C. **Reconsent Date** – Populate with the current date *ONLY if the participant reconsents to the LTFU Study*. This field is not populated if the participant has an LAR.

D. **Verbal Consent SI ID** – Populate with the SI ID *ONLY if the participant reconsents to the LTFU Study*. This field is not populated if the participant has an LAR.

2. Update the **PARTICIPANT** tab, **Notes** form**–** On the Participant tab, click the **Notes** button to access the form and add a dated note with SI ID documenting the reconsent outcome.

For all questions, please consult with the Coordinator or an LSI.

Revision Record Printed

Current Filename:		Reconsenting Calls ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/25/2020	J. Ford, A. Cobble, D. Rinehart, R. Daniels	Initial Development

Reconsenting St Jude Life Cases to LTFU

Background

Former St. Jude patients who return to St. Jude for a St. Jude Life study visit may be eligible for the LTFU study. (Only adults are eligible for St. Jude Life.) If they ARE eligible for LTFU, we must determine (a) whether they have already been recruited to the study, and (b) if they HAVE already been recruited, whether they were a minor when they were recruited. If they *were* recruited as a minor, then we need to reconsent them to the LTFU as adults. If they have *not* been recruited, then we will try to recruit them during the study, using the current procedure as outlined in *Processing St Jude Life In-Hospital Recruits*. The current procedure SUPPLEMENTS the existing procedure, addressing those who need to be reconsented or who need a signed LTFU MR release.

Procedures

Has NOT YET been fully recruited to LTFU

1. If they **have NOT YET been recruited to the LTFU study**, follow the procedure outlined in *Processing St Jude Life In-Hospital Recruits*. (If they are NOT in the Expansion Tracking database, that means they have not yet signed the initial St. Jude HIPAA.)

2. If they are in the Expansion Tracking database, but we **do NOT** yet have the baseline survey (no date in **DateSurveyReturned** on Baseline tab; not yet consented to the study):

    - Recruit the participant, obtain the signed LTFU consent and the signed LTFU MR.

3. PROCESS the documents as outlined in *Processing St Jude Life In-Hospital Recruits*, starting at the Expansion Tracking database section.

WAS RECRUITED to LTFU *as an ADULT*

1. If we **DO** have a baseline survey (there IS a date in **DateSurveyReturned** on Baseline tab; has consented to the study), BUT we do NOT YET have a signed LTFU MR release (MR Status on the Baseline tab is NOT a "1").

    - Obtain a signed LTFU MR Release. Update Baseline tab with tracking comments, entering **Date MR Signed** and enter "1" in **MR Status**. File signed MR in the Recruited during SJLife visit file.

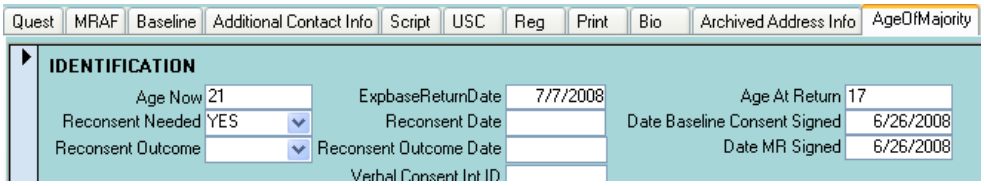
2. If we **DO** have a baseline survey and we **DO** have a signed MR Release, there is nothing more to be done.

CRA

RECRUITED to LTFU *as a MINOR*

1. Run **qry_JB_SJ_ReconsentNeeded** for a quick list of LTFU St Jude cases who DO need to be reconsented. Query also gives name and MRN. (Check this query regularly to capture new recruits, new survey returns, as well as individuals recently turned 18.)

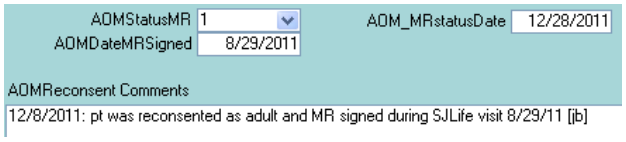
    a. Otherwise, consult the AgeOfMajority tab.
    b. Those who were minors when they were consented will have YES in **ReconsentNeeded**. Also check **ReconsentOutcome**.
    c. If there already is an outcome, there is no need to approach the individual again.
    d. But if **ReconsentNeeded** is YES, and **ReconsentOutcome** is blank, proceed to reconsent the person.



2. **Reconsent** the individual (i.e. discuss study, answer any questions, and have individual sign/date in-clinic LTFU consent form: *CCSS Consent_Buccal-DNA Collection Amendment 14.0*), obtain a signed LTFU MR Release, and record it in the database:

    a. **DateMRSigned** on **Baseline** tab:
        i. If there *already is a date* in **DateMRSigned**, document this historical data for the *original* LTFU MR signature date in the Tracking comments. E.g.,
            - *mm/dd/yy: original LTFU MR provided by parent/guardian on mm/dd/yy.*
        ii. After documenting any existing MR signature date, enter the date of the NEW MR signature in **DateMRSigned**, and select 1 (Complete) for **MRStatus**.
    b. **AgeOfMajority** tab
        i. In **ReconsentOutcome**, select "Consented"
        ii. In **ReconsentDate**, enter the date the consent was signed
        iii. In **ReconsentOutcomeDate**, enter the date you entered the data (probably the same date as ReconsentDate)

        iv. In **AOMStatusMR**, select 1 (Complete)
        v. In **AOM_MRstatusDate**, enter the date of data entry
        vi. In **AOMDateMRSigned**, enter the signature date.



        vii. In **AOMReconsentComments**, document the event. E.g.
            - *Mm/dd/yy: pt was reconsented as adult and MR signed during SJLife visit [inits]*

RECRUITED to LTFU *as a MINOR:* EXCEPTIONS (Guardians and Refusals)

1. **LEGAL GUARDIANS**
    a. When you go to reconsent the individual, you may discover the person has a legal guardian. In such instances, we will NOT try to reconsent the patient. Instead, let them know that we already have what we need. (We do not need the guardian to sign a new consent.) But do ask if the guardian would mind signing the additional medical record release (so that we have an updated document).
    b. Enter 2 (LAR Consented) in **ReconsentOutcome** (enter **ReconsentOutcomeDate** as above)
    c. Document in **AOMReconsentComments** the fact that pt has a LAR. E.g.,
        - *mm/dd/yy: pt has legal guardian; the original consent document remains in force [inits]*
    d. On Quest tab: Update **Send Q-aire To** to 6 (parent, eventhough pt over 18)
    e. If LAR signs a new MR Release, document on the Baseline tab, after recording the existing **DateMRsigned** field in **TrackingComments** with a note: E.g.
        - *Mm/dd/yy: original MR signed on mm/dd/yy; LAR re-signed MR during pt's SJL mm/dd/yy visit.*

2. The now-adult individual **REFUSES** the study
    a. Choose 7 (Participant Refused) for **ReconsentOutcome**
    b. Enter the **ReconsentOutcomeDate**
    c. Leave **ReconsentDate** blank
    d. Document in **AOMReconsentComments** E.g.,
        - *mm/dd/yy: pt refused study during SJL visit of mm/dd/yy [inits]*
    e. Notify the CRA2 that the now-adult case has refused the study. (CRA2 will post a study outcome 37 (refused all else).

3. If the now-adult individual CONSENTS to the study but REFUSES to sign the MR release
    a. In **ReconsentOutcome**, select "Consented"
    b. In **ReconsentDate**, enter date consent was signed
    c. In **ReconsentOutcomeDate**, enter date you entered the data (probably same date as ReconsentDate)
    d. In **AOMStatusMR**, select 7 (Refused Medical Release)
    e. In **AOM_MRstatusDate**, enter date of data entry
    f. Leave **AOMDateMRSigned** blank
    g. In **AOMReconsentComments**, document the event. E.g.
        - *Mm/dd/yy: pt was reconsented as adult but refused MR during SJLife visit [inits]*

Revision Record Printed 9/20/2013 1:25 PM

Current Filename:		Reconsenting St Jude Life cases to LTFU ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	1/23/12	J.Bates	Initial Development
1_1	9/20/13	J. Ford	Clarified Need for Signed LTFU Consent Form

Recruiting Participants for the Low Grade Brain Tumor Study

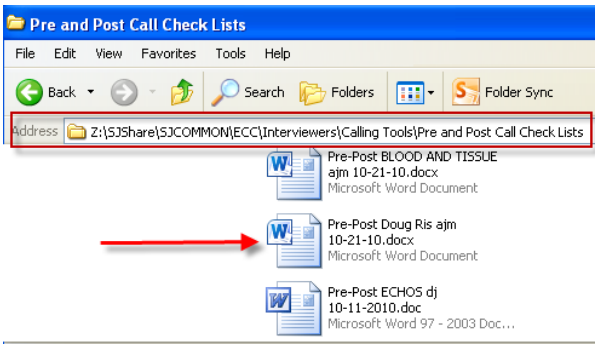
Background

The purpose of this CCSS ancillary study is to gain a better understanding of the types of challenges faced by adult survivors of childhood brain tumors. The Principal Investigator is Doug Ris, PhD at Texas Children's Hospital/Baylor University. All participants will come from the original cohort. Note that some of the participants being recruited will represent a "control" comparison group, that is, "siblings" from the LTFU Study who were never treated for brain tumors. The eligible participants are mailed an introductory letter by 5th floor staff members. Survey interviewers then conduct phone call follow-up to recruit participants to the study. Successfully recruited participants are referred to Wendy Levy, study project coordinator, to arrange the testing details and further study participation. Our task is to recruit cases for the study.

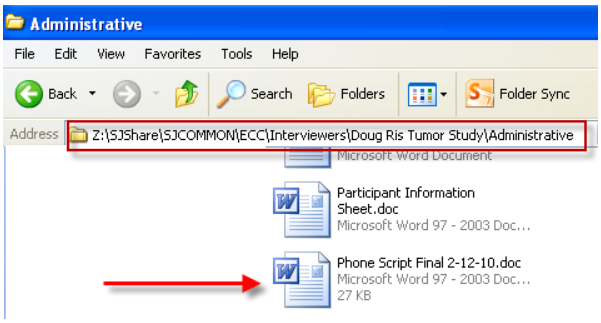
Processing a Doug Ris call uses these 6 tools, which you can find in these locations:

1. **Doug Ris Excel Call Assignments Workbook** (in **Z:\…\ECC\Interviewers\Doug Ris Tumor Study**). Obtain and update your call assignments for the study here.

2. **Pre-Post Doug Ris Call Check List** for this study (in: **Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools\Pre and Post Call Check Lists.**) Follow this pre- and post-call checklist.



3. **Phone Script** prepared for this study (in: **Z:\…\ECC\Interviewers\Doug Ris Tumor Study\Administrative**). Use this phone script.



4. The **Doug Ris database** (located on the ECC Databases Switchboard. A copy of the Switchboard should be available on each SI desktop). You will update this database.

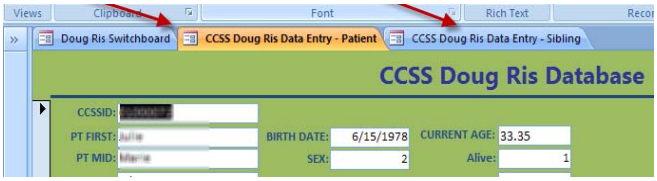
5. MS Word **Phone Contact Log** (in **Z:\… \ECC\Interviewers\Original Cohort Call Logs - Reg db**). Log the call to a participant here, in the Word document for the specific CCSSID.

6. The **Call Outcomes Log** (in **Z:\… \ECC\Interviewers\ Expansion Survey Calls**).

Procedures

Before making the call

1. Open the **Doug Ris Study database**. Open both the Patient and Sibling data entry forms (click the **Patient Entry** and **Sibling Entry** buttons).
   a. Having both forms open at the same time will maximize efficiency and productivity, giving you quicker access to a participant's or sibling's record.



2. Open the **Doug Ris Excel Call Assignments Workbook**. Be sure you log the call date, time, day record the appropriate call outcome (OC), and enter your intID number.

3. Open the MS Word **Phone Contact Log** for the participant, or create one. Refer to the SOP, **Using (and Creating) Participant MS Word Call Logs ("PHONE CONTACT LOG")** located in the SOP Library. Use this form to enter the date, day, time, INTID#, contact, if yes, whom, the outcome of the call (e.g. 2 = No answer), and detailed notes regarding your call.

4. Open the **phone script** located at **Z:\SJShare\SJCOMMON\ECC\Interviewers\Doug Ris Tumor Study**

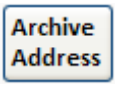
5. In the **Doug Ris Database**, search for the person (case or sibling) you are about to call.
   a. Review the CCSS study outcome code, vital status, LGBT outcome code, previous notes in the database and on the Word Call Log.
   b. If the study outcome is a 37 (Refused All Else) or 38 (Deceased), review the Expansion Tracking or the REG database to copy the notes reflecting the appropriate code. Paste the notes in the Recruit Notes section, found on the tracking tab of the Doug RIS database.
   c. Follow all other steps on the pre-call section of the call checklist document.

Make the call, following the phone script

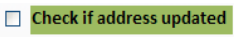
After making the call according to the script, record information in the Doug Ris database:

Important note - If you contact a patient/sibling's residence and are told the participant is deceased, complete the **Expired Participant Information Sheet**. Record the appropriate study outcome code (6) on the TRACKING tab of the "Ris" Database.

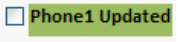
1. **QUEST TAB**:
   a. IMPORTANT: Prior to updating the ADDRESS, click on the **Archive Address** button to save the old address.



   b. Update the patient/sibling's address, phone number(s) and email address(es).
      i. ADDRESS
         1. Enter **ADDRESS DATE** and **ADDRESS SOURCE**
         2. If you update an address, click **Updated** checkbox for address.



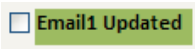
      ii. PHONE NUMBERS
         1. If you update/add a phone number, check the Updated checkbox for that number.



         2. Enter **Phone Type**, **Relationship**, **Phone Date**, and **Phone Source**.
         3. Select the phone number Rank from the drop-down box.
            a. 1 – 5 = Preferred ORDER in which to call
            b. 9 = disconnected phone number
            c. 37 = Do Not Call number (enter a note in the COMMENTS field, using standard format, *"**12/5/2014: DO NOT CALL 901-687-1234, PER PT'S UNCLE'S REQUEST.[89]."*

      *Note: **DATE LAST PHONE CALL** will automatically update after the database call log has been updated.*

      iii. EMAIL ADDRESSES
         1. If you update/add an email address, check the Updated checkbox for that email address.

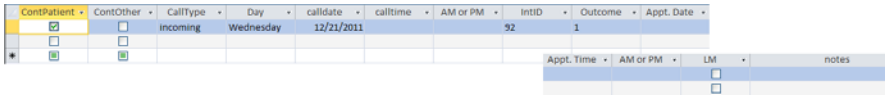


         2. Enter **EMAIL # DATE** and **EMAIL # SOURCE**
   c. Enter applicable comment in the **COMMENTS** field regarding the call you made.
      Note: the purpose of the **COMMENTS** field is to store critical information at a glance, including:
      i. Acceptance or denial of participating in the study
      ii. Phone Rank "37" numbers (see PHONE NUMBERS section above)
      iii. Participant and/or additional contact person address or phone number changes
      iv. Legally authorized representatives (LAR) not listed in the database
      v. Database header changes (i.e., Name, DOB, Spanish Status, Gender, Vital Status correction- enter requests for these changes in the **Call Outcomes Log**)

      Example: *"01/01/2013: Called pt at 901-545-1234. Participant advised of new married name, Smith. [92]"*

   d. Open **Call Log** for phone number you called by clicking on associated Pencil icon.

      i. Check the box for either **ContPatient** or **ContOther**, when contact has been made for patient/sibling.



      ii. **ALWAYS** fill out **CallType, Day**, **CallDate**, **CallTime**, **AM or PM**, **IntID**, and **Outcome** fields

iii. If a message is left on an answering machine (instead of with a live person), place a check mark in the "LM" check box
iv. Be sure to continue to tab to the right to enter all required information
v. Once all required information has been entered on the call log, click on the exit door button to exit and save your data.

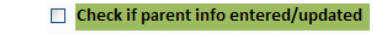
2. **TRACKING tab** (Note – the tracking tab will show you the date the introductory study letter was sent to the participant.)
   a. Enter or update the **OUTCOME CODE** field with outcome of each call. Enter or update the call date in the **OUTCOME DATE** field.
      i. If a person **Agrees to Participate** (outcome code 1) or is Interested, but **wants more information** (outcome code 2) about the study, then we send these cases to Wendy Levy for follow-up.
         1. Make sure you enter information in these fields too: **Prefer days by Baylor Call**; **Prefer times by Baylor call**
         2. **Alternate contact** information (if provided: this is someone Wendy Levy can contact if she cannot reach the participant)
            a. **Name**
            b. **Relationship** of alternate contact
            c. Alternate contact **phone 1** and/or 2 (phone #s for alternate point of contact)

1	Agreed to participate
2	Interested, more info
3	Refused/not interested
4	Non-responder
5	Ineligible
6	Deceased
7	Refused all else
8	3 month hold
9	6 month hold
10	Left Message
11	No answer
12	D/C or Wrong #
13	Other
14	Call back scheduled
15	Survey Only

      ii. If a person **refuses to participate**, determine the level of refusal.
         1. If participant is refusing this study only, select Outcome Code 3, "Refused/not interested."
         2. If the participant refuses this study AND further participation in CCSS, select Outcome Code 7, "Refused all else", and enter a request in the **Call Outcomes Log** to update the appropriate database with the "Refused all else" outcome.
         3. Enter the appropriate comment in the **Reason not interested** field.
      iii. If a person wants to participate by **Survey Only**, select Outcome Code 15, "Survey Only."
   b. Document brief call notes in the **Recruit Notes** section.

3. **Archive address tab:** Displays all of the patient/sibling's addresses that have been archived. No data entry is allowed on this page. This is read only.

4. **Parents tab:** This tab includes contact information for patient's Father and Mother.
   a. If you need to update an address, remember to first click the **Archive Address** button. Then update address. Check **updated** box after making changes.



   b. If you call a parent phone number that is not on the Quest tab, then enter the information in the call log for that phone number (pencil icon button).

   c. To view previous call information, click the paper magnifying glass button.

   d. Although you can add notes at the bottom of the form in the **Notes** field, please also put the notes regarding phone calls in the Recruit Notes field on the Tracking Tab.

5. **Spouse tab**: This tab includes the patient/sibling's spouse information.
   a. If you need to update an address, remember to first save the old address by entering a note in the Comments field of the Quest tab, indicating what the address was changed from (Example: "*12/5/2014: updated Spouse address from 123 Fourth St, Manhattan Beach, TN, 380023*"). Then update the address and mark the check box, "Check if spouse info entered/updated."
   b. If you call a phone number on this tab that is not on the quest tab, then enter the information in the call log for that phone number (pencil icon button).
      i. You can view previous call information by clicking on the button with the paper and magnifying glass
   c. Although you can add notes at the bottom of the form in the **Notes** field, please also put the notes regarding phone calls in the Recruit Notes field on the Tracking Tab.

6. **Additional Contact Tab**
   a. If you need to update an address, remember to first click the **Archive Address** button to save the old address. Then update the address and check the updated box after changes have been made.
   b. If you call a phone number that is not on the quest tab, then enter the information in the call log for that phone number (pencil icon button).
      i. You can view previous call information by clicking on the button with the paper and magnifying glass
   c. Although you can add notes at the bottom of the form in the **Notes** field, please also put the notes regarding phone calls in the Recruit Notes field on the Tracking Tab.
   d. *Note, at the bottom of the Additional Contact Info tab screen you may see, for example, 'Record 1 of 4'. You can click the right arrow [▶✱] to add information for a new additional contact.

REMINDERS:

Remember to update the CALL ASSIGNMENTS SHEET and the CALL LOG for the participant.
Did you follow the pre- and post- call checklist for this study?

Revision Record — Printed 5/13/2013 8:07 AM

[180] Current Filename:		Brain Tumor (Ris) Study Recruitment ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/10/11	D. Jackson/D. Rinehart	Initial Development
1.1	5/1/12	A. McDonald	Formatting and content revisions
1.2	12/21/12	D. Jackson	Add processing detail and content revision
1.3	5/10/2013	D. Jackson	Add processing detail, content revision and Comments section guidelines

Recruiting Production Schedules

Background

When a batch of surveys is to be produced and mailed, we generate data files from the appropriate database. The data files are distributed to the production staff. The production timeline is based on the total numbers of packets that are to be produced, and considers the 200 packet daily limit for first class mailing. An accompanying production schedule provides details about the associated documents needed to accompany the survey, as well as the staff assignments.

Samples of an initial mailing schedule and a non-response mailing for the recruitment database are presented here.

Sample Initial Mailing Production Schedule

Texas Childrens **Initial mailing** *(instcod 28)*

Texas Children's Cancer Center

Initial volume	Adults	Minors	Deceased	TOTAL
10/22/2010	482	127	12	621
SpanPacket	3	6	0	9

INITIAL Mailing LETTERS are located here:

Z:\sjShare\SJCommon\ECC\CCSS\Expansion Recruiting\28-Texas Childrens\IRB-Approved Letters. Use **INTRODUCTORY** letters

Date / Batch	October 25, 2010 Monday	October 26, 2010 Tuesday	October 28, 2010 Wednesday	October 29, 2010 Thursday	October 30, 2010 Friday		BATCH LTR DATE
Batch 1: DECEASED n 12	Production: CHERYL	Assemble, QC (KESHA), & MAIL					October 26, 2010
Batch 2: Minors n 127	Production: KESHA	Assemble, QC (DAVIDA), & MAIL				6 Spanish packets: Get packets from Davida and insert them in the proper envelope	October 26, 2010
Batch 3: rows 2-101 Adults 100		Production: KESHA	Assemble, QC (DAVIDA), & MAIL				October 27, 2010
Batch 4: Rows 102-201 Adults 100		Production: CHERYL	x Assemble, QC (KESHA), & MAIL				October 27, 2010
Batch 5: Rows 202-301 Adults 100			Production: CHERYL	X Assemble, QC (KESHA), & MAIL		1 Spanish packet Get packet from Davida and insert it in the proper envelope	October 28, 2010
Batch 6: Rows 302-401 Adults 100			Production: DAVIDA	X Assemble, QC (CHERYL), & MAIL			October 28, 2010
Batch 7: Rows 402-end Adults 85				Production: DAVIDA	x Assemble, QC (CHERYL), & MAIL	2 Spanish packets: Get packets from Davida and insert them in the proper envelope	October 29, 2010
ALL SPANISH PACKETS (9)	Production & assembly: DAVIDA	(1) Generate (a) cover letters for 6 minors and 3 adults needing Spanish packets and (b) personalized authorization documents (which include name, CCSSID, and DOB). (2) Assemble each individual envelope with a "Spanish materials" stick-on label, insert the letter, authorization form, and the appropriate "Participant Copy." (3) Give Sp packet to person whose batch needs it					
Daily Mail Total		135	200	200	82		

Principal Investigator:
Dr. Zoann Dreyer

Notes:
1. Print in color
2. In AUTOMERGE Publisher, use the TexasChildrens documents!
3. See SpanishPacket instructions for further information
   - Generate vital Status specific personalized authorization packet using mailmerge
   - Generate age-specific SPANISH cover letter (adult/minor/deceased) using mail merge

revFinal-Print-mail schedule-TexasChildrens-10-22-2010.doc Page 1 Printed 11/16/2010 10:59 AM

LeadCRA

Sample Non-response (Day28) Production Schedule

Children's HOSPITAL • ST. LOUIS

St. Louis Day28 Resend mailing *(instcod 21)*

Initial volume	Adults	Deceased	Minors	TOTAL
	229	11	49	289
QueryDate	5/10/2010	5/10/2010	5/10/2010	5/10/2010

Non-Response Mailing LETTERS are located here:
S:\ECC\CCSS\Expansion Recruiting\21-St. Louis\IRB-Approved Letters

Date	May 10	May 11	May 12							BATCH LETTER DATE
Batch	Monday	Tuesday	Wednesday							
StLouis Batch 1: 115 **Adult** Rows 2-116	Kesha (Print & assemble w. Juanita)	Assemble QA & Mail: Cheryl								May 11
StLouis Batch 2: 115 **Adult** Rows 117-230	Cheryl (Print & assemble w. Juanita)	Assemble QA & Mail: Kesha								May 11
StLouis Batch 3: 11 **Deceased** Rows all		Davida (Print & assemble w. Juanita)	Assemble QA & Mail: Kesha							May 12
StLouis Batch 4: 49 **Minors** Rows all		Davida (Print & assemble w. Juanita)	Assemble QA & Mail: Kesha							May 12
Daily Mail Total		229	60	289	Total					

Principal Investigator:
Robert J. Hayashi, MD

Notes:

1. PAY CLOSE ATTENTION to the SeqNo's in your data file!
2. NO PEN or $2 bills
3. Be sure to use the NON-RESPONSE letters
4. Print letters IN COLOR
5. Juanita will work on ALL assembly jobs. The individual who PRINTS a batch will help Juanita out with the assembly of that batch.
6. In AUTOMERGE Publisher, be sure to use the St Louis documents!

Print-mail schedule-StLouis-DAY 28-05 10 2010 ff.docx Page 1 Printed 11/16/2010 11:29 AM

Revision Record

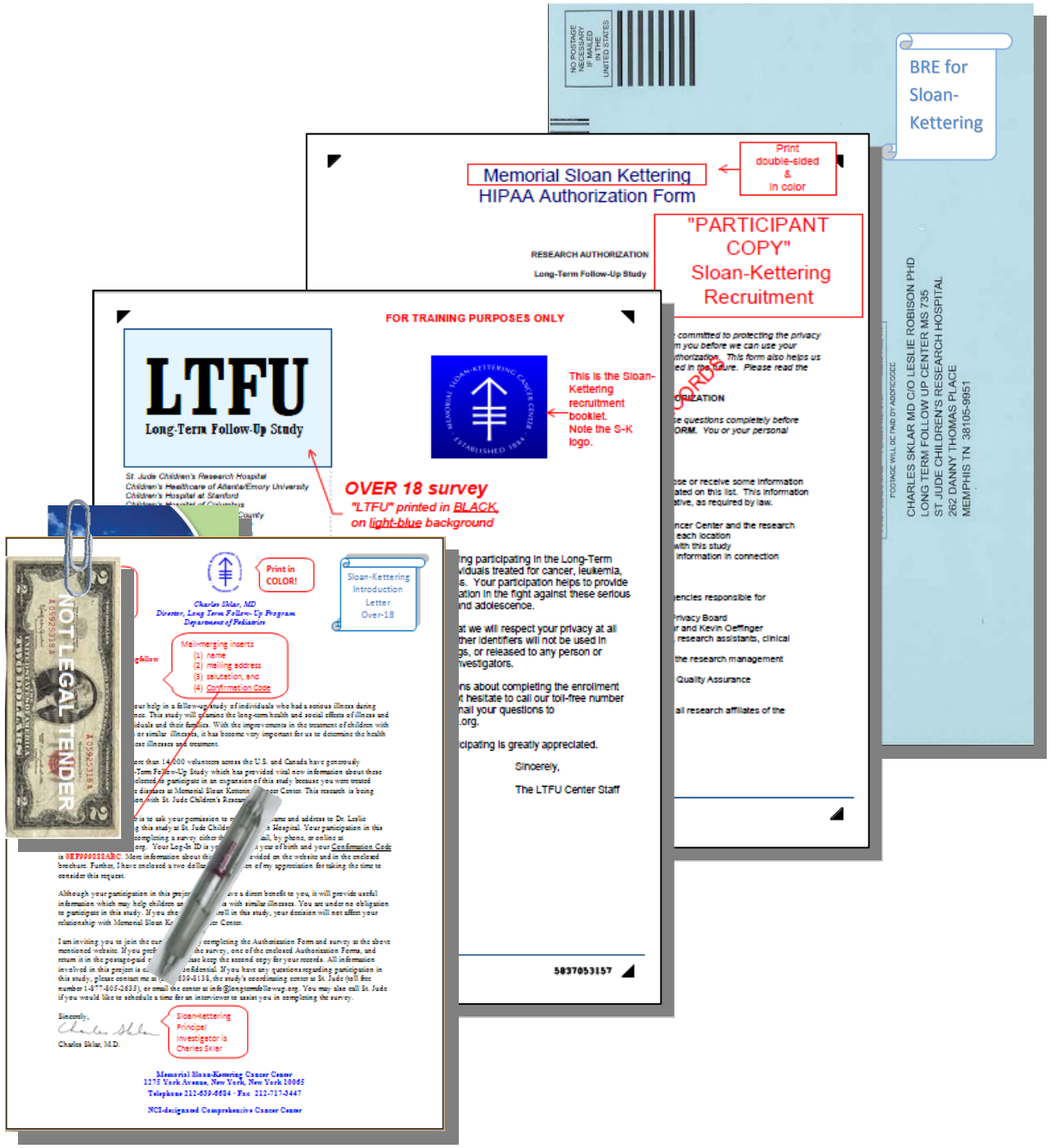
Printed 7/6/2012 8:03 AM

Current Filename:		Production Schedules ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	11/16/10	J.Bates	Initial Development

Recruiting Survey Packet Illustration

Assemble the contents in the order shown here

1. ON TOP: Currency, cover letter, brochure paperclipped in upper left corner
2. Booklet
3. "Participant Copy"
4. ON BOTTOM: Blue BRE
5. St. Jude pen

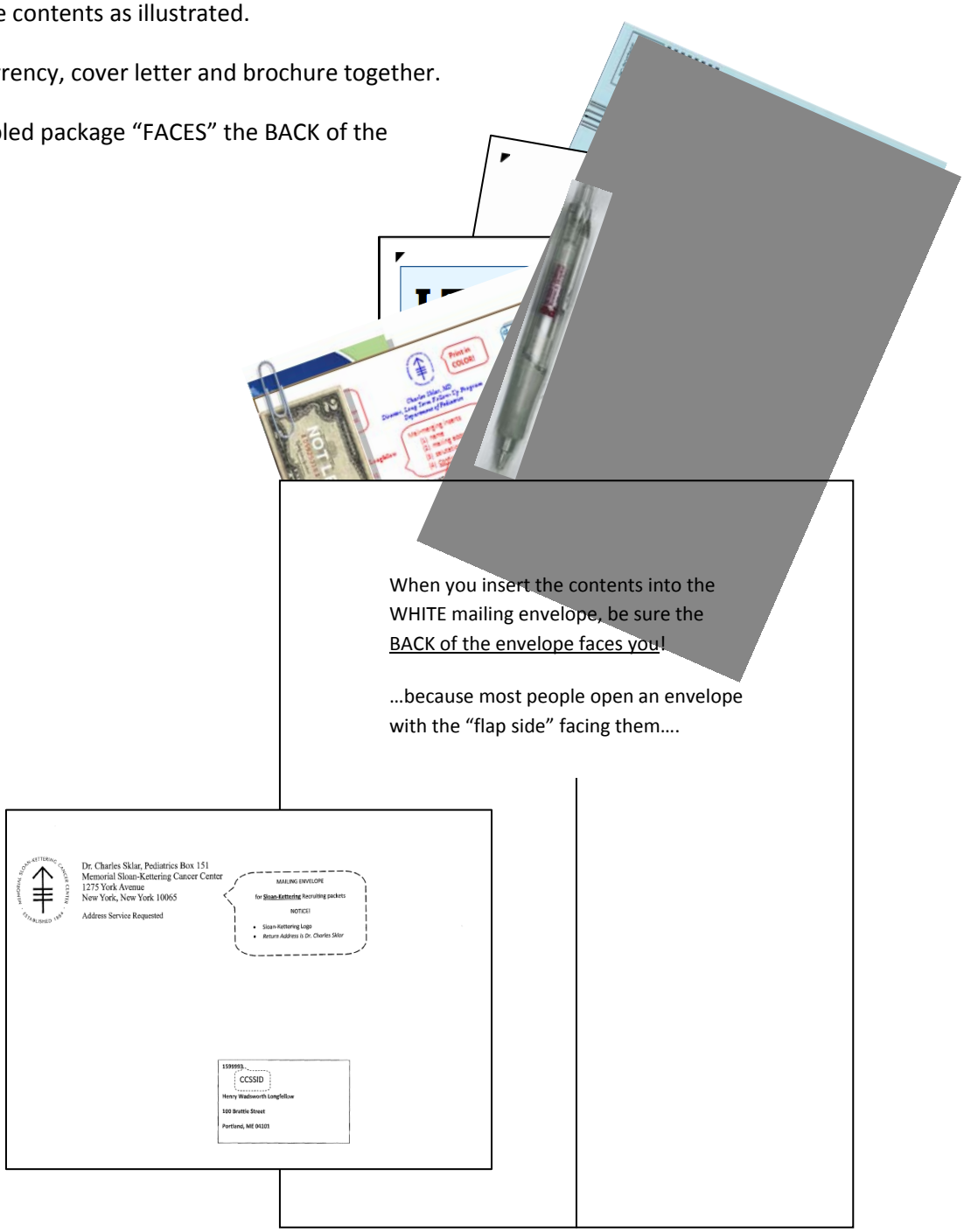


CRA

Assemble and stuff the contents as illustrated.

Paperclip JUST the currency, cover letter and brochure together.

Make sure the assembled package "FACES" the BACK of the mailing envelope!



Revision Record

Printed 7/2/2012 3:17 PM

Current Filename:		Recruitment Packets ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/14/09	J.Bates	Initial Development
1.1	6/29/11	J.Bates	Retitle

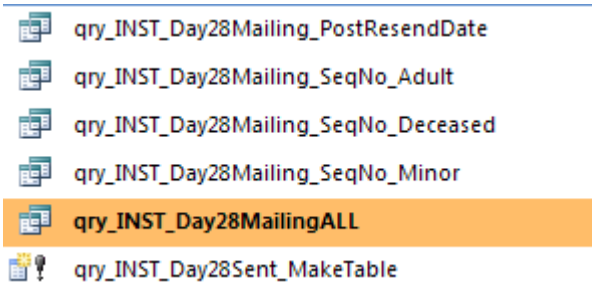
Recruitment Day 28 Resend Queries

Background

Four weeks (28 days) after the initial recruiting mailing for an institution, we send the packet again to non-responders who are not in tracing. The day28 resend uses the non-response letter. No pen or money is included. This document outlines the database process for generating the day28 resend data files. (A separate procedure outlines the "requested resend" process.)

Procedure

1. MAIN QUERY: Open ***qry_INST_Day28MailingALL*** in design view
    a. Set the INSTCOD criteria for the institution.
    b. Save the query
    c. View results
        i. Are there any INELIGIBLES? (should not be)
        ii. Spanish translation of the non-response letter does not exist. Thus, the day28 mailing does not differentiate for potential Spanish speakers.



    d. Close the query
    e. IMPORTANT: PROCEED through all the following steps *before you change the Day28Mailing query to a different institution*! (That is, you can only process one institution's day28 resend at a time.)

<u>Generate data files for each group: Adults, Minors, Deceased</u>

2. ADULTS: Open ***qry_INST_Day28Mailing_SeqNo_Adult*** in design view
    a. Delete the print table left over from the previous use of the query.
    b. Pull in the **ADULT** print table for the institution.
    c. Link it to the Day28MailingALL query by CCSSID
    d. Change the data source for Seq_num field to <u>this institution's print table</u>
    e. Remove the PREVIOUS institution's print table.
    f. Sort the query by SeqNum
    g. <u>See if any have died</u>. If so, request the record be moved from adult to decease print table. (You will need to wait for this to be done before generating the data file.)
    h. **Save** the query design.

3. MINORS: Open ***qry_INST_Day28Mailing_SeqNo_MINOR*** in design view
    a. Delete the print table left over from the previous use of the query.
    b. Pull in the **MINOR** print table for the institution.
    c. Link it to the Day28MailingALL query by CCSSID
    d. Change the data source for Seq_num field to <u>this institution's print table</u>

e. Remove the PREVIOUS institution's print table.
f. Sort the query by SeqNum
g. See if any have died. If so, request record be changed to minor to deceased print table
h. See if any have turned 18 or will turn 18 in the next 14 days. If so, request record be changed to adult print table.
i. **Save** the query design

4. DECEASED: Open ***qry_INST_Day28Mailing_SeqNo_DECEASED*** in design view
    a. Delete the print table left over from the previous use of the query.
    b. Pull in the DECEASED print table for the institution.
    c. Link it to the Day28MailingALL query by CCSSID
    d. Change the data souce for Seq_num field to this institution's print table
    e. Remove the PREVIOUS institution's print table.
    f. Sort the query by SeqNum
    g. **Save** the query design.

5. IMPORTANT: If there were adults or minors who have died, or minors who turned 18, you must WAIT until changes from one print table to another are made before generating the data files. THEN rerun the queries and output them to Excel!

6. Output each of the queries to excel, adding inst name and n-count to excel file name.

7. Once you output all 3 data files output for the production group, double-check the n-count to be sure you have everybody in the list accounted for in one of the seqNo files.

8. Open ***qry_INST_Day28Sent_MakeTable*** in design view
    a. Run the query
    b. This will add the CCSSID of each record in the Day28MailingALL to the table "**tblDay28Resent**", deleting the table that was left from the last time.

9. CAUTION: You need to run this MakeTable query RIGHT AFTER you produce the data files.

10. NOTE: if any records are REMOVED from production (due to received survey), find the record in the **tblDay28Resent** and DELETE IT.

AFTER the surveys have been sent:

11. Open ***qry_INST_Day28Mailing_PostResendDate*** . This shows fields to update, for every record in tblDay28Resent.

12. Scan through the records to find records which have already had a resend. Post their resend date/mode (2) by entering them in the "next available" resend date field.

13. Work back through the records, posting the resend date in "next available" slot, until you are down to resend1.

14. Locate any records with a RESENDREQUEST/DATERESENDREQUEST. (S/b NONE due to query criteria!)
    a. If the DATERESENDREQUEST occurred during the resend window, it's possible we have gotten a new address that was not reflected in the data files sent to the production team. Investigate individually.
    b. Clear the request and request date (for those that are older than the resend window).

15. NOTE: What date to use for posting the resend: we decided to use the same "last day" for those that are sent over a span of days. This makes it easier than having to post an INDIVIDUAL date.

Revision Record Printed 7/6/2012 10:09 AM

Current Filename:		Recruitment Day28 Resend Queries ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/7/10	J.Bates	Initial Development

Recruitment Initial Mailing - Queries

Background

We mail initial recruitment materials to all eligible cases with viable addresses. Packets include Spanish materials for cases flagged as needing them. We refer non-viable addresses to the tracing center.

For initial mailings that include the baseline survey, we maintain institution-specific print tables in the recruitment database for each of the 3 groups: adults, deceased, and minors. We do not use print tables for initial mailings using the HIPAA only process.

This procedure outlines producing data files and updating the database after mailing the packets. (For more technical information, refer to the query directory.)

Procedures

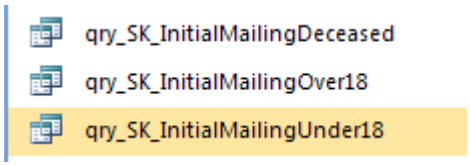
HIPAA only Packets

1. Create the initial mailing data tables using the **InitialHIPAA_Inst** queries.
    a. Open qry_JB_InitialHIPAA_Inst query and set the criteria for the instcod field (Institution code).
    b. Save the query.
    c. Export the query to Excel, replacing "Inst" in the file name with the institution name. Later, you will use the list of CCSSIDs from this file to identify which records need to have the DateInstHIPAAsent posted.
    d. Run each of the following queries, exporting each in turn to Excel, again replacing "inst" in the file name with the name of the institution.
        i. qry_JB_InitialHIPAA_Inst___Adults
        ii. qry_JB_InitialHIPAA_Inst___Deceased
        iii. qry_JB_InitialHIPAA_Inst___Minors
2. Create the production schedule and distribute the 3 data files (adults, deceased, and minors) to the production team.
3. After the packets are mailed, update the database with the mailing date in the DateHIPAAonlySent field. Clear any resend codes that may be on file. (Refer to the Query Directory for more information about posting the mailing date.)
4. Add the mailing date to the end of the excel file names. File the data files in the institution's !InstMailings folder on the server.

Survey Booklets (no longer in use)

1. Create initial mailing data tables using **InitialMailing** queries

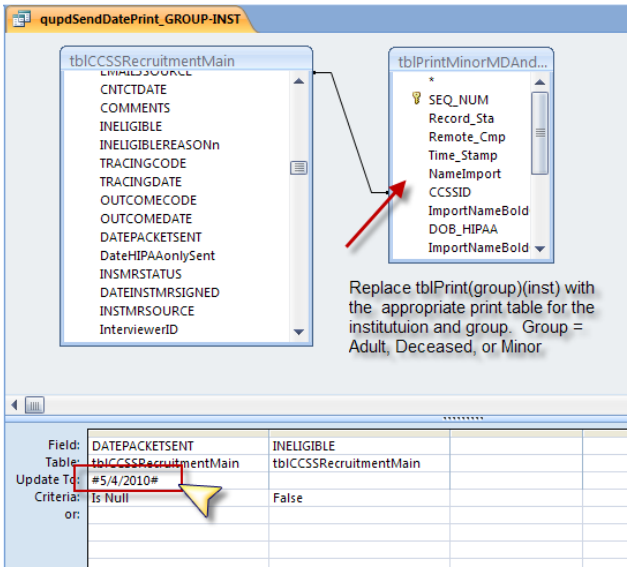
Create the initial mailing survey queries, based on the most recent institution mailed out. These 3 queries pull records from the institution-specific print table for adults, deceased, and minors. The queries present fields needed by staff to prepare the mail merge letters, mailing labels, and to identify the sequence number used in Teleforms Automerge publisher. These specific queries exclude ineligibles. (There will be a separate query for each different print table…. Deceased, Over18, and Under18).



2. Export each query to Excel.

3. After the data tables are distributed and the packets mailed, update the database with the DatePacketSent.

Open the query **qupdSendDatePrint_GROUP-INST** in DESIGN view. Add the institution's print table for the particular group (Adult or Deceased or Minor), then remove the print table that was left from the previous use. Key in update value for DatePacketSent. Test the query as a select query first, then run the update query. Repeat for each group (adult, minor, deceased).



4. Add the mailing date to the end of the excel file names. File these data files in the institution's !InstMailings folder on the server.

Revision Record
Last Printed: 7/2/2012 3:15 PM

Current Filename:		Recruitment Initial Mailing ver2.doc	
Revision No.	Date	Responsible Author	Change Description
1	11/5/10	J.Bates	Initial Development
2	7/7/11	J.Bates	Include initial HIPAA only mailings

Recruitment Packet Illustration - Former USC Institutions

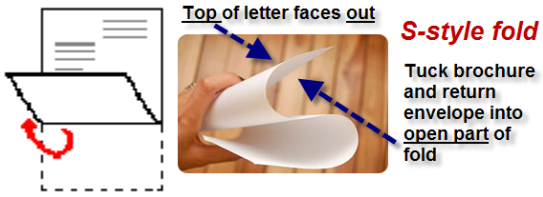
Background

We use the "HIPAA only" packet process to recruit the remaining individuals from the 7 institutions initially recruited by USC. We continue to use the #9 return envelopes for all materials, adding the MailStop 735-JBates labels to the #9 envelopes. However, instead of 10x13 mailing envelopes, we use standard business-sized envelopes, preprinted for each institution.

Procedure

English packets use the business-sized envelopes. As a result, we must FOLD documents before placing them in the envelope. Insert the ENGLISH documents into the business-sized envelopes in this manner:

1. Stack together:
   a. Cover letter (on top)
   b. Personalized HIPAA, with the contact information sheet stapled to it
   c. Participant copy
2. Hold the 3 documents together, and then fold them in thirds. In the second fold, the top of the letter (with the letterhead) should face outwards. (See sample for this S-style fold.)
3. Tuck the **brochure** and the **#9 return envelope** into the open part of the fold, behind the letterhead. (See sample.)



4. Insert into envelope, with letterhead facing *up* and facing the *back* of the envelope.
5. Attach the mailing address label to the front of the envelope.
6. AFTER QC is complete, use a moistener (with glue) to seal the envelope.

Spanish packets still require the larger 10x13 envelope so we can continue to include Spanish material envelope in addition to the English materials. The procedure is the SAME as we currently use for Spanish packets, with one exception: Since there are no preprinted 10x13 envelopes for these 7 institutions, we attach a preprinted return address label to a blank 10x13 envelope.

1. Spanish materials envelope includes (a) Spanish letter, (b) Spanish HIPAA, and (c) Spanish participant copy.
2. Insert Spanish materials into the 9x12 envelope that has the "Spanish Materials Enclosed" label on the outside.
3. Tuck the flap in, but do not seal it.
4. Paperclip the English documents, brochure, and return envelope together. Insert them into the 10x13 envelope, together with the 9x12 Spanish packet. Attach the institution-specific return address label to the 10x13 mailing envelope in the upper left corner. Attach the mailing address label to the front of the 10x13 envelope in the lower right quadrant.

Properly stuffing the #10 business envelope

Notice that the top front of the letter faces the BACK of the envelope. Tuck the brochure and #9 return envelope inside the fold (or behind the letter).

Revision Record

Printed 7/6/2012 8:13 AM

Current Filename:		Recruitment Packet Illustration-USC institutions ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	7/11/11	J. Bates	Initial Development

Recruitment Requested Resends - General Information

Background

This document summarizes what to include in requested resends sent to people who have NOT YET BEEN RECRUITED. (Also referred to as "recruitment requested resends"). The production schedule used to assign the batches specifies batches by institution, and type (Adult, Deceased, Minor). The Data file sent with the production schedule indicates what to send (packet only, or include $2) and whether a Spanish packet is needed. Inst 26 is the only institution where we send the teleform-generated Survey. All others use the "HIPAA only" documents

What to include

- **Brochure**
- Mail merged cover **Letter** (*institution and group specific*)
- Mail merged institution-specific **HIPAA-only document**. Select according to the group (e.g., Deceased or Living). HIPAA documents are located in the institution's InstHIPAA folder.
    - NOTE: For Inst 26, we send the teleform-generated recruitment full packet which includes the baseline survey, instead of the HIPAA-only document.
- Separately mail merged **Contact Information Update Sheet** (printed one-sided then stapled) (NOT used for Inst 26). Shortcut to this file is located in each institution's InstHIPAA folder.
- **Participant copy** (*institution-specific*; has watermark; all *except* Sloan-Kettering have separate deceased and living versions). Preprinted stock is available in the file cabinet. If needed, print fresh participant copies from the institution's main folder in the Expansion Recruiting folder. Printed double-sided and stapled if more than one page.
- **Return envelope**: Either the *Institution-specific* BRE (has PI name in the address) or #9 BRE with Mailstop 735 label.
- Insert assembled materials into the *Institution-specific* **mailer** (has institution-logo/address for return address). (Packets are sealed by the individual assigned to QA the batch.)
- Additional items:
    - **May or may not** include the pen and the $2. The data file tells you what to send
    - **Spanish inserts** (consult data file)
    - If packet includes the $2, be sure to paper clip money to letter to brochure.

LETTERS: mail merge the letter appropriate to the age and vital status specified in the production schedule. Letters are located in the institution's "IRB-Approved Letters" folder. Use the HIPAAonlyIntroLetter specific to the age/vital status group. For Inst 26, use **intro** (NOT the NonResponse) letter.

- Print all *except* St Jude letters in color so embedded institution-specific letterhead is in color
- Print St Jude letters on St Jude letterhead

Participant types

- Adults: use adult letter (GT18). Name of person used in mailing label address, inside address, and salutation
- Minors: use the minor letter (LT18). "The Parents of…." Used in mailing label address, inside address, and salutation

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- Deceased: use the deceased letter. "The Family of…." Used in mailing label address, inside address, salutation

STOP labels are institution-specific and survivor-specific. Used now **ONLY with Michigan**

- Located in the institution's folder in Z:…\ECC\CCSS\Expansion Recruiting\
- The institution's number is on the label
- Labels for deceased do NOT include the reference to completing the survey.

SURVEYS in Automerge Publisher: are institution specific AND participant type specific

Institution	PI	Participant copy information	Letter Location	HIPAA only merge documents
01: University of Minnesota	Joseph P. Neglia, MD	2 Separate versions: Deceased; Living (Adult/Minor)	Z:…\ECC\CCSS\Expansion Recruiting\##-InstName\IRB-Approved Letters…	Z:…\ECC\CCSS\Expansion Recruiting\##-InstName\InstHIPAA
02: Childrens (Denver)	Brian S. Greffe, MD			
03: Pittsburgh	Jean M. Tersak, M.D			
04: Stanford	Neyssa Marina			
06: Emory	Lillian R. Meacham, MD			
07: Children's National (CNMC, Washington)	Gregory H Reaman & Sadhna Shankar			
08: MD Anderson	Louise C. Strong			
09: Sloan Kettering	Charles Sklar	Same Living & Deceased		
11: UCSF	Robert E. Goldsby, MD	To be determined		
12: Seattle	K. Scott Baker, MD	Separate versions		
13: Toronto	Mark Greenberg	3 Separate versions: adult, minor, deceased		
15: St Jude	Melissa M. Hudson	2 Separate versions: Deceased; Living (Adult/Minor)		
16: Nationwide (Columbus Childrens)	Randal S. Olshefski, MD			
17: Roswell Park	Denise Rokitka, MD MPH			
19: Minneapolis Childrens	Joanna L Perkins MD MS			
20: Childrens Philadelphia (CHOP)	Jill Ginsberg			
21: St Louis Childrens (Washington U)	Robert J. Hayashi			
22: Childrens Los Angeles (CHLA)	Kathleen Ruccione			
23: UCLA	Jacqueline Casillas			
24: Riley	Terry A Vik, MD	Same Living & Deceased		
25: UAB	Kimberly Whelan	2 Separate versions: Deceased; Living (Adult/Minor)		
26: Michigan	Raymond Hutchinson			
27: UT Southwestern	Daniel C. Bowers MD			
28: Texas Childrens	Dr. Zoann Dreyer			
29: City of Hope	Smita Bhatia, MD			

Revision Record Printed 3/29/2013 11:29 AM

(21) Current Filename:		Recruitment Requested Resends - General Information ver 3_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	7/9/10	J.Bates	Initial Development
2	5/11/11	J.Bates	Update list; HIPAA information
2.1	9/28/11	J.Bates	Add USC institutions
3.0	3/29/13	J.Bates	Separate Information Sheet

Recruitment Requested Resends - Surveys and Institutional HIPAAs

Background

On a regular schedule, we check the recruitment database for survey (and institutional HIPAA) resend requests. These occur generally as a result of interview or tracing activity. Requests may be for the "full packet" (includes pen and $2), or the packet (without gifts). Certain resends will require also sending Spanish materials. When the materials have been sent, we update the database to record the resend and clear the request. NOTE: Refer to the recruitment query directory for detailed information about the separate queries involved in this process.

Procedures

1. Run **qry_JB_OpenResendRequests** to determine the total number of open requests. Export this query to excel to use subsequently as a master posting reference. Save to Desktop **Recruitment Resend** folder.

2. Run **qry_JB_OpenResendRequests_countWhat-v2.** Use the output from this query to generate the production schedule. The query shows, by institution, how many adult, deceased, and minor packets are needed, as well as how many also require Spanish inserts and/or gifts. Print this query.

3. **Generate the data files**.

   a. Use **qry_JB_OpenResendRequests_CountWhat-Inst_Group** as a guide to show you WHICH institutions, and subgroups you need. E.g., Denver needs adult, minor, and deceased; but MD Anderson only needs adult.

   b. Find the **OpenResendRequests_Inst_group** query for each needed institutional subgroup. Run the query, export it to excel. Leave the filename the same as the query name.

INS	instname	Counti	Adult	Decea	MINO
2	Denver Childrens	4	adult		
2	Denver Childrens	2			minor
2	Denver Childrens	2		decease	
8	U.T.M.D. Anderson Cancer Center	3	adult		
12	Seattle Children's Hospital	6	adult		
12	Seattle Children's Hospital	1			minor
12	Seattle Children's Hospital	1		decease	
15	St. Jude Children's Research Hospital	1	adult		
15	St. Jude Children's Research Hospital	1			minor
15	St. Jude Children's Research Hospital	3		decease	
16	Nationwide	2	adult		
21	StLouis Childrens	2	adult		
22	Childrens Los Angeles	3	adult		
22	Childrens Los Angeles				
26	Michigan				
26	Michigan				minor
29	City of Hope				

qry_OpenResendRequests_CHOP_Adult
qry_OpenResendRequests_CHOP_Deceased
qry_OpenResendRequests_CHOP_Minor
qry_OpenResendRequests_Denver_Adult
qry_OpenResendRequests_Denver_Deceased
qry_OpenResendRequests_Denver_Minor

   c. If there is no query for a needed institutional subgroup, you can make a copy (name the copy using the pattern currently in use) and then modify the copy. Copy the generic **qry_OpenResendRequests__Adults (or Deceased or Minor).** In the COPY, set the instcod value in the criteria.

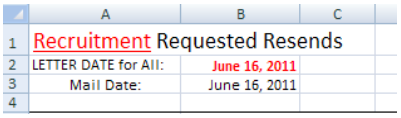
   d. Save to Desktop **Recruitment Resend** folder.

qry_JB_OpenResendRequests
qry_JB_OPenResendRequests__Adults
qry_JB_OPenResendRequests__Deceased
qry_JB_OPenResendRequests__Minors

4. **Generate the production schedule**. The schedule template provides space for each institution and material type, as well as space to indicate the number of Spanish and the number needing gifts. Enter the quantities per each, indicating how many need Spanish and how many need the gifts (w$2).

Batch	Institution	Type	Quantity		Lead production staff	Sp Pkt	w $2		QA
1	01-Minnesota	Adult	1		Lakesha Harris	0	1		Twanna
	01-Minnesota	Deceased	0						
	01-Minnesota	Minor	0						
			Inst Total	1				1	
2	04-Stanford	Adult	1		Lakesha Harris	0	0		Twanna
	04-Stanford	Deceased	0						
	04-Stanford	Minor	0						
			Inst Total	1				0	
3	08-MDAnderson	Adult	3		Lakesha Harris	0	2		Twanna
4	08-MDAnderson	Deceased	1		Lakesha Harris	0	1		Twanna
	08-MDAnderson	Minor	0						
			Inst Total	4				3	

a. Assign a batch number to each row needing production.
b. (Shade the rows where NO production is needed).
c. Assign production and QA staffing.
d. At the top of the schedule, key in the **Letter date** and **Mail date**.



	A	B	C
1	Recruitment Requested Resends		
2	LETTER DATE for All:	June 16, 2011	
3	Mail Date:	June 16, 2011	
4			

e. Save the schedule with the current date in the file name (e.g., **SCHEDULE-06-15-2011 Requested Resends-ALL**).

5. Distribute production schedule and data lists to the production team member(s) to generate the material.

6. PRODUCTION: Use mail merge, with the excel data file as data source, to generate appropriate cover letter, mailing labels, and (as applicable) institutional HIPAA. Include appropriate participant copy in the assembly.
   a. Each institution's documents are located in its institution-specific Expansion Recruitment folder.
   b. During production, staff request the number of $2 bills needed by batch. Log these in the cash register, and mark the deskcopy of schedule to indicate distribution. Bills are kept in the safe.
   c. See related procedures
      i. **Monetary Incentive Journal**
      ii. **Recruiting Packet Illustration (with Survey)**
      iii. **HIPAA-only Packet Production for Recruitment.**
      iv. For batches requiring printed surveys, see **Expansion Baseline Questionnaire Mailing** procedure. There should be a SeqNo in the data file for these batches.
      v. For Spanish cases, refer to the **Spanish Packets-Recruitment Materials** and **Merging Spanish Cover Letters and Authorization Forms.**

7. After batches are QA'd and put in the mail, staff notify the CRA2 by email. Check the batch off on the schedule.

8. Once all batches are put in the mail, **post the resend dates** and **clear the requests** in the database.
   a. Open the excel file you exported from running **qry_JB_OpenResendRequests** . Copy the columns containing the NeedsSpanish values and the CCSSID, including the row headers. Paste them on a new sheet. Name the sheet "___TEMP__ResentList". Save and close the excel file.
   b. In the recruitment database, import the external excel file you just saved.
   c. Create an ad hoc query (e.g., one that you do not save) that uses this imported table AND **tblCCSSRecruitmentMain.**
      i. Show fields for: needs Spanish, CCSSID, all the resend# fields, and the resend request and resendrequestdate fields.
      ii. As needed, also include the DatePacketSent and the DateHIPAAonlySent fields.
         1. Use these if any of the "resends" are actually a "first" mailing. This can happen when a case was put into immediate tracing while the rest of the institution's cases were being mailed. Once the address is found, a resend is posted.
         2. When that "resend" is mailed, the mailing date needs to be put in the appropriate *initial mailing field* (DatePacketSent, for surveys; DateHIPAAOnlySent for HIPAAonlys), not a "re"send field.
   d. Run the query to see which is the *highest* resend number needed. Then add the resend#mode fields for that resend and each resend below it.
   e. Set the criteria: with each resend = not null.

f. Process each resend# (in DESCENDING order) the same way: That is:
   i. Set criteria: (highest resend-x is null and each smaller Resend is NOT NULL): view query to be sure correct number of records are selected.
   ii. Change the query to an update query, updating:
      1. Clear the previous update values
      2. Update the highest Resend#date to the appropriate date.
      3. Update the matching RESEND#MODE to "7" (this is presuming all were HIPAAonly batches. For Michigan—instcod 26—cases, the resend#mode value is "2" (packet).)

Field:	RESEND1	RESEND1MODE	RESEND2	RESEND2MODE	RESEND3	RESEND3MODE	RESEND4	RESEND4MODE
Table:	tblCCSSRecru	tblCCSSRecruitmentM	tblCCSSRecru	tblCCSSRecruitmentM	tblCCSSRecru	tblCCSSRecruitmentM	tblCCSSRecrui	tblCCSSRecruitmentM
Update To:							#6/30/2011#	"7"
Criteria:	Is Not Null		Is Not Null		Is Not Null		Is Null	
or:								

   iii. Change query back to a select query and run it. You should see no records displayed
   iv. Repeat this process (i-ii), each time setting the next smaller resend date to IS NULL, until you have updated all records, using each record's "next available" resend field.
   v. Request a demonstration of this process to be sure you understand how to proceed.
   vi. After posting the resend# dates and resend#mode values for each case, clear the criteria so you can view all records.

g. **Clear the resend request codes and dates**. Change the query to an update query. Clear the previous update values, and set the update values for the ResendRequest and ResendRequestDate fields to null.

h. **Spanish**. Check for records that were to receive a Spanish packet. Look the records up in the database to determine whether a Spanish packet was sent initially. If it was NOT, then add a note in recruit notes to indicate that "Resend-x included Spanish materials".

i. After recording all the posting information, delete the **___TEMP___ResentList** table.

9. FILING:

a. Add the mailing date to the end of excel each data file.

b. Copy each institution's data files into the respective folder for mailings (e.g., **…ECC\CCSS\Expansion Recruiting\9-SloanKettering\SloanKettering_Mailings)**

c. Move the master list ("ALL" records), the individual data files, and the calendar in your local COMPLETED folder.

Revision Record Printed 7/6/2012 9:10 AM

Current Filename:		Recruitment Requested Resends ver2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/5/10	J.Bates	Initial Development
1.1	10/7/10	J.Bates	Participant copies
1.2	11/5/10	J.Bates	Standardizing format
1.3	12/8/10	J.Bates	Test for HIPAA only and Spanish packet
2.0	6/30/11	J.Bates	Major revision to match existing process

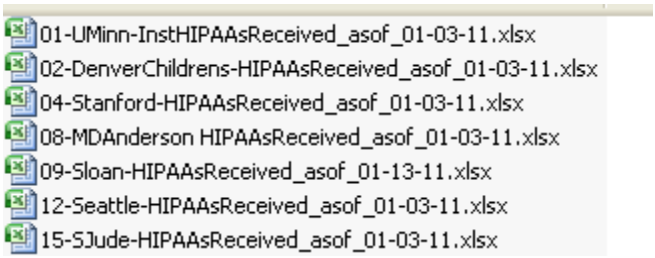
Recruitment Update Lists for Data Managers

Background

At the close of each month, we generate a comprehensive list of cases recruited to the LTFU study for each institution. We email this list through encrypted email to the data manager. This provides the data manager with a list of the cases whose photocopied medical records they are now authorized to release to us.

Procedure

- In recruitment database, use the query **qry_eligible-InstHIPAAsReceived_as_of_date**.
- Open the query in design view, and enter the instcod for a single institution.
- Save the query
- Export it to excel
- In the filename, add the instcod to the start of the file name, change "INST" to the institution name, and change "date" to the current date in mm-dd-yy format. E.g.:



- Store the file in the folder **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\Updated Recruited Lists for Institutions**
- After each institutional files are generated, put them into a date-specific subfolder in the above directory.
- Check the content of each institution's file to be SURE the cases belong to that institution.
- Email the file to the data manager using an encrypted email.

Revision Record — Printed 7/1/2015 3:27 PM

[128] Current Filename:		Recruitment Update Lists for Data Managers ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	2/2/2011	J.Bates	Initial Development
2	7/1/2015	L.Harrison	Revised, using new query for those found to be ineligible in Expansion Tracking and changing method of transfer to data manager from SJ Share site to encrypted email.

REDCap Instructions for CHIIP Non-Responder Calls

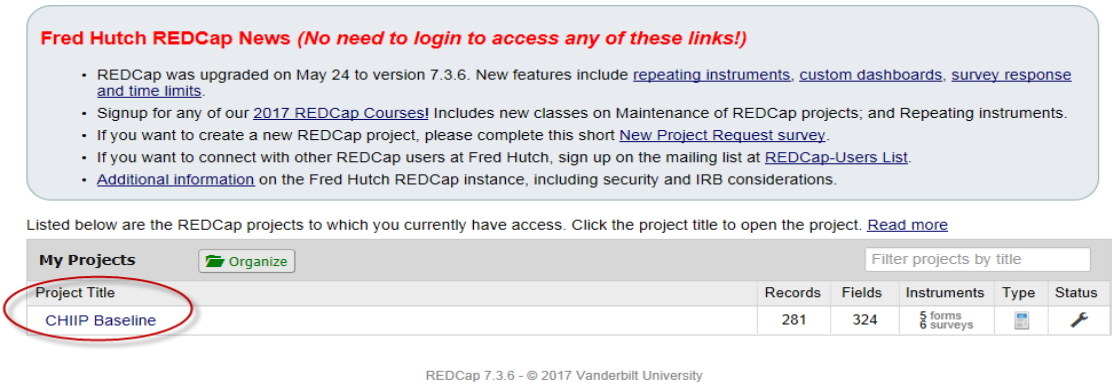
Background

REDCap is a secure web application for building and managing online surveys and databases. The REDCap website contains records for all CHIIP participants and is used to complete the CHIIP Enrollment Process and Baseline Survey.

Procedures

Getting to the CHIIP REDCap project:

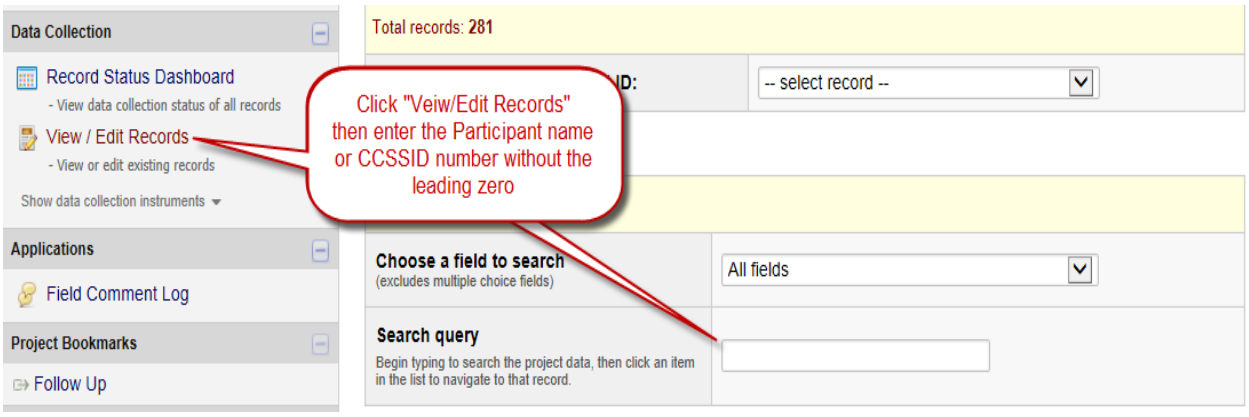
1. Go to: https://cdsweb07.fhcrc.org/redcap/
2. Log in
3. Click "My Projects" at the top of the page, then select "CHIIP Baseline"



**Depending on your access permissions, you may have different options displayed than the ones above.

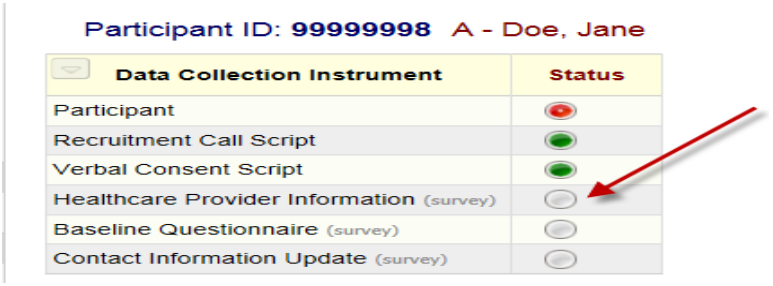
Searching for a Participant:

1. Click **View/Edit Records** in the navigation pane on the left of the screen.
   - In the "Search Query" search bar type in the participant's name or ID number.
   - Click on the participant to go to the participant instrument.

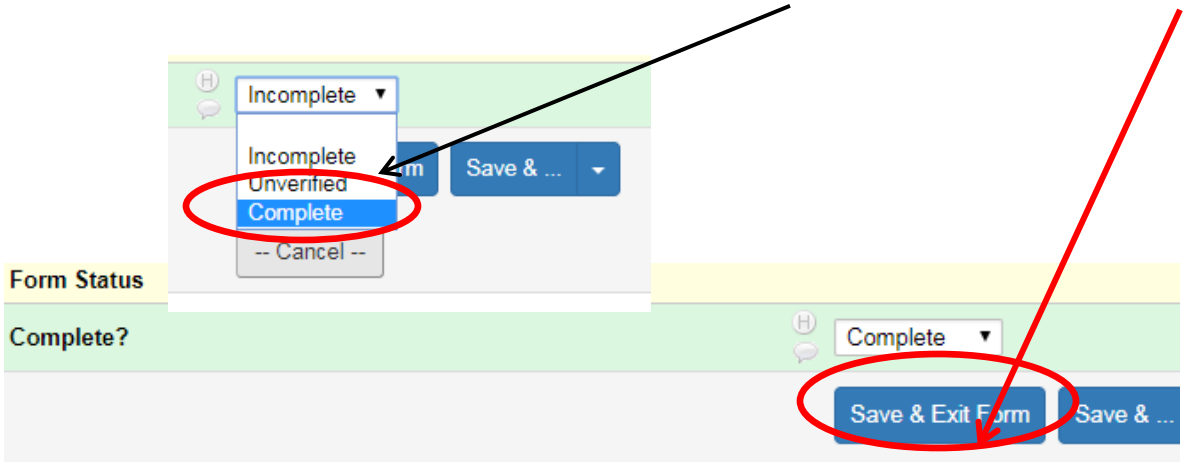


Survey Interviewer

During the Call:



1. Click on the first clear radio button to begin completing the CHIIP enrollment process with the participant.
   - As you go through the process and record the participant's responses, automatic skip logic will lead you through the process.
   - Once finished, change the form status at the bottom to complete. Be sure to click **SAVE.**

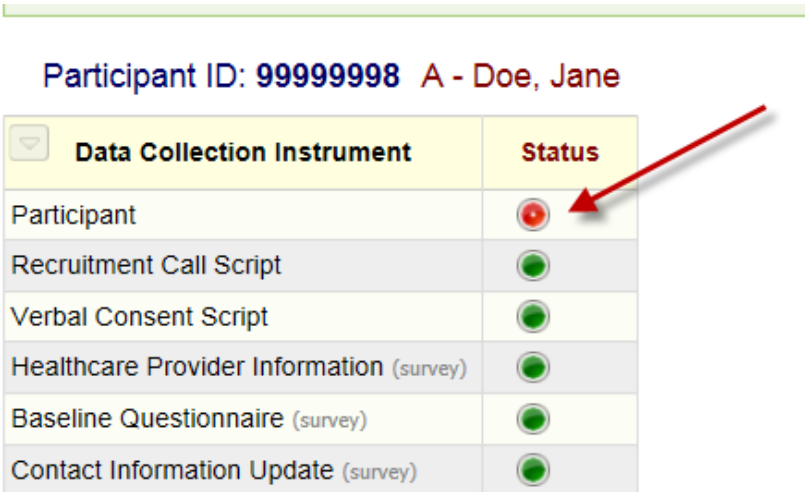


2. Continue to select each clear radio button until the CHIIP enrollment process is complete.

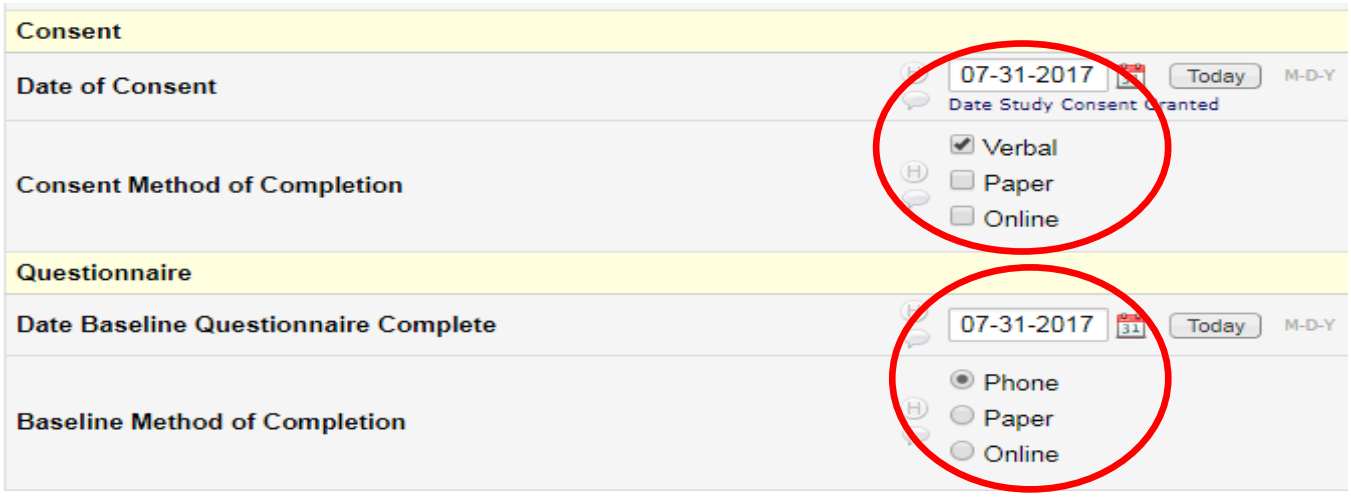
After the Call:

After completing an interview, a few things need to be entered into the participant instrument.

1. Go to the participant instrument.
2. Scroll down to "Baseline Items". Check off which items were completed during the interview. Items that could have been completed are in red.



3. If you select the questionnaire or the study consent, additional fields will display below the baseline items. Enter the date that these were completed and the method of completion



4. Click Save at the bottom of the page once you have logged the completed forms.

5. If a participant provides <u>new</u> contact info, click the "Contact Information Update" instrument.
   a. This displays the contact info currently in REDCap and provides a place to record updated contact information.
   b. Change the form status to complete and click Save once you are done.

Revision Record Printed

Current Filename:		REDCap Instructions for CHIIP Non-Responder Calls v1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/10/2017	A. Cobble, D. Rinehart, R. Daniels	Initial Development

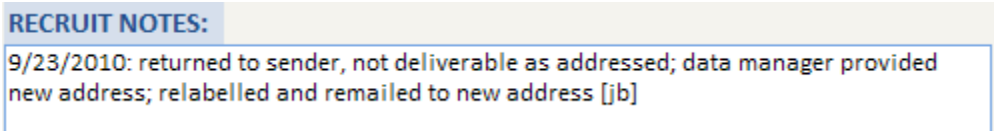
Remailing Recruiting Packets Returned to Sender

Background

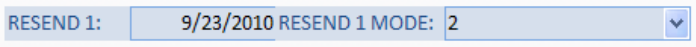
When the data manager returns undeliverable recruitment packages to us AND provides us with new addresses, we can resend the packets using the new address, if not too much time has elapsed.

Procedure

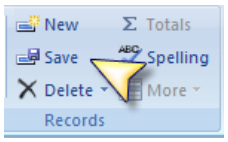
1. Find the CCSSID in recruitment
2. On the **TRACKING** tab:
   a. **FULLY ANNOTATE** the situation using the **Recruit Notes** field. This note needs to explain (i) the post office RETURNED the package; (ii) the reason the Post Office gave; (iii) the fact that the data manager provided new address, and (iv) the fact that we simply relabeled and resent the pkg to the new address. The DATE for the note needs to be the date you are writing the note (not the postmark date and not the date on the Post Office label). Be sure to add YOUR initials to the end of the date. E.g.,
      i. *mm/dd/yy: Returned to sender, attempted not known. Data Manager provided new address; packet relabeled and remailed [inits]*

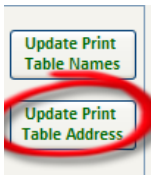


   b. Find the "*next available*" **Resend/ResendMode** field. (That is, if there already is a date in RESEND 1, but RESEND 2 is blank, RESEND 2 is the "next available.") In most cases, you will probably be using RESEND 1.
      i. In **Resendx**, record the DATE you will be putting the relabeled packet in the mail
      ii. In **ResendxMode**, record "2"



3. On the QUEST tab:
   a. Click **Archive Address** button. This appends existing address to Archive Addresses.
   b. THEN, key in the NEW address. *If name is in all caps, key address in all caps as well.*
   c. Record **address date**
   d. Select "Data Manager" from **Address Source** dropdown box
   e. Click the **Save** icon on the Records portion of the tool ribbon
   f. Click the **Update Print Table ADDRESS** button





Lead CRA

FINALLY,

- In a SEPARATE WORD document set up for printing **Avery 8163** address labels, manually enter the new mailing address and CCSSID. Be sure to include "The Parents of…." Or "The Family of…" in cases where the ORIGINAL was addressed that way. (I can provide you with a template for this if you need one.)
- **PRINT** collection of mailing labels after you process all the returns.
- Then put a **label** on a NEW white mailer (be sure it is for the same institution). Pull the contents from the returned packet (be sure to get everything), insert into labeled envelope, and set aside for QA/mailing.
- Return original white mailer to lead CRA for final QA.

Revision Record Printed 7/6/2012 10:18 AM

Current Filename:		Remailing Returned Recruitment Packets ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/23/2010	J.Bates	Initial Development

Requesting "No Proxy Available" Determination

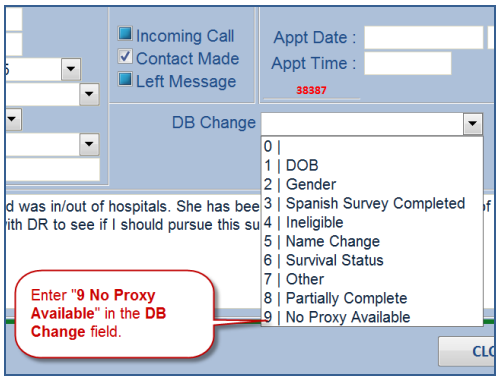
Background

In the Long-Term Follow-Up (LTFU) Study, there are individuals enrolled in the study, are 18 or older and alive, but are unable to participate without the assistance of a legally authorized representative (LAR) or approved proxy. These individuals may have consented to the study on their own but now have LAR or proxy who participates on their behalf OR were enrolled in the study by a LAR. During the course of the study, we may discover (via Survey Interviewer (SI) contact, email, or written note) there is no proxy now available for the participant. When an SI learns of these situations, s/he should alert the leadership team that the participant may need to be coded as a "No Proxy Available" participant.

Procedures

When an LTFU Study participant is unable to represent himself/herself to participate in the study and a proxy is unavailable to act on their behalf, communicate this information via the contact or trace log in the appropriate database.

1. **DB Change** field – Populate with 9-No Proxy Available.
2. **Notes** field – Fully explain the circumstances discovered and why it is believed this participant should be coded as "No Proxy Available".



The process is identical for the CCSS Recruitment database, the CCSS Expansion Tracking database, and the LTFU Participant database.

The Lead Survey Interviewer (LSI) team will review the request with the leadership team and code the record based on the final determination of the Call Center Coordinator or the Research Scientist. The study team will periodically review participant records to determine if attempts to re-establish contact are appropriate.

Revision Record

Printed 4/3/2015 7:25 AM

[290]Current Filename:		Requesting No Proxy Available Determination ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	3/13/15	D. Rinehart, R. Massey, J. Ford	Initial Development

Requesting Participant Copies of Informed Consent

Background

Before beginning a telephone survey, interviewers read an IRB-approved informed consent script to participants to obtain their consent to participate in the LTFU Study. It is important that each participant has a copy of the informed consent document for his or her records.

Some participants (e.g., the proxy of a participant known to be deceased, a participant that moved just after completing the HIPAA) may not have previously received a copy of the consent form. For these participants, the Survey Interviewer (SI) will ascertain where to send the copy of the informed consent and in what format the participant prefers to receive it (email or hardcopy).

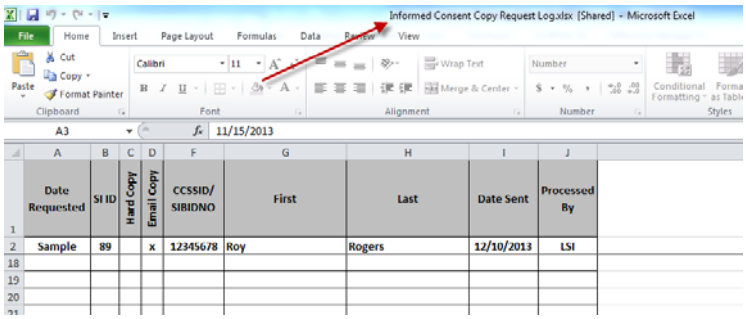
Procedures

NOTE: We currently do not have an approved Spanish participant copy of the Informed Consent. Spanish-speaking interviewers should explain this to Spanish-speaking proxies and participants and advise that we will be sending their copy in English.

Expired Surveys

After obtaining informed consent from the proxy for an expired case or expired sibling:

1. Advise the proxy that the LTFU Study will send a copy of the consent form to them for their records.
2. Ask the proxy if he or she has an email address to which we can send the copy.
    a. If yes, document the email address in the database, and update the email address date and source.
    b. If no, we will send a hardcopy.
        i. Confirm the mailing address to which the copy should be sent.
        ii. Follow the appropriate procedures to update or confirm the mailing address in the database, updating the date and source for the address.
    c. If the proxy refuses to receive a copy of the consent form:
        i. Clearly document the refusal in the telephone contact log.
        ii. Add a dated note to the **Comments** field of the Quest tab (for cases) or the Sib Info tab (for siblings) clearly documenting the refusal, and include your SI ID.
        iii. Skip steps 3 – 5, below.
3. Open the copy request form **Informed Consent Copy Request Log**, located at *Z:\SJShare\SJCOMMON\ECC \Interviewers\Expansion Survey Calls*.
4. Populate the first empty row using the column headings as a guide.



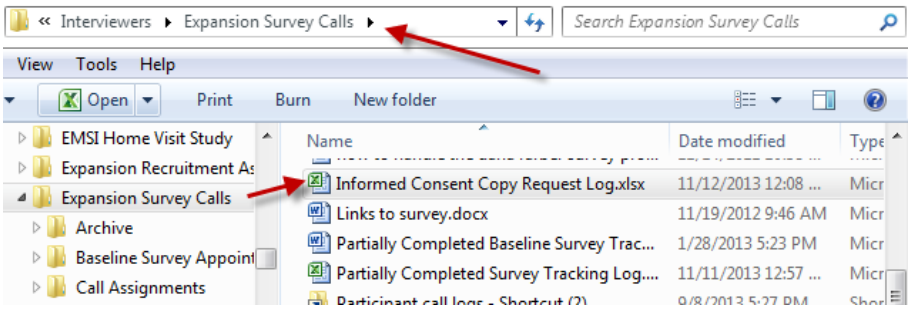
a. Enter the **Date Requested** (the date the consent was completed with the proxy).
b. Enter your **SI ID**.
c. Type an "X" in EITHER the **Hard Copy** column OR the **Email Copy** column.
d. Enter the **CCSSID/SIBIDNO** number.
e. Enter the **First** and **Last** name of the participant.
f. Leave the **Date Sent** and **Processed By** columns blank. These columns are for the party processing the copy request, indicating when the processing is completed.
g. Save and close the file.

5. A LSI or the assigned designee will process the request.

Alive Surveys

After obtaining verbal informed consent from the participant or the LAR:

1. Ask if the participant previously received our survey packet.
   a. If yes, the participant or the LAR already received a copy of the informed consent, and no further action is necessary.
   b. If no:
      i. Advise the participant or LAR that the LTFU Study will send a copy of the consent form to them for their records.
      ii. Ask the proxy if he or she has an email address to which we can send the copy.
         1. If yes, document the email address in the database, and update the email address date and source.
         2. If no, we will send a hardcopy.
            a. Confirm the mailing address to which the copy should be sent.
            b. Follow the appropriate procedures to update or confirm the mailing address in the database, updating the date and source for the address.
         3. If the proxy refuses to receive a copy of the consent form:
            a. Clearly document the refusal in the telephone contact log.
            b. Add a dated note to the **Comments** field of the Quest tab (for cases) or Sib Info tab (for siblings) clearly documenting the refusal, and include your SI ID.
            c. Skip steps 2 – 4, below.
2. Open the copy request form **Informed Consent Copy Request Log**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls*.
3. Populate the first empty row using the column



headings as a guide.

a. Enter the **Date Requested** (the date the consent was completed with the participant).
b. Enter your **SI ID**.
c. Type an "X" in EITHER the **Hard Copy** column OR the **Email Copy** column.
d. Enter the **CCSSID**/**SIBIDNO** number.
e. Enter the **First** and **Last** name of the participant.
f. Leave the **Date Sent** and **Processed By** columns blank. These columns are for the party processing the copy request, indicating when the processing is completed.
g. Save and close the file.

4. A LSI or the assigned designee will process the request.

Revision Record Printed 4/21/2014 2:05 PM

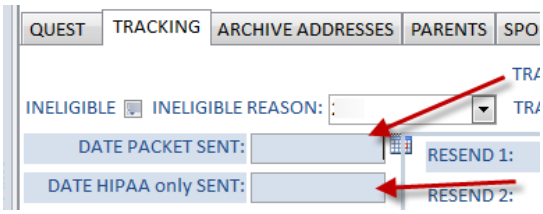
Current Filename: [268]		Requesting Participant Copies of Informed Consent ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	4/19/2014	R. Massey, D. Rinehart	Initial Development

Requesting Participant Copies of HIPAA during Recruitment

Background

In the process of completing a verbal HIPAA authorization (especially during tracing calls), you may determine that the participant never received a packet from us. There may be several reasons (e.g., we mailed to an obsolete address, the postal service lost the packet) but regardless of the reason, we must ensure that the participant has received a copy of the HIPAA authorization form.

IMPORTANT NOTE: If the fields **DATE PACKET SENT** or **DATE HIPAA only SENT** in the Tracking tab of the Expansion Recruitment database are blank (null), that means that a survey or HIPAA packet was never mailed to the participant. ***It is critical that you add the date*** that you completed the HIPAA in the field **DATE HIPAA only SENT** before leaving the record (Do not order a resend via the Expansion Recruitment database).



Procedure

After you complete the established recruitment script, say:

> "Thank you for deciding to participate in the Long-Term Follow-Up study. I am going to send you a copy of the authorization form we just completed. May I email your copy to you?"

If **Yes**:

- Say:

  > "Great! I will send your copy to (*verify their email address*). You should receive your copy within the next few days. Once you receive it, please feel free to call us if you have any questions."

- Then:

  - Add a note in the **Recruit Notes** field of the **Tracking** Tab to indicate that the participant wants their HIPAA copy emailed to them.
    - Open the **HIPAA Participant Copy Request Form** file, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Verbal HIPAA*, and enter your request as outlined below.

If **No**:

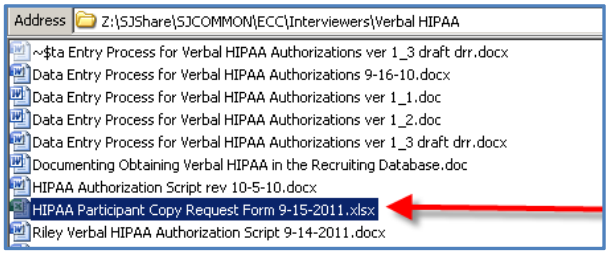
- Say:

> "No problem. I will mail your copy to (*verify their mailing address*). You should receive your copy from us within the next week. Once you receive it, please feel free to call us if you have any questions."

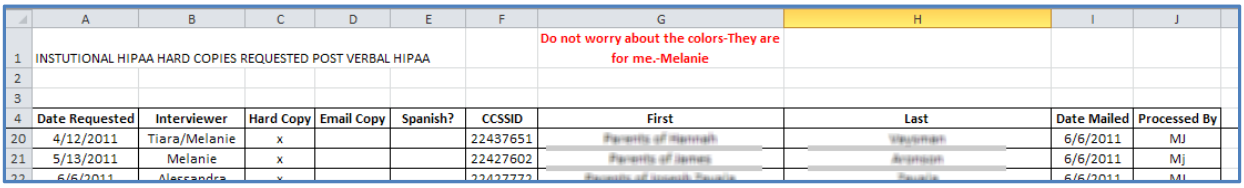
- Then
  - Add a note in the **Recruit Notes** field of the **Tracking** Tab to indicate that the participant wants their HIPAA copy sent via US Mail.
  - Open the **HIPAA Participant Copy Request Form** file, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Verbal HIPAA*, and enter your request as outlined below.

Completing the HIPAA Participant Copy Request Form:

1. Open the Excel file **HIPAA Participant Copy Request Form** rev 5 located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Verbal HIPAA*.
   a. Enter **the Date Requested.**
   b. Enter your first name in the **Interviewer** column.
   c. Type an "X" in *EITHER* the **Email Copy** column for Email copies *OR* in the **Hard Copy** column for US Mail.
   d. Also type an "X" in the **Spanish?** column *if the particpant needs the Spanish version of the HIPAA form*.
   e. Enter the **CCSSID** number.
   f. Enter the **First** and **Last** name of the participant.
   g. Leave the last two columns labled **Date Mailed** and **Processed By** blank. These columns are for the party processing the copy request, indicating when the process is completed.



2. Save and Close the file.



	A	B	C	D	E	F	G	H	I	J
1	INSTUTIONAL HIPAA HARD COPIES REQUESTED POST VERBAL HIPAA						Do not worry about the colors-They are for me.-Melanie			
2										
3										
4	Date Requested	Interviewer	Hard Copy	Email Copy	Spanish?	CCSSID	First	Last	Date Mailed	Processed By
20	4/12/2011	Tiara/Melanie	x			22437651	[redacted]	[redacted]	6/6/2011	MJ
21	5/13/2011	Melanie	x			22427602	[redacted]	[redacted]	6/6/2011	Mj
22	6/6/2011	Alessandra	x			22427772	[redacted]	[redacted]	6/6/2011	MJ

Revision Record

Printed 8/13/2013 11:46 AM

Current Filename:		Requesting Participant Copies of Recruitment HIPAA ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1.0		D. Rinehart	Initial Development
1.1	5/17/12	Procedure Team	Content and format editing
1.2	7/30/2013	R. Massey	Update Content
1.3	8/9/2013	D. Rinehart	Update Content

Resources for Locating Addresses and Phone Numbers

Tips and Suggestions
• Try all of the participant's contact information first - address, phone, work phone, cell, e-mail address, etc. • Try all listed contacts and all listed contact information for those individuals. • Check a free online people search engine (listed below) to see if you can find a current address and/or phone number. See if there is a spouse or parent listed, maiden name. • Check free searchable vital status websites • If the participant's home phone number still works (not disconnected) but you aren't sure if he/she is still at that number, try a reverse phone search on one of the websites listed on the previous page to determine who is currently at that number • If you aren't sure if he/she is still at the listed address, try a reverse address search on one of the websites listed on the previous page to determine who is currently at that address • Try calling 411 • Mail a letter to the old address with a label on the envelope reading "Change service requested." The post office should send it back with the correct address on a yellow label. This service is typically available for one year. • If you have a good address but cannot find a phone number, send a "teleletter". • Once free databases have been exhausted - submit request for use of for fee resources (listed below).

FREE Search Websites	
http://www.whitepages.com	Search by name, city, state, reverse address, reverse phone (can also look up area codes and zip codes)
http://people.yahoo.com/	Search by name, city, state, includes link to Canadian phone and address search
http://www.canada411.ca/	Search by name, city, state, reverse address, reverse phone (can also look up area codes and zip codes)
http://www.infospace.com/home/white-pages	Search by name, city, state, reverse address, reverse phone
http://www.freeality.com	Links to several people search engines that are free
http://www.searchbug.com	Search by name, city, state, reverse address, reverse phone, SSN verification up to 10 free searches per day
http://www.bop.gov/inmate_locator/index.jsp	Federal inmate locator
www.switchboard.com	Must have both name and city/state OR zip
http://www.whitepages.com/5116/person	Search by name, city, state, reverse address, reverse phone

FREE Search Websites	
http://www.webcrawler.com/info.wbcrwl/white-pages/	Search by name address, city/ state, reverse look-up
http://www.personlookup.com	Links to several people search engines; some are free
http://google.com	Search by name, address, or phone number

FREE Vital Status Search Website	
http://www.searchbug.com/peoplefinder/verify-ssn-free.aspx	10 free searches per day; indicates if SSN is active or inactive
http://ssdi.rootsweb.com/	Searchable database for vital status by SSN
http://www.obitcentral.com/	Searchable database of obituaries
http://www.legacy.com/Obituaries.asp	Searchable database of obituaries

FEE-BASED Services

- Fee based people search- Metronet & AutoTrac
- National Death Index search
- Post office change of address service
- Social Security Vital Status Search
- Experian

Revision Record

Printed 7/16/2012 1:21 PM

Current Filename:		Resources for Locating Addresses and Phone Numbers ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development

Restocking Call Center Form Supply

Background

Efficient Call Center operations require the availability of multiple paper forms for Survey Interviewers (SIs) to use during their daily routine. The supply of blank copies of these forms should be routinely checked and, when necessary, replenished. In order to conserve resources, all forms will be printed in 2-sided format when possible.

Procedures

In the short file cabinet under the Call Center's dry erase board, check the top drawer for the following folders and forms. If any folder is running low on the corresponding forms, print more *2-sided copies* from the location indicated and restock the forms:

1. Folder "Blank Expired Info. Sheets" for **Expired Participant Information Sheets**: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools* to the black-and-white printer (epi_laser1). Choose the document **Expired Participant Information Sheet**.

2. Folder "Riley (24) V.H. Blank Forms" for Riley verbal HIPAA forms: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Recruitment\Verbal HIPAA\Riley (24)* to the black-and-white printer (epi_laser1). Choose the document **Riley (24) Verbal HIPAA Information Sheet**.

3. Folder "Blank Informed Consent - Baseline" for expansion case baseline informed consent forms: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Scripts* to the black-and-white printer (epi_laser1). Choose the document **Informed Consent with Incentive Expansion Baseline**, and print only pages 2 and 3.

4. Folder "Informed Consent EXPIRED CASES" for expired expansion case baseline informed consent forms: Print more forms from forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Scripts* to the black-and-white printer (epi_laser1). Choose the document **Informed Consent with Incentive, Expired Expansion Baseline**.

5. Folder "Blank Surveys Baseline Adults" for expansion case baseline paper surveys for adult participants: There should be at least THREE copies of the survey. Print more surveys from *Z:\SJShare\SJCOMMON\ECC \Interviewers\Expansion Survey Calls\Surveys* to the color printer (epi_c-laser2). Choose the document **Baseline Expansion 2007 Adult v14**. Use a binder clip or large paper clip to secure each survey together.

6. Folder "Blank Surveys Baseline Minor" for expansion case baseline paper surveys for minor participants: There should be at least THREE copies of the survey. Print more surveys from *Z:\SJShare\SJCOMMON\ECC \Interviewers\Expansion Survey Calls\Surveys* to the color printer (epi_c-laser2). Choose the document **Baseline Expansion 2007 Under 18 v9**. Use a binder clip or large paper clip to secure each survey together.

7. Folder "Blank Surveys Baseline Expired" for expansion baseline paper surveys for deceased participants: There should be at least THREE copies of the survey plus the master copy. Print more surveys by photocopying the master copy in the folder. Use a binder clip or large paper clip to secure each survey together.

8. Folder "Additional Data Forms (BLANK)" for **New Contact Data Forms**: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Letters and Forms* to the black-and-white printer (epi_laser1). Choose the document **New Contact Data Form**.

9. Folder "Sibling Forms (A, B, & D)" for sibling permission forms A, B, and D: Note that there is a sub-folder for each of Form A, Form B, and Form D inside the hanging folder. Check each folder and form type. Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Letters and Forms\Recruitment* to the black-and-white printer (epi_laser1). Choose the document **Sibling Permission Forms SI Form Packet**, and print only the page number(s) for the form(s) needed.

10. Folder "Sibling Consent Forms (BLANK)" for expansion sibling baseline informed consent forms: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Scripts* to the black-and-white printer (epi_laser1). Choose the document **Informed Consent Expansion Sibling - Incentive**, and print pages 2 and 3.

11. Folder "Informed Consent -EXPIRED SIBS-" for expired expansion sibling baseline informed consent forms: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Scripts* to the black-and-white printer (epi_laser1). Choose the document **Informed Consent Expansion Sibling - Incentive, Expired**.

12. Folder "Blank Sibling Surveys Adult" for expansion sibling baseline paper surveys for adult participants: There should be at least THREE copies of the survey. Print more copies from *Z:\SJShare\SJCOMMON\ECC \Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Surveys* to the color printer (epi_c-laser2). Choose the document **Sibling-Baseline Expansion Adult Survey for SI**. Use a binder clip or large paper clip to secure each survey together.

13. Folder "Blank Sibling Surveys – Minor" for expansion sibling baseline paper surveys for minor participants: There should be at least THREE copies of the survey. Print more copies from Z*:\SJShare\SJCOMMON\ECC \Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Surveys* to the color printer (epi_c-laser2). Choose the document **Sibling-Baseline Expansion Minor for SI**. Use a binder clip or large paper clip to secure each survey together.

14. Folder "Blank Sibling Surveys – Expired" for expansion sibling baseline paper surveys for deceased participants: There should be at least THREE copies of the survey. Print more copies from *Z:\SJShare\SJCOMMON\ECC \Interviewers\Expansion Survey Calls\Expansion Sibling Cohort\Surveys* to the color printer (epi_c-laser2). Choose the document **Expired Sibling-Baseline Expansion for SI.ver2**. Use a binder clip or large paper clip to secure each survey together.

15. Folder "Blank EMSI Worksheets" for EMSI Home Visit Study call worksheets: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\EMSI Home Visit Study\Call Assignments* to the black-and-white printer (epi_laser1). Choose the document **EMSI Home Visit Pilot Study Call Worksheet**.

16. Folder "ASK Skin Cancer Consents" for ASK enrollment worksheets: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\ASK - Skin Cancer Study\Scripts* to the black-and-white printer (epi_laser1). Choose the document **CCSS Skin Cancer Consent Script rev 20 2 irb appr 10-13-14**.

17. Folder "LTFU RECONSENT FORM" for Follow-Up 5 (FU5) reconsenting forms: Print more forms from *Z:\SJShare\SJCOMMON\ECC\Interviewers\FU5\Procedures\Reconsenting Participants during FU5 Calls* to the black-and-white printer (epi_laser1). Choose the document **LTFU Study Age of Majority Reconsent Form_r1am**.

18. Folder "FU5 – Case – Adult" for Follow-Up 5 paper surveys for adult case participants: There should be at least FIVE copies of the survey. Print more copies from *Z:\SJShare\SJCOMMON\ECC\Interviewers\FU5\Surveys* to the color printer (epi_c-laser2). Choose the document **FU5 (SC) (50160 - Activated VersiForm)b**.

19. Folder "FU5 – Sibling – Adult" for Follow-Up 5 paper surveys for adult sibling participants: There should be at least FIVE copies of the survey. Print more copies from *Z:\SJShare\SJCOMMON\ECC\Interviewers\FU5\Surveys* to the color printer (epi_c-laser2). Choose the document **FU5 Sibling (64438 - Activated, VersiForm)_dr_1-6-2015**.

Upon completion:

1. Add the time spent on this project in your **Journal**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Journals*. See the SOP titled **Survey Interviewer Journal Data Entry** for details on how to use the **Journal**.

2. Update the document **Call Center Admin and Operational Assignments_mm-dd-yyyy**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Administrative*, to indicate the task is completed.

Revision Record Printed 3/18/2015 4:14 PM

[253] Current Filename:		Restocking Call Center Form Supply 1_3.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	7/23/13	R. Massey	Initial Development
1.1	3/26/14	R. Massey	Update folder names and file locations to current names/locations.
1.2	7/24/14	R. Massey	Add 2-sided directive, remove admin workbook directive, add FU5 survey
1.3	3/16/15	R. Massey	Update locations and file names, add directives for new documents.

Retrieving and Documenting Subsequent Neoplasm Final Reviews

Background

After the medical doctor acting as the CCSS's "final reviewer" analyzes the records obtained via the subsequent neoplasm (SN) project for reported SN conditions, s/he will make the final decision about whether the condition should be accepted into the CCSS's SN dataset. This adjudication is entered into an online survey program known as DatStat.

This SOP outlines the procedure for obtaining the DatStat final review data, obtaining related coding data, and using that data to update the SN project's tracking database. For information about sending records obtained via the SN project through the review process, see the SOP titled **Subsequent Neoplasm Pathology Report Reviews**, which precedes this procedure.

Procedure

Saving DatStat Data File

1. When the final reviewer reports that s/he has completed entry of their adjudications into DatStat:
   A. **Update** the **SN Batch Tracking** workbook, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN*.
   B. Ask the department's Director, Data and Systems, to **download and transpose the data** from a "wide" report to a "long" report (i.e. changing the downloaded data from displaying one row per CCSSID to displaying one row for each condition).

Batches for Final Review						
Pathologist Batch #	Final Batch #	Source	Number of Conditions	Date Sent For Final Review	Download Date	Date Final Review Received
	72	FU5 self-rpts	119	7/7/17	7/19/17 - Turcotte	7/30/17

      i. Remind the Director to include the leading zeros on the CCSSIDs.
      ii. Remind the Director to include the DatStat login/logout dates so the review date can be documented in the database.
2. **Save** the transposed file to the Z drive, adding the current date.
   A. Expansion batches
      i. Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, Expansion Baseline\Completed Final Reviews\DatStatBatches*.
      ii. Name the file **Completed SN Final Review, Exp Batch ## mmddyy**.
   B. FU5 batches
      i. Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, FU5\Completed Final Reviews\DatStat Batches*.
      ii. Name the file **Completed SN Final Review, FU5 Batch ## mmddyy**.
   C. FU6 batches

   i. Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, FU6\Completed Final Reviews\DatStat Batches*.
   ii. Name the file **Completed SN Final Review, FU6 Batch ## mmddyy**.
3. **Save a copy of the data dictionary**. Name the PDF file **Data Dictionary for Month YYYY Final Reviews**.
   A. Expansion batches – Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, Expansion Baseline\Completed Final Reviews*.
   B. FU5 batches – Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, FU5\Completed Final Reviews*.
   C. FU6 batches – Save at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, FU6\Completed Final Reviews*.
4. Open the DatStat download file.
5. Resave the file with "-REVISED" at the end of the file name.
6. Freeze the top row and make any other preliminary changes needed (e.g. add leading zero to CCSSIDs if it has been omitted).
7. Resave the file.

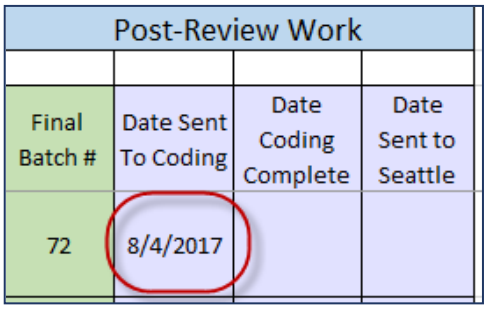
Request Coding for Accepted Conditions

Using the "-REVISED" Excel spreadsheet with the DatStat download data:

1. **Save a coding copy** in the appropriate network folder, below. Name the file by changing the "-REVISED" suffix to be "-With Coding" in the file name (e.g. **Completed SN Final Review, FU5 Batch ## mmddyy-With Coding**.)
   A. FU6 – Save the file at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, FU6\Completed Final Reviews\DatStat Batches – Coding*.
   B. FU5 – Save the file at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, FU5\Completed Final Reviews\DatStat Batches – Coding*.
   C. Expansion Baseline – Save the file at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN, Expansion Baseline\Completed Final Reviews\DatStatBatches – Coding*.
2. **Make the following updates to the file**:
   A. IMPORTANT: If copying any column to a new location, DELETE THE ORIGINAL COLUMN. Having duplicate columns in the worksheet can cause problems when the biostatistics team attempts to import the sheet into SAS.
   B. Add gridlines to the cells that have DatStat data.
   C. In the column titles row, highlight the cells to be light blue and format the cells to wrap the text.
   D. Just after the CCSSID column, add a column titled "In Db?" and then a column titled "Review Date." Highlight the columns pale orange.
   E. Just after the DX column, add a column titled "Dx Code." Highlight the column pale green.
   F. Move the Site column to be just after the Dx Code column. Be certain to delete the original column, as above.
   G. Just after the Site column, add a column titled "Site Code." Highlight the column pale green.
   H. Just after the Site Code column, add a column titled "Coder/Project Mgr Notes." Highlight the column pale purple.
   I. Move the Notes column to be just after the Coder/Project Mgr Notes column. Be certain to delete the original column, as above.
   J. Add a data filter to the adjudication column (ADJUDA).

K. Filter the sheet so that only rejected conditions display. Highlight the Dx Code and Site Code columns *for the displayed rows only* with a dark gray. Highlight the adjudication column *for the displayed rows only* in pale red.

3. **Share the spreadsheet**.
4. Sort the spreadsheet in CCSSID order, if it is not already in CCSSID order.
5. **Filter** to display only those conditions that were accepted. No gray and no red cells should now be displayed.
6. **Save** the changes.
7. **Send the file to the coders**. Ask/remind them to:
   A. Code directly in the network spreadsheet.
   B. Save after each entry since it is a shared Excel workbook.
   C. Highlight the Coder/Project Mgr Notes cell and the data cell in question (not the whole row) in the coding spreadsheet with yellow when there are questions.
   D. Use <Alt><Enter> if a cell already has a value/note and another needs to be entered.
   E. Notify the SN project manager when the coding is complete or when a meeting with the Principal Investigator and Project Director is needed.
8. **Update the SN Batch Tracking sheet** to indicate that the batches have been sent for coding.
9. When coding is complete, schedule a **meeting** with the Principal Investigator, Project Director, Research Scientist, SN Project Manager, and coding team if the coders have questions that need leadership input.
10. After the meeting to resolve coding questions, ask the coding team to make final adjustments and to alert the SN project manager when the FINAL codes are in the spreadsheet.

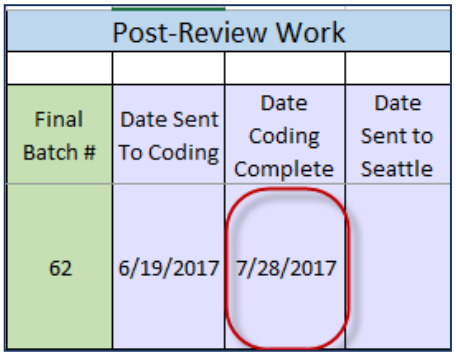


Post-Review Work			
Final Batch #	Date Sent To Coding	Date Coding Complete	Date Sent to Seattle
72	8/4/2017		

Documenting Final Review Adjudications

When the coders have finished coding the confirmed conditions, update the database with the final reviewer's findings.

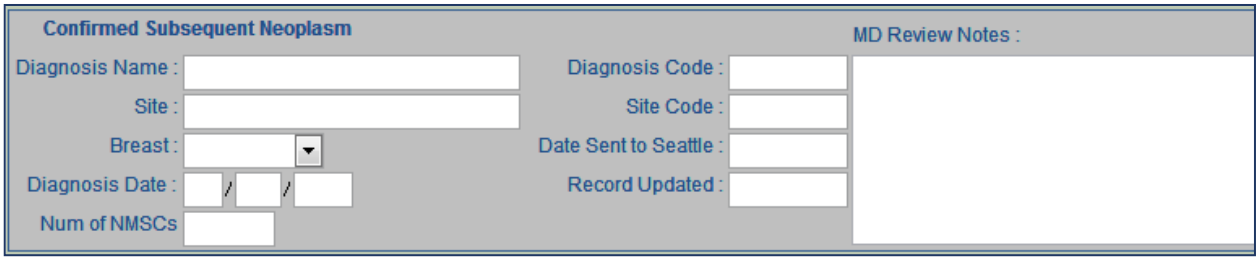
1. **Update the SN Batch Tracking sheet** to indicate that the batches have been returned from coding.
2. **Unfilter the spreadsheet** so that all conditions are displayed (accepted and rejected).



Post-Review Work			
Final Batch #	Date Sent To Coding	Date Coding Complete	Date Sent to Seattle
62	6/19/2017	7/28/2017	

3. **In the SNT database**, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx, locate the participant record and the condition record in question.
4. Confirm the **Source** is correctly recorded in the DatStat sheet. If not, update it in the sheet that will be sent to Seattle using the appropriate data dictionary.
5. **Date Returned 2nd Review** – Enter the date the final reviewer completed the review (from DatStat).

6. For accepted conditions, populate the following in the SNT database's Confirmed Subsequent Neoplasm group:



   a. **Diagnosis Name** – Copy the final reviewer's diagnosis name into this field.
   b. **Diagnosis Code** – Copy the coder's diagnosis code into this field.
   c. **Site** – Copy the final reviewer's site information into this field.
   d. **Site Code** – Copy the coder's site code into this field.
   e. **Breast** – Enter the breast laterality designated by the final reviewer.
   f. **Diagnosis Date** – Enter the diagnosis date specified by the final reviewer.
   g. **Num of NMSCs** – Enter "1" for NMSC diagnoses. This data is used by the Blood & Tissue project manager to filter conditions for that project's pursuit. See the Research Scientist or Senior Coordinator for guidance, if needed.
   h. **MD Review Notes** – Copy the notes from the final reviewer (and/or the pathologist, if appropriate) and paste into this field.

7. **Pursue Status** – Enter the appropriate outcome code based on the final reviewer's documented adjudication.
8. **Pursue Status Date** – Enter the current date.

9. **Condition Notes** – Document the changes made to **Pursue Status** and **Pursue Status Date**, above. Indicate what values the fields were changed from and changed to.
10. **If a question arises**, document the question in the coding workbook's Coder/Project Mgr Notes cell of the DatStat workbook. Do not enter anything into the tracking database until the question is resolved.
11. For items entered into the final review that represent **updates to previously confirmed conditions**, make and document the updates in the tracking database, then remove the row from the DatStat download worksheet. Seattle will need to be notified as an update. IMPORTANT: Populate the **Record Updated** field in the Confirmed Subsequent Neoplasm group to flag the condition as updated.
12. For large final review batches, consider modifying **qry_FinalReviewDataCheck_RM**, as appropriate, to **review and clean up data entry**. Ensure:
    a. All reviewed conditions have an updated outcome code.
    b. All accepted conditions have a confirmation record.
    c. All confirmation records have a dx date.
    d. All NMSC's have the appropriate flag in the confirmation record.
    e. All breast conditions specify laterality.
    f. All conditions sent for final review were returned.
    g. All flagged Seattle updates are removed from DatStat download, if appropriate.

Documenting Conditions Ready for Seattle

When the conditions in the Excel spreadsheet are fully documented and the data is ready to be submitted to Seattle, **log the batch** in the Excel workbook titled **Seattle Submission Tracking**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Seattle*.

Revision Record Printed 8/8/2017 3:18 PM

[304]Current Filename:		Retrieving and Documenting Subsequent Neoplasm Final Reviews v1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	8/8/2017	R. Massey	Combine 2 existing SOPs into a single procedure, overhaul process

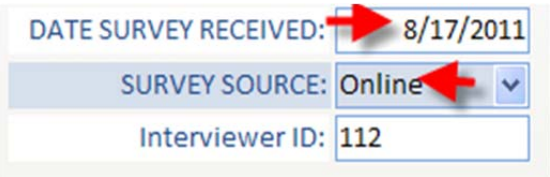
Retrieving Online Survey Responses for Comparison with Paper Responses

Background

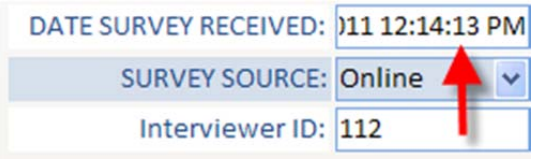
When a study participant (such as Fullerton Stroke and Insurance) submits two surveys, we must decide which set of data to use. The CRA2 compares the responses on both surveys to inform the decision (typically made by Aaron). Comparing two paper surveys is straightforward. However, when one survey is online, the online data set must first be retrieved. This procedure outlines locating, reviewing and comparing online survey data with paper survey data.

Procedure

1. **Determine when the Online Submission Occurred.** When a survey has been completed online, the Tracking tab shows Survey Source as **Online**. The value in **DateSurveyReceived** appears to be a date, but it may also include the time stamp from the submission. Having the *time stamp* submitted will help you more quickly identify the specific online record.



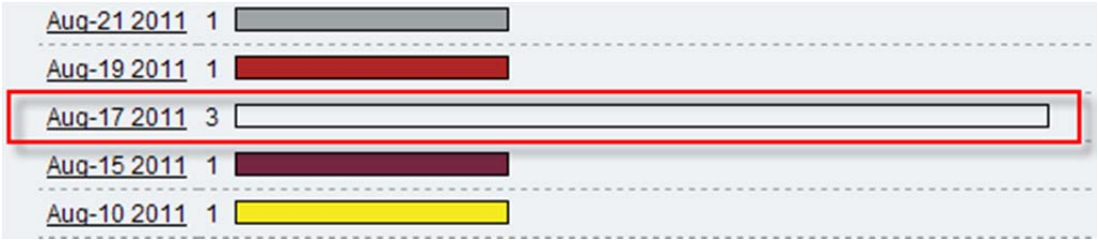
   a. To determine the time stamp, put your cursor in the **Date Survey Received** field (as if you were going to edit the field). Move the cursor past the date until you can see the time.



   b. Make note of this full date and time, but be careful NOT to modify the value. (If no time stamp is visible, note the date only.)

2. **Locate the Online Submission.** Open DatStat and logon to the system. Follow logon procedures used in the DatStat Daily Download morning routine.
   a. Select the survey you need from the list of CCSS projects.

   b. From the list of dates for online submissions, double click on the **DATE** that you need (the date from Date Survey Received).



c. If more than one online survey submission occurred on that date, you may use the time stamp to locate the appropriate row.

Page 1 of 1 (as of Dec-07 2011 10:15:43 AM)

Row	DATSTAT.SUBMISSIONID	DATSTAT.STARTDATETIME	DATSTAT.ENDDATETIME
1	95	Aug-17 2011 11:51:18 AM	Aug-17 2011 12:14:13 PM
2	96	Aug-17 2011 1:13:58 PM	Aug-17 2011 1:24:21 PM
3	97	Aug-17 2011 9:48:34 PM	Aug-17 2011 10:05:10 PM

(If you do not have a time stamp available, and there are multiple submissions for the date, double-click on the number for each row, in turn, until you locate the CCSSID you need. Read through the response set to find the CCSSID in question.)

d. Double-click on the **NUMBER** of the row for the appropriate submission. This opens the submission's dataset (questions and responses) for review.

3. **Compare Responses.** Once you locate the relevant record (either by using the time stamp or by trial and error searching for the appropriate CCSSid), review the online data with the paper copy. Note response discrepancies. (A post-it on the paper survey is one method; for more extensive differences, an Excel spreadsheet or a Word table may be useful.)
   a. If the datasets are identical, whichever survey was recorded first is kept.
   b. After identifying differences, bring information to Aaron for decision on the appropriate data to use.
   c. If the datasets are different:
      i. In most cases, the original online survey will be retained, and the subsequent paper survey set aside.
      ii. If it is decided to use the original online data, Aaron will keep the paper survey as a duplicate survey; that survey is not scanned.
      iii. If it is decided to use the subsequent paper data, it will be necessary to purge the original online record from DatStat before scanning the paper survey into teleforms. After the DatStat record is purged, document the receipt of the second (paper) survey in the database tracking notes, annotating that a subsequent paper survey completed/received on (date) supplanted original online survey submitted on (date). Change source to Paper and update the date received to reflect the date the paper survey was received.

Revision Record Printed 7/10/2012 1:46 PM

Current Filename:		Procedure for Ancillary paper online comparisons.docx	
Revision No.	Date	Responsible Author	Change Description
1	12 /5/11	L.Harrison	Initial Development

Reviewing Expired Holds

Background

Participants in the CCSS may have circumstances that indicate applying a 3-, 6-, 9-, or 12-month hold. During the defined hold period, the participant is not contacted by the CCSS by mail, by email, or by telephone. Alternatively, a "calls" hold may be more appropriate. During a "calls" hold, the participant may still receive mailings and emailings from the CCSS, but s/he will not receive telephone calls. "Calls" holds are applied for an indefinite period of time and are, therefore, reviewed every 180 days.

The Lead Survey Interviewer (LSI) team monitors holds weekly. When a 3-, 6-, 9-, or 12-month hold has expired or after a "calls" hold has been in effect for 180 days, the participant record in question is reviewed to determine if the hold should be removed (i.e. the participant is returned to call rotation for active studies) or if some other course of action is necessary. If there is no information indicating that a participant record should remain on hold, the LSI updates the appropriate database to clear the hold. If a participant record contains information to indicate the participant may need to remain on hold or some other course of action taken, the LSI will review the record with the Coordinator, CRA2, or Research Scientist and/or renew the hold, as appropriate.

Procedures

LTFU Participant Database

1. **Determine which participants have holds to be reviewed**.
    a. Run the query **qry_DR_LTFU_PTDB_OFFHOLD** in the CCSS Call Center Admin Database, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI \Tech\CCSS Call Center Admin DB*.
    b. Identify participants whose defined-period holds have expired or whose "calls" holds are due to be reviewed. Identification is based on the date in the OFFHOLD column, which is automatically calculated to display the earliest date on which each participant's hold status should be evaluated.

2. **Review each participant identified for evaluation**. Determine if the hold should remain in effect or be cleared.

3. **Update the database**.
    a. For participants with holds that WILL be removed:
        i. Clear the **CCSS Hold** and **Hold Date** fields in the header.

ii. Add a dated note with SI ID in the **Notes** field. Access this field by clicking on the **Notes** button in the Participant tab. (Example: 6*/16/2015: Hold has expired. I cleared the fields CCSS Hold = "3 month" and Hold Date = 3/7/2015. [140]*)
iii. Move the cursor to a new field of the participant's record.
iv. Press the F5 key to save the changes to the record.

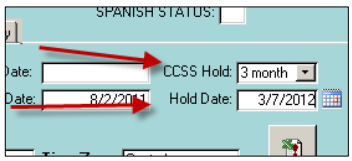
b. For participants with holds that WILL NOT be removed:
i. Update the **CCSS Hold** field in the header to reflect the new type of hold, if appropriate.
ii. Update the **Hold Date** field with the current date.
iii. Add a dated note with SI ID in the **Notes** field. Access this field by clicking on the **Notes** button in the Participant tab. (Example*: 5/16/2015: Per Coordinator, case will remain on calls hold. Updated Hold Date field from 11/1/2014 to 5/16/2015. [140]*)
iv. Move the cursor to a new field.
v. Press the F5 key to save the changes to the record.

Expansion Tracking Database - Cases

4. **Determine which cases have holds to be reviewed**.
   a. Run the query **qry_DR_3,6,9,12MonthHoldCases** in the CCSS Call Center Admin Database, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI \Tech\CCSS Call Center Admin DB*.
   b. Identify cases whose defined-period holds have expired or whose "calls" holds are due to be reviewed. Identification is based on the date in the OFFHOLD column, which is automatically calculated to display the earliest date on which each case's hold status should be evaluated.

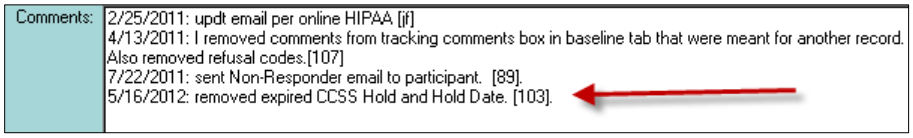
5. **Review each case identified for evaluation**. Determine if the hold should remain in effect or be cleared.

6. **Update the database**.
   a. For participants with holds that WILL be removed, go to the Quest tab and:
      i. Clear the **CCSS Hold** and **Hold Date** fields.



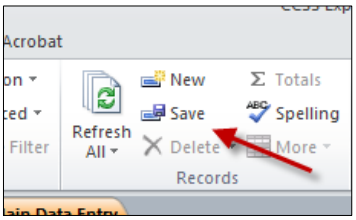
      ii. Add a dated note with SI ID in the **Comments** field. (Example: 6*/16/2012: Hold has expired. I cleared the fields CCSS Hold = "3 month" and Hold Date =*

3/7/2012. [140])



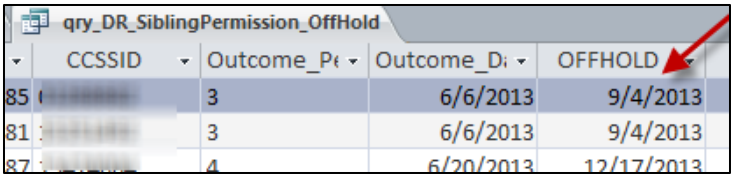
iii. Move the cursor to a new field.
iv. Click the **Save** icon in the Access Ribbon to save the changes to the record.

b. For participants with holds that WILL NOT be removed, go to the Quest tab and:
   i. Update the **CCSS Hold** field to reflect the new type of hold, if appropriate.
   ii. Update the **Hold Date** field with the current date.
   iii. Add a dated note with SI ID in the **Comments** field. (Example*: 5/16/2015: Per Coordinator, case will remain on calls hold. Updated Hold Date field from 11/1/2014 to 5/16/2015. [140]*)
   iv. Move the cursor to a new field.
   v. Click the **Save** icon in the Access Ribbon to save the changes to the record.



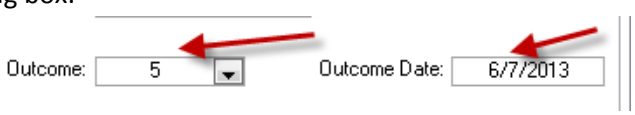
Expansion Tracking Database – Sibling Permissions

1. **Determine which sibling participants have holds to be reviewed**.
   a. Run the query **qry_DRRM_SiblingPermission_OffHold** in the CCSS Call Center Admin Database, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI \Tech\CCSS Call Center Admin DB*.
   b. Identify sibling participants whose permission holds are due to be reviewed.
   c.
   d. Identification is based on the date in the OFFHOLD column, which is automatically calculated to display the earliest date on which each sibling participant's hold status should be evaluated.



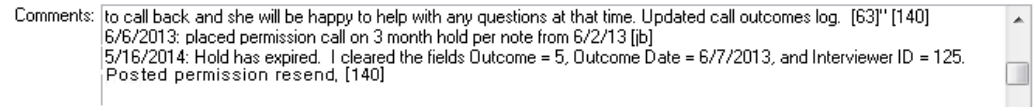
2. **Review each sibling participant identified for evaluation**. Determine if the hold should remain in effect or be cleared.

3. **Update the database**.
   a. For participants with holds that WILL be removed, go to the Permission tab and:
      vi. Clear the **Outcome**, **Outcome Date**, and **Interviewer ID** fields of the Permission Tracking box.



vii. Provided there is not a value of "18" or "13" in the **Tracing Status** field of the Permission Tracking box to indicate a bad address, request a resend by updating the **Tracing Status** field to be "82" and the **Tracing Date** field to be the current date.

viii. Add a dated note with SI ID in the **Comments** field. (*Example: 5/16/2014: Hold has expired. I cleared the fields Outcome = 5, Outcome Date = 6/7/2013, and Interviewer ID = 125. Posted permission resend. [140]*)



ix. Move the cursor to a new field.

x. Click the **Save** icon in the Access Ribbon to save the changes to the record.

c. For participants with holds that WILL NOT be removed, go to the Permission tab and:

i. Update the **Outcome** field to reflect the new type of hold, if appropriate.

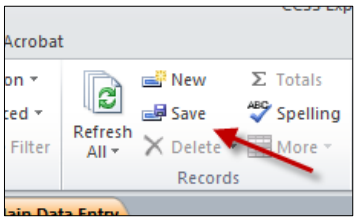
ii. Update the **Outcome Date** field with the current date.

iii. Update the **Interviewer ID** field with your ID.

iv. Add a dated note with SI ID in the **Comments** field. (Example*: 8/1/2015: Case previously advised sibling will be jailed for 18 months. Sibling permission effort will remain on hold for an additional 9 months. Updated Outcome Date field from 11/1/2014 to 8/1/2015 and Interviewer ID field from 121 to 140. [140]*)

v. Move the cursor to a new field.

vi. Click the **Save** icon in the Access Ribbon to save the changes to the record.

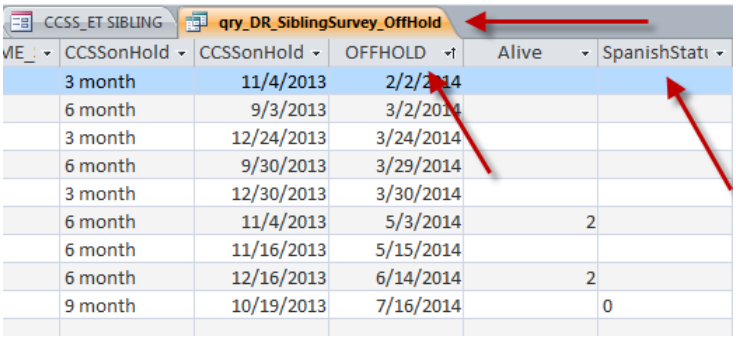


Expansion Tracking Database – Sibling Surveys

1. **Determine which sibling participants have holds to be reviewed**.

a. Run the query **qry_DR_SiblingSurvey_OffHold** in CCSS Call Center Admin Database, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI \Tech\CCSS Call Center Admin DB*.

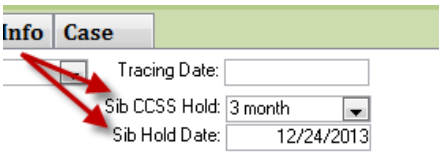
b. Identify sibling participants whose defined-period holds have expired or whose "calls" holds are due to be reviewed. Identification is based on the date in the OFFHOLD column, which is automatically calculated to display the earliest date on which each participant's hold status should be evaluated.

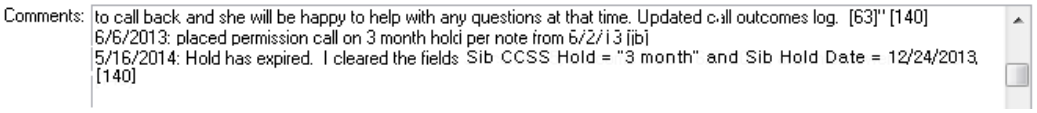


ME_	CCSSonHold	CCSSonHold	OFFHOLD	Alive	SpanishStati
	3 month	11/4/2013	2/2/2014		
	6 month	9/3/2013	3/2/2014		
	3 month	12/24/2013	3/24/2014		
	6 month	9/30/2013	3/29/2014		
	3 month	12/30/2013	3/30/2014		
	6 month	11/4/2013	5/3/2014	2	
	6 month	11/16/2013	5/15/2014		
	6 month	12/16/2013	6/14/2014	2	
	9 month	10/19/2013	7/16/2014		0

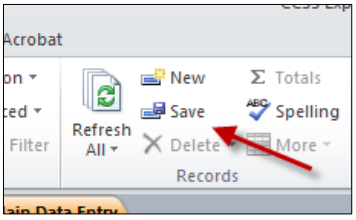
2. **Review each sibling participant identified for evaluation**. Determine if the hold should remain in effect or be cleared.

3. **Update the database**.
   a. For participants with holds that WILL be removed, go to the Sib Info tab and:
      i. Clear the **Sib CCSS Hold** and **Sib Hold Date** fields.
      ii. Add a dated note with SI ID in the **Comments** field. (Example: 3*/26/2014: Hold has expired. I cleared the fields Sib CCSS Hold = "3 month" and Sib Hold Date = 12/24/2013. [140]*)





      iii. Move the cursor to a new field.
      iv. Click the **Save** icon in the Access Ribbon to save the changes to the record.
   b. For participants with holds that WILL NOT be removed, go to the Sib Info tab and:
      i. Update the **Sib CCSS Hold** field to reflect the new type of hold, if appropriate.
      ii. Update the **Sib Hold Date** field with the current date.
      iii. Add a dated note with SI ID in the **Comments** field. (Example*: 5/16/2015: Per Coordinator, sibling pt will remain on calls hold. Updated Sib Hold Date field from 11/1/2014 to 5/16/2015. [140]*)
      iv. Move the cursor to a new field.
      v. Click the **Save** icon in the Access Ribbon to save the changes to the record.



Recruitment Database

1. **Determine which participants have holds to be reviewed**.
   a. Run the query **qry_DRRM_ExpRec_OffHold** in CCSS Call Center Admin Database, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI \Tech\CCSS Call Center Admin DB*.
   b. Identify participants whose holds have expired. Identification is based on the date in the OFFHOLD column, which is automatically calculated to display the earliest date on which each participant's hold status should be evaluated.

2. **Review each participant identified for evaluation**. Determine if the hold should remain in effect or be cleared.

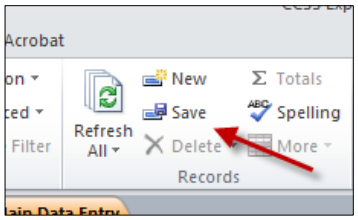
3. **Update the database**.
   a. For participants with holds that WILL be removed:
      i. Clear the **Outcome Code** and **Outcome Date** fields in the Tracking tab.

ii. Add a dated note with SI ID in the **Recruit Notes** field of the Tracking tab. (Example: 6*/16/2015: Hold has expired. I cleared the fields Outcome Code = 7 and Outcome Date = 3/7/2015. [140]*)

iii. Copy the note entered in the **Recruit Notes** field of the Tracking tab and paste it into the **Comments** field of the Quest tab.

iv. Move the cursor to a new field of the participant's record.

v. Click the **Save** icon in the Access Ribbon to save the changes to the record.



b. For participants with holds that WILL NOT be removed:

i. Update the **Outcome Code** field in the Tracking tab to reflect the new type of hold, if appropriate.

ii. Update the **Outcome Date** field with the current date.

iii. Add a dated note with SI ID in the **Recruit Notes** field of the Tracking tab. (Example*: 5/16/2015: Per 5/16/2014 note, case's mother reported she will be incarcerated for 18 months. Updated Outcome Code field from 9 to 8 and Outcome Date field from 5/16/2014 to 5/16/2015. Case will remain on hold for another 6 months. [140]*)

iv. Copy the note entered in the **Recruit Notes** field of the Tracking tab and paste it into the **Comments** field of the Quest tab.

v. Move the cursor to a new field of the participant's record.

vi. Click the **Save** icon in the Access Ribbon to save the changes to the record.

Revision Record — Printed 10/3/2014 1:22 PM

[151] Current Filename:		Reviewing Expired Holds ver3_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	5/16/12	D. Rinehart, B. Carson	Initial Development
1.1	5/23/12	Procedure Team	Formatting and Content refinement
1.2	5/30/13	R. Massey	Content Revision
2.0	6/25/13	D.Rinehart, R. Massey	Content Revision, Include Sibling Processes
2.1	1/23/14	R. Massey	Content and Format Revision: resend permission when hold expires, updated title, updated screen shots, "calls" holds
3.0	10/1/2014	D. Rinehart, R. Massey	Content Revision: changed title, added LTFU db, added Recruitment db, removed directives for assigning off-hold participants

RILEY (24) VERBAL HIPAA INFORMATION SHEET

LSI initials_____
Date_____

1. **Complete this form during the Verbal HIPAA Process. (DO NOT use the web site.)**
2. **Update the Recruitment database (the same as with other Verbal HIPAA approved Institutions)**
3. **Place completed form in Riley Folder**
4. **Email the LSI Team and Cc the CRA2(s) and the Coordinator that a Riley Verbal HIPAA has been completed.**

PARTICIPANT IN **RBAL HIPAA**

CCSSID: _____

Nam

Stre

City

Phoı

Ema

Name of Legally Authorized Representative (LAR): _____

**If completed with a legal representative; state the relationship and identify below the authority to act on behalf of the individual's behalf.*

Individual is: ☐ a Minor ☐ Incompetent ☐ Disabled ☐ Deceased

Legal Authority:

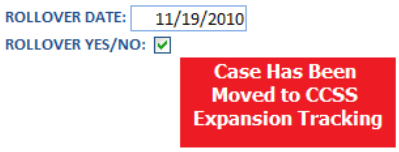
- ☐ Custodial Parent
- ☐ Legal Guardian
- ☐ Executor of Estate of the Deceased
- ☐ Power of Attorney Healthcare
- ☐ Authorized Legal Representative
- ☐ Other: _____

SI Printed Name Signature SI ID Date

Rolling Over Recruited Cases

Background

When we obtain institutional HIPAA for an eligible case, we record the recruitment in the Recruitment database. The final step in processing the returned institutional HIPAA is to perform the "rollover" procedure. This procedure involves a series of queries to move the recruited records and their associated contact information into the necessary tables in the Expansion Tracking database. The procedure also posts the rollover date in both databases, clearly marking the record in the recruitment database as having been moved to CCSS Expansion Tracking.



Procedure

1. Be sure that paper HIPAAs have been properly logged in the database. (See *Processing Returned LTFU Recruitment Packets* and *Processing Institutional HIPAAs*.)

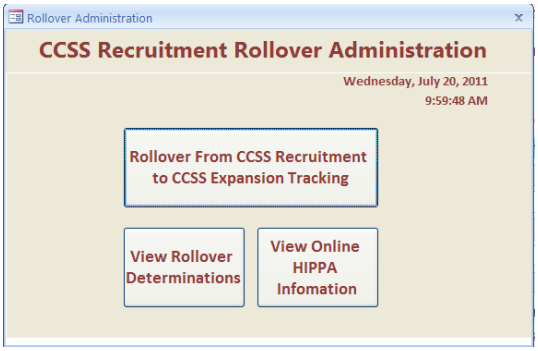
2. Be sure online HIPAAs have been imported and the update query run. (See *Importing Online Recruits*).

3. Locate the Rollover Administration form (frmAdmin) in the Recruitment database.

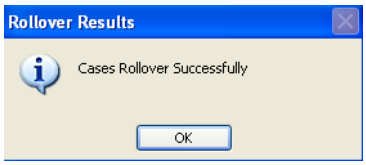
4. Click the "**Rollover From CCSS Recruitment**…" button

   a. If you receive an error message, then capture an image of the error message, try to determine what caused the error, fix it, and retry the rollover.

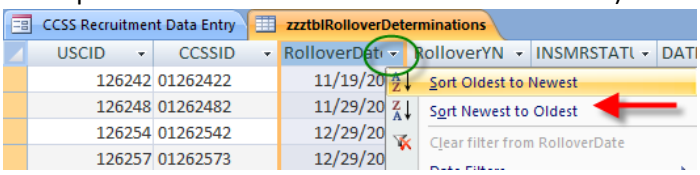
      i. If you are unable to resolve the issue on your own, then send the info to Chris V.



5. The message "Cases Rollover Successfully" displays when the rollover finishes. Click the **OK** button to close the message box.



6. It is a good idea to verify that the number of records moved to Expansion Tracking matches the combined number of records you processed that day (from paper HIPAA and imported from the online recruitment database). To do this, use the **View Rollover Determinations** button on the Rollover Administration form.



   a. To view the newest rollovers, sort the list by **RolloverDate**, sorting Newest to Oldest.

b. Check the number of records for the date in question to make sure the count reconciles with the number of online HIPAAs plus the paper HIPAAs processed on that date.

   i. The "1" in **INSTMRSOURCE** indicates an online HIPAA; "2" designates a paper HIPAA.

7. If the counts do not match, identify the missing CCSSID in your in-processed paper copies and the beforeRollover Excel file and investigate the database record for the CCSSID. Probable causes are:

   a. <u>For online HIPAAs</u>: Both DatePacketSent and DateHIPAAonlySent are blank. (Occurs when neither type was mailed but verbal HIPAA *was* obtained, typically during tracing.) Review the notes. When you verify verbal HIPAA was obtained, enter the verbal HIPAA date into DateHIPAAonlySent and annotate in Recruit notes.

USCID	CCSSID	RolloverDat	RolloverYN	INSMRSTATI	DATEINSTMRSIGNED	INSTMRSOURCE
147136	20471362	7/19/2011	-1	1	7/7/2011	2
150175	12501752	7/19/2011	-1	1	7/8/2011	2
145418	29454181	7/19/2011	-1	1	7/18/2011 8:14:28 PM	1
142289	25422891	7/19/2011	-1	1	7/16/2011 10:43:29 AM	1
139766	26397666	7/19/2011	-1	1	7/18/2011 3:43:56 PM	1
151243	02512432	7/19/2011	-1	1	7/17/2011 7:47:14 PM	1
151595	02515951	7/19/2011	-1	1	7/18/2011 1:50:37 PM	1
139757	26397572	7/19/2011	-1	1	7/18/2011 12:30:37 PM	1
149952	12499526	7/19/2011	-1	1	7/17/2011 8:33:20 PM	1
131274	12312741	7/19/2011	-1	1	7/13/2011	2
148996	20489965	7/19/2011	-1	1	6/26/2011	2
139754	26397546	7/19/2011	-1	1	7/18/2011 11:19:32 AM	1
139784	26397846	7/19/2011	-1	1	7/18/2011 2:28:32 PM	1
143169	22431691	7/19/2011	-1	1	7/17/2011 5:04:36 PM	1
143431	22434316	7/19/2011	-1	1	7/19/2011	2
149825	12498253	7/19/2011	-1	1	7/16/2011 12:56:25 PM	1
149812	12498126	7/19/2011	-1	1	7/16/2011 12:45:49 PM	1
126349	01263498	7/19/2011	-1	1	7/16/2011 10:44:34 PM	1
126745	01267452	7/19/2011	-1	1	7/1/2011	2
126277	01262772	7/19/2011	-1	1	7/9/2010	2
151120	02511201	7/19/2011	-1	1	7/18/2011 10:42:56 AM	1
142587	25425878	7/19/2011	-1	1	7/17/2011 11:46:06 PM	1
132689	08326897	7/19/2011	-1	1	6/24/2011	2
135956	08359561	7/19/2011	-1	1	7/11/2011	2
151825	02518252	7/19/2011	-1	1	7/16/2011 1:47:04 PM	1
149604	09496048	7/19/2011	-1	1	7/18/2011 1:16:12 PM	1
151436	02514362	7/19/2011	-1	1	7/18/2011 1:44:28 PM	1
139576	23395761	7/19/2011	-1	1	7/18/2011 11:39:28 AM	1
126541	01265415	7/19/2011	-1	1	7/6/2011	2

1=online
2=paper

   b. <u>For paper HIPAAs</u>: data entry omission of one of the fields necessary for rollover: INST MR STATUS (needs to be 1), DATE INST MR SIGNED (cannot be blank), INST MR SOURCE (cannot be blank).

   c. <u>Repeat the Rollover procedure</u> after correcting the problem.

Revision Record
Printed <u>3/29/2016 10:11 AM</u>~~8/3/2015 1:01 PM~~

(123) Current Filename:		Rolling Over Recruited Cases ver1_4.doc	
Revision No.	Date	Responsible Author	Change Description
1	7/20/11	J.Bates	Initial Development
1.1	12/6/11	J.Bates	AgeOfMajority update
1.2	10/13/12	J.Bates	Reorder items
1.3	1/22/13	J.Bates	AOM update cross reference
1.4	8/3/15	J.Ford	Removed AOM cross reference; clarified process for rollover errors

Saliva Kit Follow-Up Calls

Background

The purpose of the Saliva Study is to collect DNA from CCSS participants (i.e. childhood cancer survivors and siblings who are actively enrolled in the CCSS) via a saliva sample. Researchers hope to learn about genetic factors that may predispose some people to develop cancer or specific treatment-related health problems.

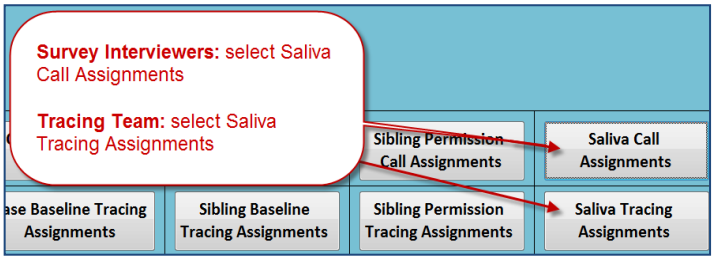
The Coordinating Center will mail a saliva collection kit along with a $25 gift card to the participants selected for the Saliva Study. For those participants who do not respond to the mailing, Survey Interviewers (SIs) will make follow-up calls to recruit the individual into the Saliva Study or to request a new saliva sample if a previous sample has been exhausted or is no longer viable.

The CCSS DNA Tracking database is used to track the project's information, and the LTFU Participant database is used to record the calls.

Tools:

1. **CCSS SI Assignments** database, located at: https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
2. **CCSS DNA Tracking** database, located at: *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
3. **CCSS LTFU Participants Database**, located at: *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
4. **Saliva Study Call Script**, located at *Z:\Departments\ECC\common\Interviewers\Saliva Study\Scripts*
5. **Possible Participant Questions for Interviewers**, located at *Z:\Departments\ECC\common\Interviewers\Saliva Study\Scripts*
6. **Pre-Post Call Checklist – Saliva (Oragene) Kit**, located in the CCSS SOP Library at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
7. **Phone Message Guidance_Rev 5-30-2014**, located at *Z:\Departments\ECC\common\Interviewers\Calling Tools*
8. **LTFU Database Data Entry**, located in the CCSS SOP Library at *https://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*

Procedures:

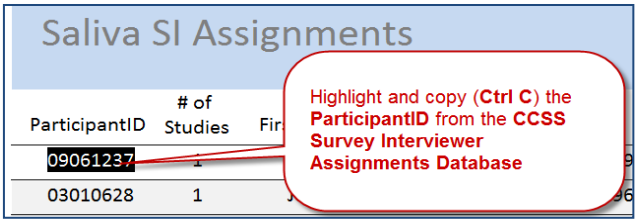


Pre-Call Procedures

1. Open the CCSS SI Assignments, CCSS DNA Tracking, and CCSS LTFU Participants databases.

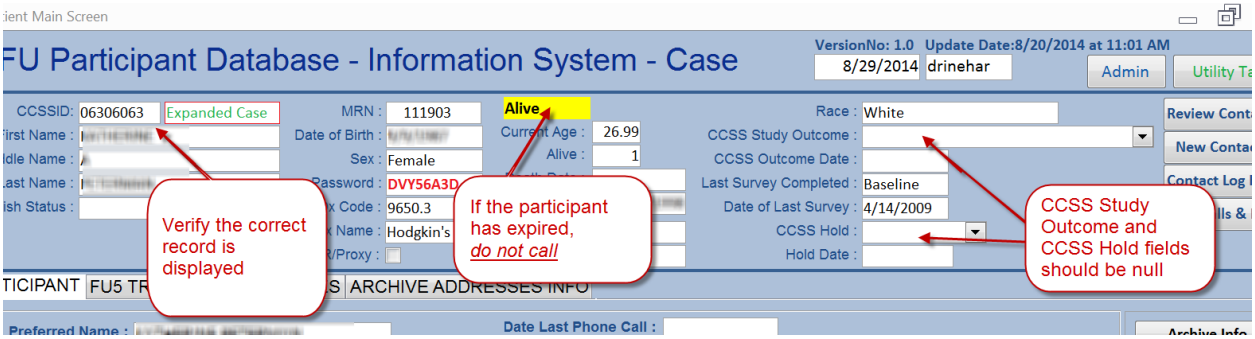
2. In the CCSS SI Assignments database, click on the **Saliva Call Assignments** button, enter your Survey Interviewer ID at the prompt, and click the **OK** button.

3. From the assignments list, copy the **Participant ID** number of the case to be called.



4. Paste the ID into the **Participant ID** field of the LTFU Participant database search form, and click the **Search** button. When the search results appear, double-click on the name of the participant to display the participant record.

5. Review the following fields in the participant's record.
   A. Header:
      i. **CCSSID** or **SIBID**, **First Name**, and **Last Name** – Verify the participant displayed is the person in your assignments list.
      ii. **Alive –** Verify the participant is alive (**Alive** = 1). *DO NOT CALL deceased participants.*
      iii. **CCSS Study Outcome** and **CCSS Hold** - *DO NOT CALL participants who have refused or are on hold.*



      iv. **Current Age**, **Spanish Status**, **LAR/Proxy** status, gender
      v. **Contact Log History** – Review all call history for important profile information. If the participant was recently called for another study project:
         a. Ensure the saliva call is within study calling parameters (i.e. Calls should not be made to any telephone number more frequently than once every 3 days.).
         b. Determine if the other project's objective was met. If not, the saliva study SI should either address both study projects during the call or coordinate with the SI working on the other project so that both projects can be handled in the same call.
   B. PARTICIPANT tab:
      i. **Preferred Name** and **Care of:** fields, address and date, phone numbers and dates

ii. **Preferred Contact info/time**

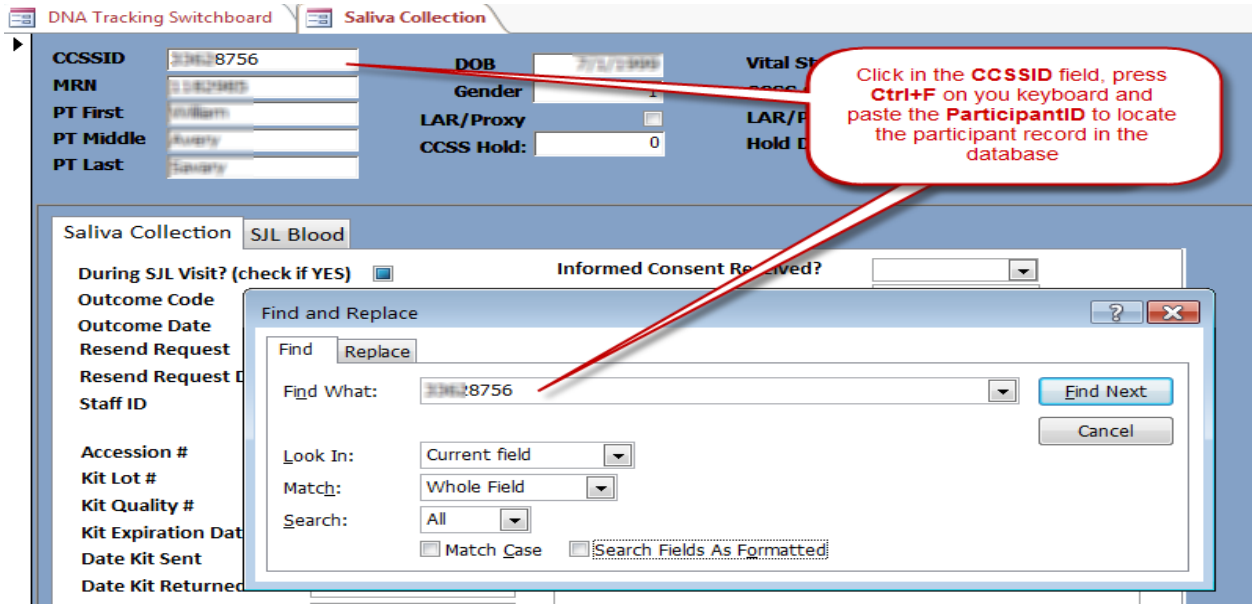
iii. **Tracing Code/Date** – If the participant is in tracing, review any notes in the header's **Trace History**. If the Tracing code is due to an invalid address (i.e. **Tracing Code** = 18 or 81), call all available phone numbers (participant and associates) in an attempt to verify the contact information.

iv. Check the **Notes** button for any additional information.

C. ASSOCIATES tab – Review the names, phone numbers, **Contact Status**, and **Notes** fields of all associates.

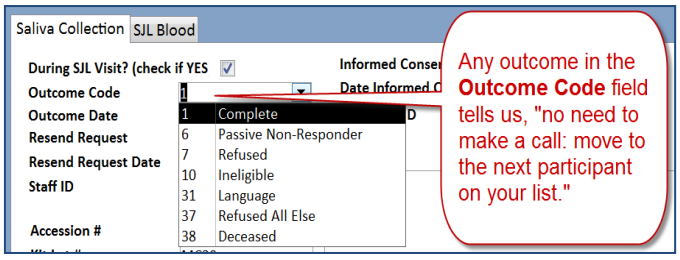
6. Follow remaining standard Survey Interviewer operating procedures. (e.g. Determine how many calls have been made to each phone number, determine who is likely to answer the phone, etc.)

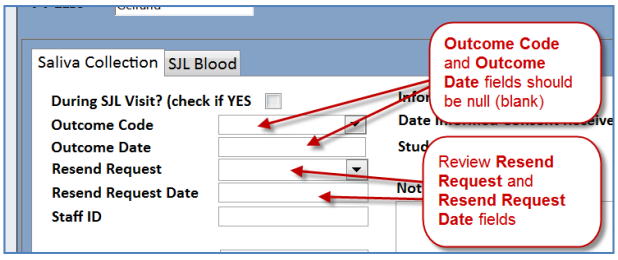
7. In the CCSS DNA Tracking database, click on the button for cases (**DNA Tracking-Cases**) or siblings (**DNA Tracking-Siblings**), as appropriate. Use the MS Access Find function to locate the participant's record.



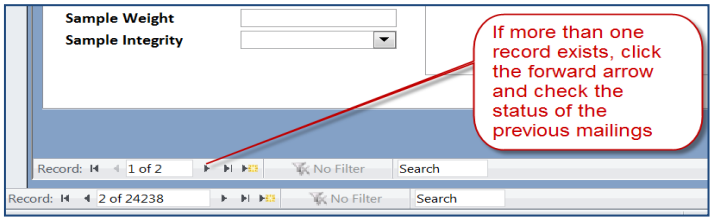
8. Review the Saliva Collection tab of the participant's record in the DNA Tracking database.

A. **Outcome Code** – *DO NOT CALL if the field is populated.*

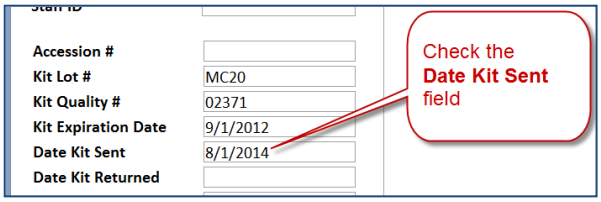




B. Determine how many times a saliva kit has been mailed.
   i. Look at the number of records using the arrows in the Saliva Collection tab's Record bar.
   ii. If more than one kit was mailed, there will be additional records. The most recent record appears first.



C. Review each record.
   i. Determine the status of each saliva kit by reviewing the **Date Kit Sent** and **Date Kit Returned** fields.
   NOTE: If the **Date Kit Returned** field is populated for the most recent record, *no call is necessary*.



   ii. Participants who previously provided a saliva sample may ask why we need another. (See the document titled **Possible Participant Questions for Interviewers** for guidance in answering this question.)

Calling Procedures

Once it has been determined the participant SHOULD be called, use the **Saliva Study Call Script** to make the call.

1. If **unable to speak to the participant or an associate**, proceed to the section of this document titled *Call Documentation*, below.
2. If someone is contacted, confirm the appropriate party has been reached before providing information. Use **standard identify verification procedures** (e.g. verify name and DOB, verify relationships such as LAR, parent, etc.). If an associate has been reached, attempt to obtain/verify contact information (e.g. best phone number at which to reach the participant, best day and time to reach the participant, etc.).
   A. Saliva kit **received**?
      i. No – Determine if the participant has moved. Gather correct mailing address and other contact information.
      ii. Yes:
         a. Inquire about outstanding questions or barriers to participation. If necessary, refer to **Possible Participant Questions for Interviewers**.
         b. Determine willingness to participate.
            1) If the participant is **willing to participate**:
               A) Ask for an approximate date when s/he will return the kit.
               B) If willing to participate but unable to provide a saliva sample in our standard kit, advise the participant of the swab kit option.
            2) If the participant **refuses**:
               A) Try to capture a reason. If there are concerns that can be addressed, do so.
               B) Clarify whether the refusal is for the Saliva Study only or for the entire LTFU Study.

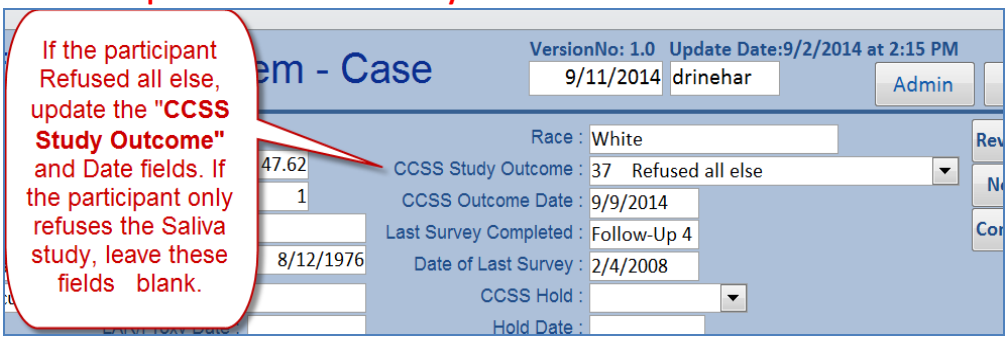
iii. Misplaced - If the participant has misplaced the kit and the study has not sent the maximum number of kits, offer to send another.
Important Note: As a general rule, no more than three to four kits will be mailed to a given participant. However, if the participant has moved several times or we mailed one or more kits to an incorrect address *AND* s/he is highly motivated to participate, we will mail another kit. These will be handled on a case-by-case basis. Email the Saliva Study CRA contact(s) for a determination.

B. Confirm or update all participant and associate **contact information**, noting any additional information they may provide.

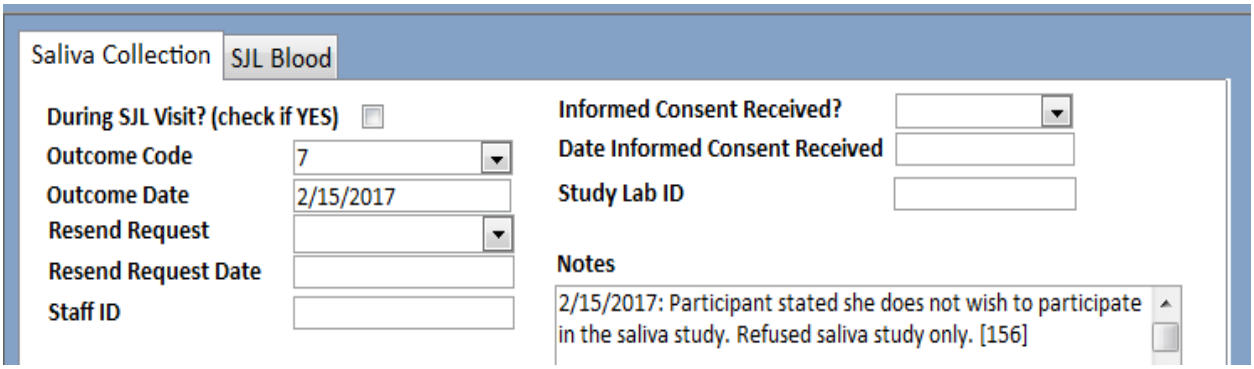
C. If a Participant is found to be **deceased**:
   i. Offer condolences to the person who provides this information.
   ii. If they are willing, complete the **Expired Participant information Sheet**.
   iii. It is not necessary to request the associate or proxy return the kit to the LTFU Study.

Post-Call Documentation

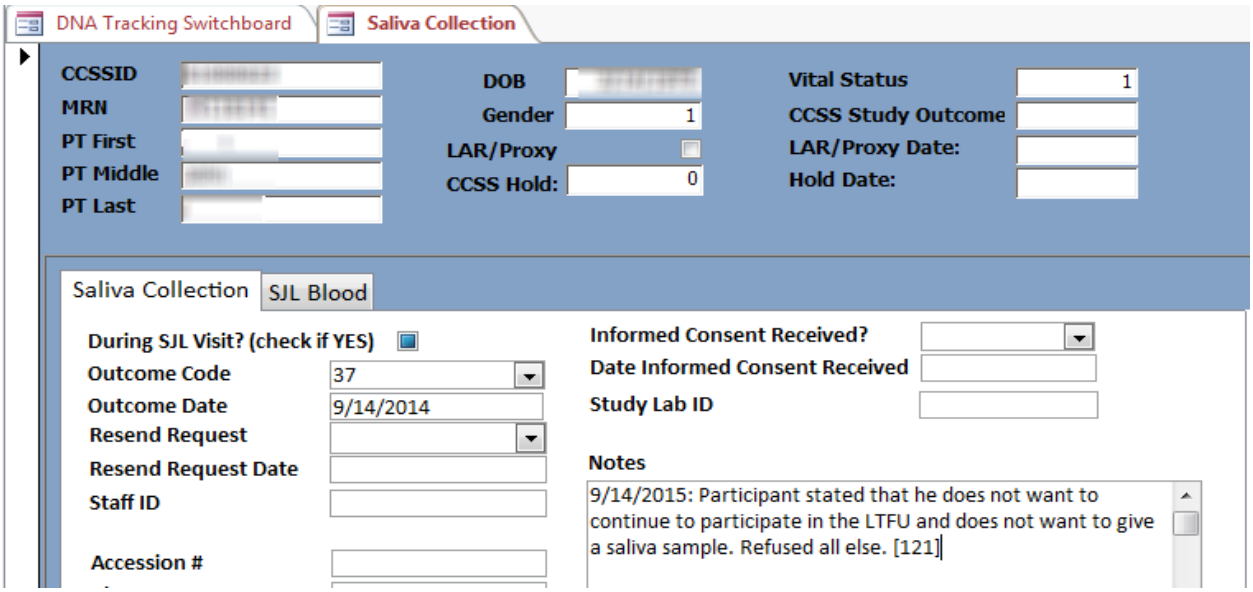
1. Update the LTFU Participant Database**:**
   A. In the contact or trace log, document the call. Populate the **Project** field with 8-Saliva and the **Contact Reason** field with 7-Specimen.
   B. Update the participant's record in the LTFU Participant database with all confirmed contact information. See the SOP titled **LTFU Participant Database Data Entry** for details.
   C. Refusals
      i. **Refused Saliva Study** *ONLY* - Do not update the **CCSS Study Outcome** or **CCSS Outcome Date** fields.
      ii. **Refused All Else** (i.e. the participant refused all further participation in the LTFU Study) – Update the **CCSS Study Outcome** and **CCSS Outcome Date** fields. See the SOP titled **LTFU Participant Database Data Entry** for details.



2. If you learned that a participant is now deceased and were able to complete the **Expired Participant Information Sheet**, submit the completed form in the forms file cabinet. NOTE: This outcome should be documented in the **DB Change** field of the LTFU Participant database contact or trace log.
3. Update the CCSS DNA Tracking Database – Saliva Collection Tab:
   A. Document any information that may be helpful to the 5th floor team in the **Notes** field.
   B. Refusals –
      i. **Refused Saliva Study** *ONLY* - Update the **Outcome Code** field with 7-Refused, add the date in the **Outcome Date** field, and enter a dated note with SI ID in the **Notes** field. Outcomes other than refusals and deceased will be entered by the CRA.



ii. **Refused All Else** (i.e. the participant refused all further participation in the LTFU Study) - Update the **Outcome Code** field 37-Refused all else, add the date in the **Outcome Date** field, and enter a dated note with SI ID in the **Notes** field. Outcomes other than refusals and deceased will be entered by the CRA.



C. Deceased - Update the **Outcome Code** field with 38-Deceased, and add the date in the **Outcome Date** field. Outcomes other than refusals and deceased will be entered by the CRA.

D. Resend – As appropriate, update the **Resend Request** field with 1-Saliva Kit, 2-Swab Kit, 3-Saliva & Swab Kit, or 4-Consent, and add the date in the **Resend Request Date** field.

4. For any unusual circumstances or any additional information provided by the case or family member, email the Call Center Coordinator, LSI team, and/or the Saliva Study Project Coordinator, as appropriate.

Revision Record

Printed 3/20/2017 10:36 AM

Current Filename:		Saliva Kit Follow Up Calls ver 4_3.doc	
Revision No.	Date	Responsible Author	Change Description
1	12/2008	Rebecca Pack	Initial Development
2	12/2010	Twanna Smith	Revision
2.1	3/30/2010	J. Bates	Formatting
3.1	9/27/11	J. Bates	Call tracking database updated
3.2	11/18/11	J. Bates	Call tracking db upgrade v 5: Expansion cases
3.3	12/5/11	J. Ford	Revised data entry procedures
3.4	12/19/11	J. Ford	Revised procedures for resend requests for standard and swab kits
3.5	3/22/12	J. Ford	Expanded call logging database feature; contact call log
4.0	8/28/14	J. Ford, B. Lewis, D. Rinehart, R. Massey	Revised data entry procedures – new call assignments and DNA databases
4.1	9/12/14	D. Rinehart, R. Massey	Content Revision: Clarify refusal directives, add screen shots
4.2	11/14/2016	A. Cobble, D. Rinehart, R. Daniels	Content Revision: Updated hyperlinks
4.3	3/20/2017	A. Cobble, D. Rinehart, R. Daniels	Revised DNA database screen shots, added hyperlinks

Saliva Sample Collection-Mailing

Background

When saliva kits need to be mailed to participants, whether original cases or siblings, or expansion cases (and expansion siblings when applicable), we use the following general production procedure. (To prepare saliva kits for collection during a St Jude Life visit, see *St. Jude Life CCSS Appointments*. In addition, *Processing Returned Saliva Samples* documents in-processing returned saliva samples.) Mass mailings may use the Bulk Mail rate; repeat or requested mailings may use first class mail. The production schedule will indicate which mailing method to use. Bulk mail batches of less than 300 saliva packages may not meet USPS weight requirements; 1st Class batches cannot exceed 200 pieces per day (see *Bulk vs. First Class Mail Guidelines*). An adequate supply of materials will be kept in Rm S4011. The bulk of the saliva kits, mailing envelopes, and return address envelopes are housed in the basement cage. The project CRA generates and distributes the data file and production schedule for the cases/siblings designated mailing. Actual production, assembly, and QA is performed by CRAs. This document covers procedures for the original cohort.

Procedures (Original Cohort)

PREPARING FOR PRODUCTION

(Preparing) Mass Resends:

Producing Data Files and Production Schedule for Mass Resends

1. Follow *Managing Saliva Study Participant Status* procedures
2. Open the design view of qry_JF_SalivaResendMailingInfo
    a. Adjust the 'Criteria' to the needs of the mailing/resend
    b. Run query
    c. Take note of **CountOfsa_kitsent** field (number of kits sent to a participant). If a participant has been mailed 4 or more kits, you will need to review notes for the CCSSID because we typically do not want to mail more than 4 kits. Certain situations will allow for the mailing of 4 or more kits (e.g. participant moved several times; package sent to wrong address; received a kit from participant that was unusable; etc.)

3. Export and save the file as *Saliva Resend Master List [current date]* in: **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Archive**
    a. Any subsequent sorting or adjusting of the file should be saved here
        i. For example, ALWAYS include any participants with a Resendwhat value; there may be 2,000 participants in the file but only 500 will be sent a kit during the current week; etc.
    b. Create a new excel file that contains only the participants scheduled for a resend in the current week; the fields below must be included in the new file

CCSSID	Initials	FirstNm	LastNam	sendname	sendcareof	sendaddr	sendcity	sendstate	zipsort	sendCountry	instnam

    c. Save the file as *Saliva Kit Resend n[x] [current date]* in: **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings** (this file will be used to generate mailing materials)
    IMPORTANT: IF YOU ARE USING BULK MAIL ENVELOPES, YOU MUST SORT THE FILE ACCORING TO ZIPCODE BEFORE YOU SAVE THE FILE

4. Create a production schedule
    a. Previous schedules are located in **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Production Schedule**
    b. Save schedule as *Print-mail schedule-Saliva Kit Resend_Week of [XX-XX-XX]*

5. Distribute production schedule and batch file(s) (*Saliva Kit Resend n[x] [current date]*)

Preparing "To Be Uploaded" File for Mass Resends

1. Open *Saliva Kit Tracking Info-To Be Uploaded* in: **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Kit Tracking Info**
2. Do not remove the first row of the file but DO delete the rows containing previous participant information
3. Copy and paste the **CCSSID**, **FirstNm**, and **LastNam** from the *Saliva Kit Resend n[x] [current date]* file

CCSSID	First Name	Last Name	Kit Lot #	Kit Quality #	Kit Expiration Date	Date Kit Sent
[redacted]	[redacted]	[redacted]				

4. Highlight the CCSSID records for participants with a **Resendwhat** value of 2 or 3 to identify the swab kit resend requests.
5. Save the file
6. Proceed to *PRODUCTION* section

(Preparing) Requested Resends:

Producing Data Files and Production Schedule for Requested Resends

1. Follow *Managing Saliva Study Participant Status* procedures

2. Run qry_JF_RequestedResends_Reg
    a. Take note of the **Resendwhat** and **CountOfsa_kitsent** fields. **Resendwhat** displays the type of resend needed, while **CountOfsa_kitsent** shows how many kits have been mailed to a participant. If a participant has been mailed 4 or more kits, you will need to review the notes for the CCSSID because we typically do not want to mail more than 4 kits. Certain situations will allow for the mailing of 4 or more kits (e.g. participant moved several times; package sent to the wrong address; received a kit from participant that was unusable; etc.)

3. Export file and save as ***qry_JF_RequestedResends_Reg n[#] [current date***] in: **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings**

4. Create production schedule
    a. Previous schedules are located here: **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Production Schedule**
    b. Save schedule as *Print-mail schedule-Saliva Kit Resend_Week of [XX-XX-XX]*

5. Distribute production schedule and batch file (*qry_JF_RequestedResends_Reg n[#] [current date]*)

***Preparing "To Be Uploaded" File for Requested Resends*:**

NOTE: Utilize steps below only if the number of requested resends contains 10 or more participants.

1. Open ***Saliva Kit Tracking Info-To Be Uploaded*** from **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Kit Tracking Info**
2. Do not remove the first row of the file but DO delete the rows containing previous participant information
3. Open batch file ***qry_JF_RequestedResends_Reg n[#] [current date]***

CCSSID	First Name	Last Name	Kit Lot #	Kit Quality #	Kit Expiration Date	Date Kit Sent
[redacted]	[redacted]	[redacted]				

   a. Filter file to include only **Resentwhat** values **1**, **3**, **5**, and **6**
   b. Copy and paste the **CCSSID**, **FirstNm**, and **LastNam** from qry_JF_RequestedResends_Reg n[#] [current date] file

4. Highlight the CCSSID records for participants with **Resendwhat** value **3**
   a. This identifies resend requests for a swab kit
5. Save file
6. Proceed to *PRODUCTION* section

PRODUCTION

(Production) Mass Resends:

1. Generate cover letters (**Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation**)
   a. Open *New Letter 11-3-11 MERGED*, mailmerge with your batch list, update the "Date" (see production schedule for mass resends; use intended mail date for requested resends); print all

2. Generate consent forms
   a. Open *CCSS Consent_Buccal-DNA_Collection_Amendment 14.0 IRB Appr 1-4-12*, mailmerge with your batch list, print all two-sided, and staple by hand
   b. Open *CCSS Consent_Buccal-DNA_Collection_Amendment 14.0 IRB Appr 1-4-12 Participant Copy* , print enough for your batch (set printer to print two-sided and stapled)

3. Print enough *Saliva Collection Kit Instructions_Final Copy* for your batch

4. Generate labels for jiffy lite envelops (only if preprinted are unavailable)
   a. Open *Did You Remember to Sign_Date Labels 5163* and print enough for your batch

5. Generate labels for peach 9x10 return address envelopes (only if preprinted are unavailable)
   a. Open *Exempt Human Specimen Labels 5163* and print enough for your batch

6. Generate labels for the saliva kits
   a. Open *Saliva Kit Labels 5167 MERGED*, mailmerge with your batch list, and print

7. Generate mailing labels
   a. Open *Saliva Kit Mailing Labels 5163 MERGED*, mailmerge with your batch list, and print

(Production) Requested Resends:

1. Open batch file *qry_JF_RequestedResends_Reg n[#] [current date]* (**Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation**) and determine type of resend(s) (**Resendwhat** column)

1 Resend saliva kit.....Participant requested saliva kit
2 Resend swab kit .....Participant has saliva kit but needs swab
3 Resend swab & saliva kit .....Participant requested swab and saliva kit
4 Resend consent.....We received sample without consent
5 Resend kit (sample leaked) .....We received consent and kit but sample leaked
6 Resend kit (consent received) .....We received consent without sample

2. Print **cover letter** based upon **Resendwhat** type

[1, 2, 3] Saliva Kit, Swab & Saliva Kit, Swab Kit:	[4] Consent Only:	[5] Saliva Kit (Sample Leaked):	[6] Saliva Kit (Consent Received):
Open **New Letter 11-3-11 MERGED**, mailmerge with your batch list (*must select **Resendwhat** values **1**, **2**, and **3** from Edit Recipient List*), update the Date (use intended mail date for requested resends); and print all	Open **Resend Request_Kit Received-No Consent Cover Letter 4-5-12 MERGED**, mailmerge with your batch list (*must select **Resendwhat** value **4** from Edit Recipient List*), update the Date (use intended mail date for requested resends); and print all	Open **Resend Request_Leaked Sample Cover Letter 3- 22-12 MERGED**, mailmerge with your batch list (*must select **Resendwhat** value **5** from Edit Recipient List*), update the Date (use intended mail date for requested resends); and print all	Open **Resend Request_Consent Received-No Kit Cover Letter 4-5-12 MERGED**, mailmerge with your batch list (*must select **Resendwhat** value **6** from Edit Recipient List*), update the Date (use intended mail date for requested resends); and print all

3. Generate **consent forms** (if applicable)
   a. Open *CCSS Consent_Buccal-DNA_Collection_Amendment 14.0 IRB Appr 1-4-12 MERGED*, mailmerge with your batch list (*must select **Resendwhat** values **1**, **2**, **3**, and **4** from Edit Recipient List*), print all two-sided, and staple by hand
   b. Open *CCSS Consent_Buccal-DNA_Collection_Amendment 14.0 IRB Appr 1-4-12 Participant Copy*, print enough for your batch (set printer to print two-sided and stapled)

4. Print enough *Saliva Collection Kit Instructions Final Copy* for your batch (if applicable)

5. Generate **labels** for jiffy lite envelops (if applicable; only if preprinted are unavailable)
   a. Open *Did You Remember to Sign_Date Labels 5163* and print enough for your batch

6. Generate **labels** for peach 9x10 return address envelopes (if applicable; only if preprinted are unavailable)
   a. Open *Exempt Human Specimen Labels 5163* and print enough for your batch

7. Generate **labels** for the saliva kits (if applicable)
   a. Open *Saliva Kit Labels 5167 MERGED*, mailmerge with your batch list (*must select **Resendwhat** values **1**, **3**, **5**, and **6** from Edit Recipient List*), and print

8. Generate mailing **labels**
   a. Open *Saliva Kit Mailing Labels 5163 MERGED*, mailmerge with your batch list, and print

ASSEMBLING PACKAGES

(Assembling) Mass Resends:

1. Gather saliva kits, biohazard bags, jiffy lite envelopes, peach 9x10 envelops (postage-paid for US address and non-postage-paid for international addresses), white tyvek envelopes (Bulk Mail)
    a. While collecting saliva kits, be sure to note the Box # from which you pulled the kit (so we can maintain an accurate count of our inventory; see *Maintaining Saliva Kit Inventory*)

2. Open *Saliva Kit Tracking Info-To Be Uploaded* located here**: Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Kit Tracking Info**

3. Open kit and remove instructions provided by Oragene

4. Attach 5167 CCSSID kit label to the bottom of specimen container

5. Search *Saliva Kit Tracking Info-To Be Uploaded* for CCSSID on kit
    a. Record Kit Lot #, Kit Quality #, and Kit Expiration Date in file
    b. Kit Expiration Date = Collect Saliva by: on kit (convert kit date to this format m/1/yyyy)
    c. Save file
    d. Set kit aside for further processing

6. Affix labels to jiffy lite, peach return address, and white envelopes
    a. *Be sure to keep white envelopes in zip code order*
    b. Attach *three* Canadian postage stamps to peach envelopes (if applicable)

7. Assemble package in the following order but do not seal
    a. Letter
    b. Informed consent
    c. Participant copy of consent
    d. Collection instruction sheet
    e. Peach envelope
    f. Jiffy lite envelope with biohazard bag enclosed
    g. Saliva kit
    h. Swab kit (if applicable)

8. Place packages in a USPS mail bin for quality assurance (QA) check
    a. Label bins according to zip code order (box 1, 2, 3, etc)

9. Notify individual responsible for QAing that your batch is ready for inspection

(Assembling) Requested Resends:

Gather Materials for Batch:

	RESEND WHAT values					
Required Materials	**1**	**2**	**3**	**4**	**5**	**6**
1st Class LTFU Tyvek Envelope						
1st Class LTFU Standard Envelope (non-Tyvek)						
5163 Shipping Labels						
5167 Kit Labels					X	X
St. Jude Letterhead (ALL packages)	X	X	X	X	X	X
Informed Consent	X	X	X	X		
Participant copy of consent	X	X	X	X		
Collection Instruction Sheet	X	X	X		X	X
Postage-paid envelope-Peach	X	X	X		X	X
Postage-paid envelope #9 white return reply with J.Ford label				X		
Jiffy lite Envelope with biohazard bag enclosed	X	X	X		X	X
Saliva Kit*	X		X		X	X
Swab Kit		X	X			

* While collecting saliva kits, be sure to note the Box # from which you pulled the kit (so we can maintain an accurate count of our inventory; see *Maintaining Saliva Kit Inventory*)

*For **Resendwhat** Values of **1**, **3**, **5**, or **6** (10 or more participants):*

1. Open **Saliva Kit Tracking Info-To Be Uploaded** located in: **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Kit Tracking Info**
2. Open kit and remove instructions provided by Oragene
3. Attach 5167 CCSSID kit label to the bottom of specimen container
4. Search **Saliva Kit Tracking Info-To Be Uploaded** for CCSSID on kit
   a. Record **Kit Lot #**, **Kit Quality #**, and **Kit Expiration Date** in file
   b. **Kit Expiration Date** = **Collect Saliva by:** on kit (convert kit date to this format *m/1/yyyy*)
   c. Save file
   d. Set kit aside for further processing
5. Proceed to *Preparing Packages*

*For **Resendwhat** Values of **1**, **3**, **5**, or **6** (10 or less participants):*

1. Open Registration database and **frmSalivaCollection_New**
2. Open kit and remove instructions provided by Oragene
3. Attach 5167 CCSSID kit label to bottom of specimen container
4. Search database for CCSSID# on kit
   a. Record the **Date Kit Sent**, **Kit Lot #**, **Kit Quality #**, and **Kit Expiration Date** on a new record
   b. **Kit Expiration Date** = **Collect Saliva by:** on kit (convert kit date to this format *m/1/yyyy*)
   c. For requests for a swab kit, be sure to include a note "m/d/yy: swab kit sent with saliva package [initials]"
5. Proceed to *Preparing Packages*

*For **Resendwhat** Value of **2**:*

1. Open Registration database and **frmSalivaCollection_New**
2. Search database for CCSSID#
3. Go to *last* record (e.g. 2 of 2; 3 of 3, etc)
4. Add a note "m/d/yy: swab kit sent to pt [initials]"
5. Proceed to *Preparing Packages*

*For **Resendwhat** Value of **4**:*

1. Open Registration database and **frmSalivaCollection_New**
2. Search database for CCSSID#
3. Find record where **Date Kit Returned** is not blank but **Informed Consent Received?** Equals **2** and **Date Informed Consent Received** is blank
4. Add a note "m/d/yy: saliva consent form sent to pt [initials]"
5. Proceed to *Preparing Packages*

Preparing Packages:

1. Affix labels to required documents (mailing label, jiffy lite envelope, peach return address envelope, etc.)
2. Assemble package(s) in the following order but do not seal:

	RESEND WHAT values					
ASSEMBLE ITEMS in package, in the following order….	1	2	3	4	5	6
a. Letter (ALL packages)	X	X	X	X	X	X
b. Informed Consent	X	X	X	X		
c. Participant copy of consent	X	X	X	X		
d. Collection Instruction Sheet	X	X	X		X	X
e. Postage-paid envelope-Peach	X	X	X		X	X
f. Postage-paid envelope #9 white return reply with J.Ford label				X		
g. Jiffy lite Envelope with biohazard bag enclosed	X	X	X		X	X
h. Saliva Kit	X		X		X	X
i. Swab Kit		X	X			

3. Place packages in a USPS mail bin for quality assurance (QA) check
4. Notify individual responsible for QAing that your batch is ready for inspection

QUALITY ASSURANCE (QA) CHECK

1. QA 25% of the packages you did not assemble using the methods below (If an error is discovered, all envelops will be re-checked for accuracy and all issues resolved before a second QA is performed)
    a. Verify that name, CCSSID, and address on package match Registration database contact info
    b. Remove all items from the package
    c. Make certain all required items are present
    d. Make sure letter was printed on SJ letterhead and date matches mailing date
    e. Ensure name/CCSSID on the white envelope, letter, informed consent, and kit all match
    f. Ensure jiffy lite envelope contains a biohazard bag and “Did you remember to sign…” label
    g. Make certain peach envelope contains a “Exempt Human Specimen” label and appropriate postage (1st class envelops for US address versus Canadian postage)
    h. Place items back inside white envelope and seal
2. For the remaining 75%, ensure all packages contain all required materials

COORDINATING PACKAGE PICK-UP FOR BULK MAIL

1. Contact the mail room 24 hours prior to the mail date to inform them of mailing (ext 4951; current contact Samantha Watson)
    a. Include number of packages

2. Day of mailing: place mail bins in a low-traffic area (e.g. 5th floor work area) and in box order
    a. Place a contact name and “Cost Center 0400” sheet of paper on first box

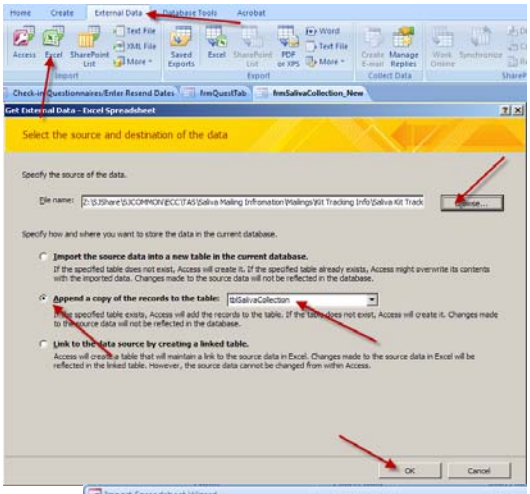
3. Contact the mail room to schedule pick up
    a. Include the number and location of bins

POST-MAILING DATA ENTRY: Mass and Requested Resends of 10 or More Participants

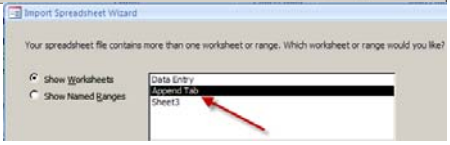
Updating Saliva Kit Tracking Sheet

1. Open *Saliva Kit Tracking Info-To Be Uploaded* **(Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Kit Tracking Info)**
2. Update **Date Kit Sent** field for all CCSSIDs
3. Go to Append Tab sheet
    a. Do not remove the first row of the file but DO delete the rows containing previous participant information
    b. Copy and paste the **CCSSID**, **Kit Lot #**, **Kit Quality #**, **Kit Expiration Date**, and **Date Kit Sent** for all records to the corresponding fields in the Append Tab sheet. *All information must remain intact*.
        i. **CCSSID** = **CCSSID**
        ii. **Kit Lot #** = **sa_kitlot**
        iii. **Kit Quality #** = **sa_qualno**
        iv. **Kit Expiration Date** = **sa_kitexp**
        v. Date Kit Sent = **sa_kitsent**
        vi. For participants who were mailed a swab kit (**ResendWhat** value 2 or 3; i.e. highlighted records), add note to **Memo** field "m/d/yy: swab kit sent [initials]"
4. Save file with same name (*Saliva Kit Tracking Info-To Be Uploaded*) in same location.
5. Save file again, but as *Saliva Kit Tracking Info-Uploaded [current date]* in: **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Kit Tracking Info\Uploaded**

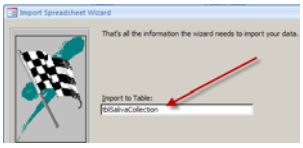
Appending Records to Database



1. Open Saliva Call Tracking database
2. On the Toolbar's External Data tab, in the Import section, click the Excel button.
3. Click Browse, then browse to *Saliva Kit Tracking Info-To Be Uploaded* (in **Z:\SJShare\SJCOMMON\ECC\TAS\Saliva Mailing Infromation\Mailings\Kit Tracking Info**)
4. Click the radio button for Append a copy of the records to the table:, then pick tblSalivaCollection from the drop down list of tables. Then click OK.
5. In the Import Spreadsheet Wizard screen, select Append Tab from the list and click Next…



6. Ensure First Row Contains Column Headings is checked and click Next
7. Make sure tblSalivaCollection is listed in Import to Table: and select Finish
6. Proceed to *CLEARING RESEND REQUESTS*



CLEARING RESEND REQUESTS

10 or Less Resend Requests:

1. Open batch file
2. Search Saliva Call Tracking database by CCSSID
3. Delete the **Resend What:** code
4. Proceed to *Maintaining Saliva Kit Inventory*

Greater Than 10 Resend Requests:

1. Import CCSSIDs from resend batch file into a temporary table in database
2. Create and run an update query using the CCSSIDs in the temporary table as the foundation to remove codes from the **Resendwhat** field
3. Proceed to *Maintaining Saliva Kit Inventory*

NB: Procedures to be developed for Expanded Cohort; Sibling Cohort

Revision Record

Printed 7/12/2012 3:41 PM

Current Filename:		Saliva Sample Collection Mailing ver 3_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/2008	Rebecca Pack	Initial Development
2	12/2010	Twanna Smith	Revision
2.1	3/30/2010	J.Bates	formatting
3.0	7/5/12	J.Ford	Major revision to match current practice

Scanning a Paper-based Document into a PDF file

1. Log onto the computer connected to the Canon scanner (in the front work area)

2. Open Adobe Acrobat
   a. Start/Programs/Adobe Acrobat 9 Standard (version name may change)

3. File/Create/PDF from Scanner/Configure Presets
   a. Indicate what sides will be scanned: (**Front Sides** or **Both Sides**)
   b. If you want to have the ability to search for words within the PDF file, then leave the Make Searchable (Run OCR) option checked. If this is not necessary, then deselect this option.
   c. Click Save (Apply; OK, as applicable)

4. File/Create/PDF From Scanner
   a. Choose appropriate color option

5. Load the document to be scanned face up in the scanner. Make sure staples and paper clips are removed
   a. The scanned pages will be displayed on the screen. You can review them here to see if you need to rescan any of the pages.

6. Save the file to an appropriate location (usually the Z:Drive)

7. Close Adobe and log off the computer

Revision Record Printed 8/6/2012 12:56 PM

Current Filename:		Scanning document into PDF ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	2/24/09	A. McDonald	Initial Development
1.1	8/6/12	J.Bates	Update menu flow to new version

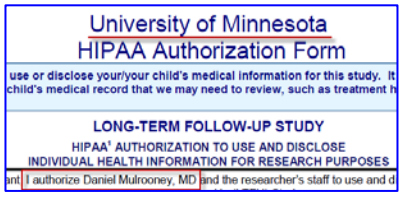
Scanning and Logging Institutional HIPAAs for Data Managers

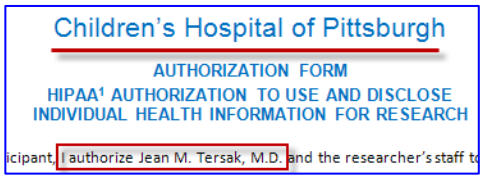
Background

The LTFU Coordinating Center obtains signed institutional HIPAAs as part of the recruitment activity on behalf of the original institution. We later provide each institution with a copy of each completed signed HIPAA. To do this, we create an electronic copy of the signed HIPAA by scanning the entire HIPAA into a pdf file. The CRA2 generates and periodically updates an assignment list of cases that need to be scanned. As HIPAAs are scanned and stored in a designated location, the CRAs document each scanned HIPAA in an electronic log in the Recruitment Tracking database and return the original to the files.

Procedures

1. The CRA2 distributes a list of CCSSIDs that need to have the institutional HIPAA scanned. CRAs use this list to identify which cases they have been assigned to scan.
2. Using the assigned list as a guide, find the physical document containing the actual signed **institutional** HIPAA.
   a. Recognizing the institutional HIPAA:
      i. Has the institution's name
      ii. Has "I authorize…." Statement with the name of the institution's PI
      iii. NOTE: (HIPAAs authorizing Leslie L. Robison Ph.D. are NOT institutional HIPAAs.)


University of Minnesota
HIPAA Authorization Form
use or disclose your/your child's medical information for this study. It
child's medical record that we may need to review, such as treatment h
LONG-TERM FOLLOW-UP STUDY
HIPAA[1] AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES
I authorize Daniel Mulrooney, MD and the researcher's staff to use and d


Children's Hospital of Pittsburgh
AUTHORIZATION FORM
HIPAA[1] AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH
icipant, I authorize Jean M. Tersak, M.D. and the researcher's staff to


LONG-TERM FOLLOW-UP STUDY
HIPAA[1] AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH
t and at my request I authorize Leslie L. Robison, Ph.D. and the researcher's staff

   b. Look in THREE places for the signed HIPAA:
      i. the filed full recruitment booklet/surveys
      ii. the filed recruitment booklets for deceased cases
      iii. the filed HIPAA-only documents for living and deceased cases
   c. Surveys/HIPAAs should be filed in order by CCSSID, but sometimes they are out of order, so check in the neighborhood.
   d. *If you find a document for a case in more than one place*, choose the document that has the dated signature of the participant/LAR. Check with the CRA2 to be sure.
   e. For deceased recruitment booklets, cut off the spline. For others, remove the staples.

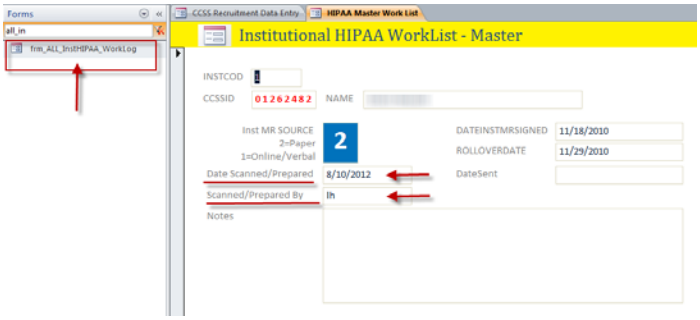
3. If you can **NOT** find the document, email the CRA2 immediately, providing the CCSSID you cannot find.

4. Scan the entire institutional HIPAA, and make sure all pages are fully rendered (not crooked, parts cut off, etc.). In most cases, the HIPAA is a single page. For institutions with multi-page HIPAAs, scan the entire institutional HIPAA.
   a. 09: Memorial-Sloan Kettering (4 pages)
   b. 03: Children's Hospital of Pittsburgh (2 pages)
   c. 22: Children's Hospital Los Angeles (2 pages)
   d. 23: (UCLA): University of California (PI: Casillas) (2 pages)
   e. 24: (Riley): IUPUI-Clarian (PI: Vik) (3 pages)
   f. 26: University of Michigan (3 pages)

5. Scan the pages to PDF (see ***Scanning a Paper-based document into a PDF file*** procedure for instructions).
   a. For a multi-age HIPAA, scan into a single document.
   b. For HIPAA-only documents, do NOT scan the separate address update page.
   c. NAME the scanned document with the 8-digit CCSSID (e.g., 01234567.pdf)
   d. INSPECT the scanned image. Rescan if pages are crooked or part of the page is cut off.
   e. SAVE the scanned file in the institution-specific folder **"!INST_XX_SIGNED HIPAAS**" in the institution's Expansion Recruiting folder: E.g.,
   Z:\SJShare]SJCOMMON\ECC\CCSS\Expansion Recruiting\21-St. Louis\!INST_21_SIGNED HIPAAs

6. The Recruitment database contains a WorkLog form for recording the date the HIPAA was scanned. This log does NOT contain cases where the initial HIPAA was obtained online or through a verbal HIPAA process.

7. After scanning and saving the electronic document, LOG the scanned HIPAA into the recruitment database's **Institutional HIPAA WorkList Master**
   a. Open the Recruitment Tracking database.
   b. If necessary, use the shutter bar to open the list of database objects. In forms, double-click the object **frm_ALL_InstHIPAA_WorkLog**
   c. In the form, search by CCSSID.
   d. *If you do NOT find the CCSSID in the WorkList, notify the CRA2 immediately, providing the CCSSID*.
   e. Enter the **DateScanned**
   f. Enter your initials in **ScannedBy**. Put your initials inside square brackets (e.g., [jb])
   g. If you need to add notes, use the **Notes** field, following the standard notation format. (E.g., "mm/dd/yy: HIPAA signed by xxx yyy, mother [inits]"



8. Reassemble the original source document in correct page order and staple pages together.

9. REFILE the original source document (paper HIPAA/Survey), making sure you file it in order and in the correct file drawer.

10. Periodically the CRA2 will update and distribute the work list again, removing scanned HIPAAs that have been logged, and adding CCSSIDs for new recruits.

11. The CRA2 will transmit the scanned HIPAAs for an institution to the data manager and record the **DateSent** in the WorkList.

Revision Record
Printed 1/9/2013 10:06 AM

210 Current Filename:		Scanning and Logging Institutional HIPAAs for Data Managers ver2_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	8/6/12	J.Bates	Initial Development
1.1	8/30/12	J.Bates	Dealing with exceptions; clarifications
2.0	12/5/12	J.Bates	New form
2.1	1/9/13	J.Bates	Corrected cross reference

Scanning Paper Questionnaires

Background

Paper questionnaires are processed and coded following initial receipt, and then the surveys are scanned and verified. The scanning process creates a digital copy of the paper survey that can be "read" by the appropriate software in order to send the data in a standardized format to a database. Scanned data is visually inspected and verified to ensure accuracy.

This procedure describes the scanning process. For instructions on the verification process, which follows scanning, see the SOP titled **Verifying Scanned Paper Questionnaires**.

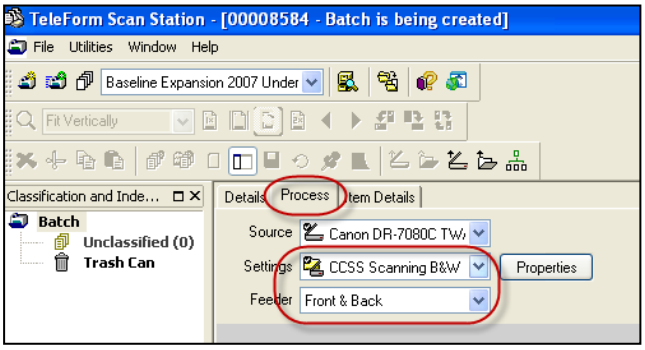
Procedure

1. **Surveys assigned to a CRA** to be scanned and verified will be placed in the CRA's work-in-progress (WIP) folder and documented in the appropriate tracking spreadsheet:
   A. Expansion baseline cases and siblings – **!TrackingBaselineScanning-QA**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\!ASSIGNMENTS*
   B. FU5 cases and siblings – **!FU5TrackingScanning**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5*
   C. CARTOX II family history, medical history, and medication inventory – **!CartoxIITrackingScanning**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Cartox II Tracking*
   D. CARTOX Functional Assessments – **!CartoxTrackingScanning**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Cartox Functional Tracking*

2. Carefully **cut the left side of the questionnaire** to remove the booklet fold and staples without cutting into the data field the software uses to "read" the paper survey.

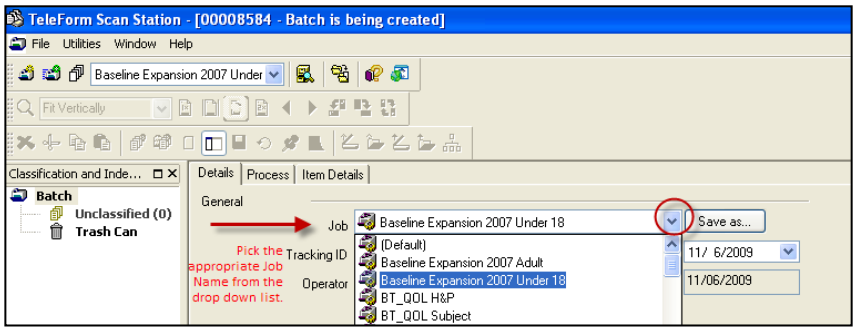
3. At a computer with an attached scanner, **open the Cardiff TeleForm programs** called TeleForm Scan Station, TeleForm Verifier, and TeleForm Reader. This will open 3 separate program windows.

4. Place the questionnaire face up in the scanner feeding tray.



5. In the Scan Station window:
   A. Open the File menu from the menu bar, and **select the "New Batch" option**.
   B. Navigate to the **Process tab**. Ensure the following fields are properly set:
      i. **Settings** – Set to "Questionnaires."
      ii. **Feeder** – Set to "Front & Back."

C. Navigate to the Details tab. In the **Job** field, **select the option that matches the survey being scanned** (e.g., "Baseline Expansion 2007 Adult with Incentive").



D. **Record the batch number** being created on a sticky note to be attached to the first page of the survey/batch *after* scanning. The batch number will be used to identify the job later in the process.

E. Click the **Start** button in bottom left corner of the tab to **begin the scan**. An image of each page will appear on the screen when the pages are finished scanning.

F. **Ensure the display of the scan includes** the correct number of pages and that each page displays a scanned image.

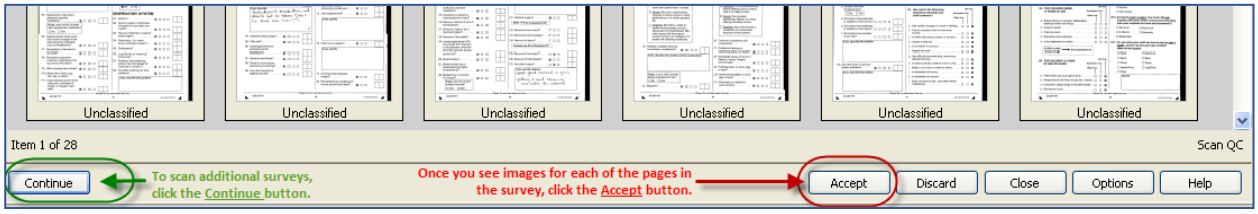
G. If all pages are scanned appropriately, remove the questionnaire from the scanning output tray, and staple the pages together in the upper left corner.

H. If you have one or more **additional surveys** to scan *in the same batch*:

   i. Place the next survey face up in the scanner input tray to begin the process again.

   ii. Click the **Continue** button to have TeleForm Scan Station create page images of the additional survey.

   iii. Complete the scan review process, as described above.



I. When all pages are scanned appropriately for all surveys included in the batch, click the **Accept** button.

J. **Attach the sticky note** with the batch number to the top page of the first survey in the batch.

6. The TeleForm Reader program now begins to read the pages.

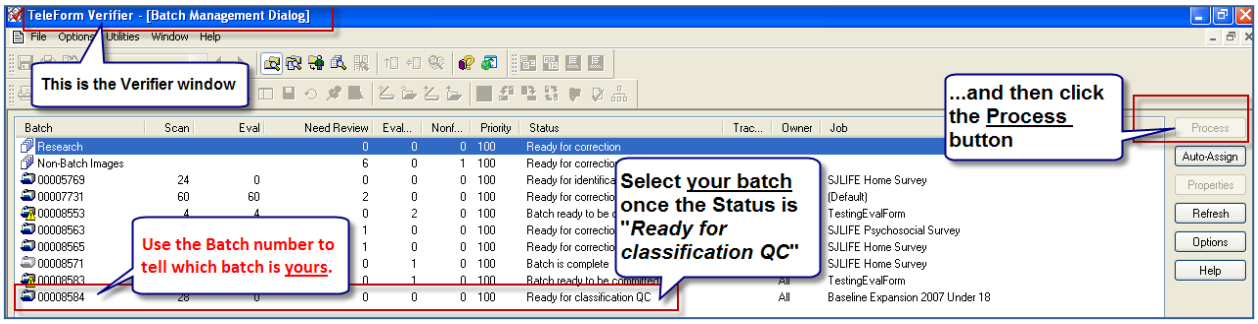
7. In the TeleForm Verifier window:

   A. Using the batch number, locate the batch in question from the batch list.

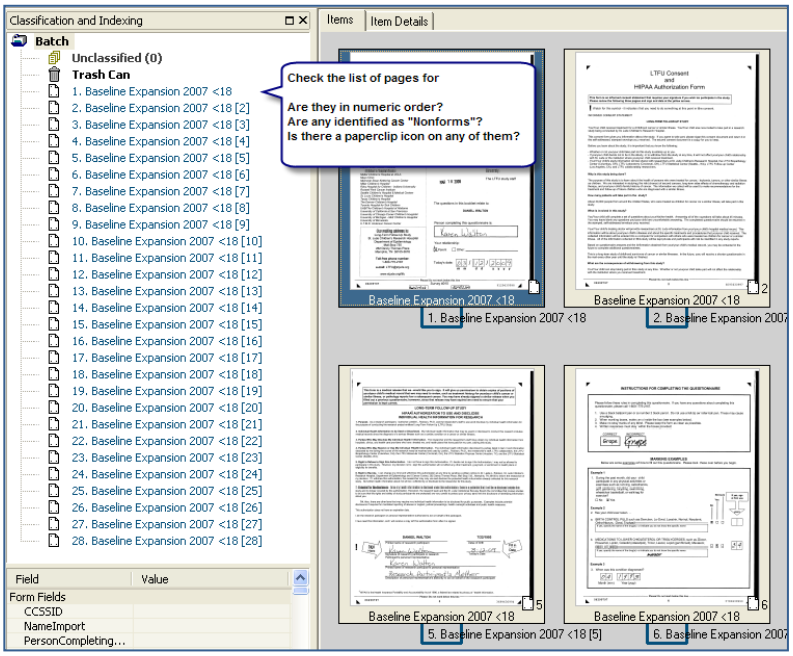
   B. When the Status column indicates the batch is "Ready for classification QC":

      i. Select the row for the batch in question.

ii. Click the **Process** button or double-click the batch number to **open the batch**. The pages of the survey(s) in the batch will display.



C. **Review the Classification and Indexing pane** to ensure none of the pages are out of numeric order or have a paper clip icon.

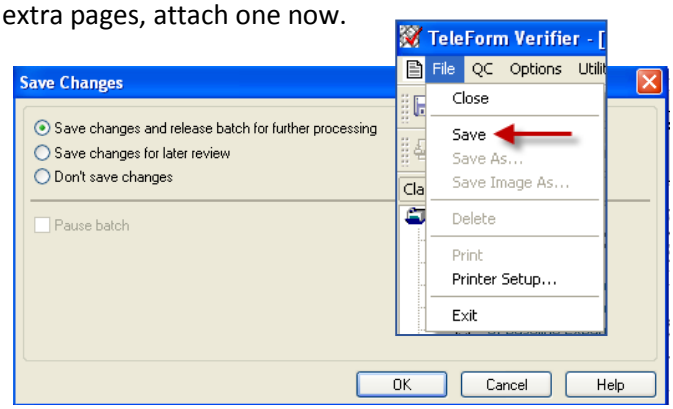


i. If pages are out of numeric order:
   a. Select the page to be evaluated.
   b. On the menu bar, open the QC menu, select "Classification," then select "Evaluate As."
   c. Select the correct questionnaire name, and type the correct page number in the **Page number** field.
   d. Click **OK**.

ii. If a paper clip icon appears:
   a. If a standard survey page has been identified as an attachment in error:
      1) Right-click each page with a paper clip icon in the Classification and Indexing pane.
      2) Select "Unclassify" from the menu. This will move the pages to the Unclassified node in the Batch tree.
      3) Double-click the Unclassified node to display the pages.
      4) Right-click each unclassified page, and select "Classification," then select "Evaluate As."
      5) Select the correct questionnaire name, and type the correct page number in the **Page number** field.
      6) Click **OK**.

b. If the participant included extra pages with the survey that are now attached to a standard survey page:
   1) Double-click the page with the paper clip in the Classification and Indexing pane to open the survey page and all attachments.
   2) Right-click on the first extra page sent by the participant.
   3) In the menu, choose "Classification," then select "Unclassify."
   4) Repeat the "Unclassify" process for all attached extra pages (i.e. pages that are not part of the standard survey).
   5) Confirm the correct number of extra pages appears in the Unclassified node of the Batch tree in the Classification and Indexing pane.
   6) Click on "Batch" in the Classification and Indexing pane to return to the batch view.
   7) If a sticky note is not already attached to the front of the survey alerting the user that there are extra pages, attach one now.

D. **Save the batch** – When all pages are in order and there are no paper clip icons (all survey pages have been properly classified, all extra pages have been unclassified):



   i. Open the File menu from the menu bar, and choose the "Save" option.
   ii. Select the "Save changes and release batch for further processing" radio button in the Save Changes dialog box.
   iii. Click the **OK** button.

8. TeleForm Reader now evaluates the forms, which may take several minutes. When Reader finishes the evaluation, Teleform Verifier will display the Status column for the batch as, "Ready for correction."

9. Scan a new batch or begin the verification process for the current batch. See the SOP titled **Verifying Scanned Paper Questionnaires** for instructions on the verification process.

Revision Record — Printed 11/30/2015 1:39 PM

Current Filename:		Scanning Paper Questionnaires ver 1_5.doc	
Revision No.	Date	Responsible Author	Change Description
1	11/6/09	C. Houston/J. Bates	Initial Development adapted from FU2007
1.1	11/18/9	J. Bates	More screen shots
1.2	12/15/09	J. Bates	Using flags to mark discrepancy corrections
1.3	1/22/10	J. Bates	Layout
1.4	6/21/11	J. Bates	Separate from verifying and examples
1.5	11/30/15	R. Massey, J. Ford	Content Revision

Scanning Sibling Expansion Baseline Questionnaires

Background

After Sibling Baseline questionnaires are processed and coded, they are scanned and verified. The scanning process "reads" the questionnaire and sends the data to a database. The verification process is a visual inspection of the scanned data to ensure accuracy. The scanning process for the Sibling Expansion Baseline Questionnaire follows the same general process as scanning the Baseline Questionnaires for cases. Similarly, verifying and review for quality assurance use the same general process. This procedure details only those elements are that unique to the Sibling Baseline scanning and verifying process.

Procedure

Cross Reference

For greater detail about scanning and verifying, as well as item-by-item guide for verifying survey items, see the following procedures:

1. Scanning Expansion Baseline Questionnaires
2. Verifying with Teleforms
3. Expansion Baseline Questionnaire Scanning and Verifying Guide
4. Expansion Baseline Questionnaire Quality Assurance Review after Verifying

Teleform Scan Station

When ready to scan, select the Job Name from the list of available jobs:

1. Sibling-BaselineExpansion 2007 Adult
2. Sibling-BaselineExpansion 2007 <18

Discrepancy Logs

The Discrepancy Logs for the sibling baseline surveys are stored on the server in **Z:\SJShare\SJCOMMON\ECC\CCSS**. Look for the survey-specific Excel file:

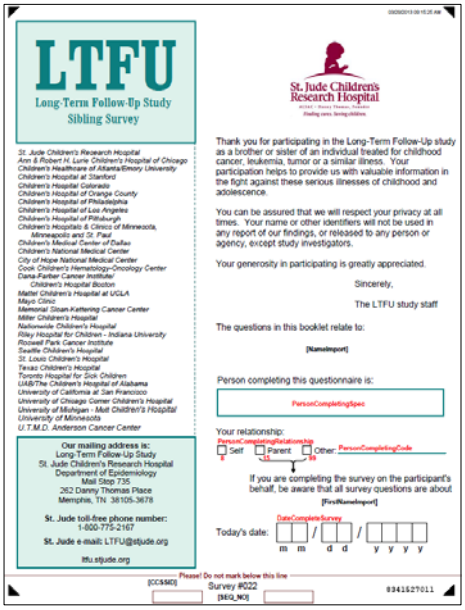
1. Expansion Baseline-UNDER 18_SIBLING_Discrepancies
2. Expansion Baseline-Over18_SIBLING_Discrepancies

A	B	C	
	Expansion Baseline SIBLING (UNDER 18) Discrepancies [SHARED]		
SIBID#	PROBLEM	PAGE NUMBER and QUESTION	RESOLUTION

A	B	C	D
	Expansion Baseline SIBLING (OVER 18) Discrepancies [SHARED]		
SibID#	PROBLEM	PAGE NUMBER and QUESTION	RESOLUTION

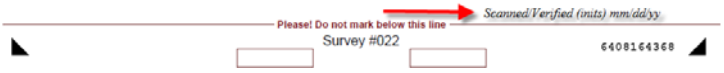
Answer Key

The answer key for the Sibling Baseline survey is located on the server (in **Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\BASELINE ANSWER KEYS-SIBLING**). You may find it helpful to print this pdf document in booklet format, to use as a desk reference while verifying and QA checking.


LTFU
Long-Term Follow-Up Study
Sibling Survey
St. Jude Children's Research Hospital
Thank you for participating in the Long-Term Follow-Up study as a brother or sister of an individual treated for childhood cancer, leukemia, tumor or a similar illness. Your participation helps to provide us with valuable information in the fight against these serious illnesses of childhood and adolescence.
You can be assured that we will respect your privacy at all times. Your name or other identifiers will not be used in any report of our findings, or released to any person or agency, except study investigators.
Your generosity in participating is greatly appreciated.
Sincerely,
The LTFU study staff
The questions in this booklet relate to:
Person completing this questionnaire is:
Your relationship:
Self
Parent
Other:
If you are completing the survey on the participant's behalf, be aware that all survey questions are about
Today's date:
m m / d d / y y y y
Our mailing address is:
Long-Term Follow-Up Study
St. Jude Children's Research Hospital
Department of Epidemiology
Mail Stop 735
262 Danny Thomas Place
Memphis, TN 38105-3678
St. Jude toll-free phone number:
1-800-775-2167
St. Jude e-mail: LTFU@stjude.org
ltfu.stjude.org
Please! Do not mark below this line
Survey #022

Completing the scanned batch

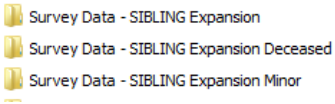
1. After scanning, verifying and committing the batch, write "***Scanned/Verified (your initials) mm/dd/yy***" in the lower right corner of the first page of the survey, just above the horizontal line.



2. Give the survey to the person assigned to the quality assurance (QA) review.

Scanned Data Databases

When a Teleform batch is committed, its data are sent to the survey-specific database, which is where you will find the data when QA'ing the jobs. The databases can be found on the server in **Z:\SJShare\SJCOMMON\ECC\CCSS\Databases,** in the survey-specific specific subfolder:



1. Survey Data – SIBLING Expansion
2. Survey Data – SIBLING Expansion Deceased
3. Survey Data – SIBLING Expansion Minor

Quality Assurance (QA) completion

After the verified survey is reviewed for quality assurance, mark the survey in the bottom right "***QA: date (initials)***" and file the survey.

Filing Surveys

The Sibling Expansion Baseline surveys are filed separately from the case baseline surveys, in the locked file cabinets clearly indicated for scanned and QA'd Sibling Baseline Surveys. File the surveys in order by SIB ID number, from low (on the left) to high (on the right). Adult and minor surveys are filed together.

Revision Record — Printed 5/16/2013 2:21 PM

[238] Current Filename:		Scanning Sibling ExpansionBaseline ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/16/13	J.Bates	Initial Development

Scanning Teleform Definitions for University of Minnesota (Inst 01)

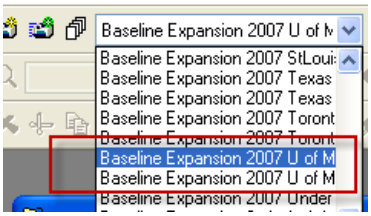
Background

We have 4 University of Minnesota baseline expansion 2007 survey teleform definitions. Two (1 each for adults and minors) are for the "full recruitment packet" which contains the institutional HIPAA, consent, LTFU HIPAA, and the survey. The second version (again 1 each for adults and for minors) omits the institutional HIPAA. This institution does not use the standard consent form, which makes version 2 necessary. (We are not able to use the standard Baseline Expansion 2007 survey for post-recruited University of Minnesota cases.) Use the **logo on the front of the survey** to determine which version and teleform definition to use when scanning.

RECRUITMENT VERSION: University of Minnesota with this **"single" logo** on front of survey:

Use Baseline Expansion 2007 U of Minnesota Adult/Minor

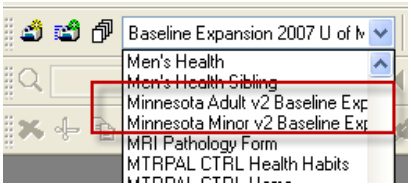
This is the "original" full-recruitment-packet version of the survey.



VERSION 2 (post recruitment): University of Minnesota with this **"double" logo** on front of survey:

Use Minnesota (Adult/Minor) v2 Baseline Expansion 2007

This is the post-recruitment version of the survey. It's different from other Baseline Expansion 2007 surveys that just show the St. Jude logo. (Minnesota v2 has a special version of the consent form.)



Revision Record

Printed 7/9/2012 1:32 PM

Current Filename:		Scanning Teleforms for University of Minnesota ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	3/31/11	J.Bates	Initial Development

Sending a Missed Appointment Follow-up Email

Background

Unfortunately, some survey appointments made with participants are not kept. When this happens, we send a follow-up email if we have a valid email address to reschedule the appointment. We also continue follow-up phone calls.

Procedure

1. Check the appropriate database and Participant Call Log, to see if we have an email address. (Do not use email addresses that are ranked "9" or "37.")
   a. If no email address is available, stop here.
   b. If an email address is available, proceed to step 2.
2. In MS Outlook, open a new email message.
3. Type the following in the subject line:
   a. **Appointment Follow-up**
4. Copy and paste the template (file name: Missed Appointment Follow-Up Email Template.docx, located at: **z:\SJShare\SJCOMMON\ECC\Interviewers\Email Requests**) into the body of the email
5. Customize the message by adding the participant's name; and month/day/year of the missed appointment.
6. Carefully proofread the email
7. Send the email
   a. BCc: the LSI team and Coordinator

Email template:

> Dear [participant name]:
>
> We're sorry we were not able to reach you for the phone survey appointment on [month, day, year]. Please let me know a convenient day and time to complete the survey with you, and we will be happy to make arrangements on our end. You can reply to this email (I will be checking my email again on [day of the week, mm-dd-yyyy]) or you can call the study coordinating center toll-free at 1-800-775-2167.
>
> Thank you again for your time and participation in this very important study. We look forward to talking with you soon.
>
> Sincerely,
>
> [Interviewer signature block]

Revision Record — Printed 7/11/2012 3:04 PM

Current Filename:		Missed Appointment Email ver 1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	7/02/12	Rinehart/McDonald	Initial Development
1.1	7/10/12	Procedure Team	Content revision

Sending Participant Copies of the LTFU Informed Consent

Background

Survey Interviewers (SIs) who obtain a verbal informed consent will determine whether we need to send the participant a copy of the informed consent document. The SIs document these requests on the informed consent form and indicate if the copy should be mailed or emailed. Once the informed consent has been processed, those needing a participant copy will be filed in the "Needs Consent" folder in the Call Center's file cabinet A. A Lead Survey Interviewer (LSI) or Coordinator designee then fills the requests.

Procedures

Preparing Mailed Copies

1. The needed files are located in *Z:\SJShare\SJCOMMON\ECC\CCSS* as follows:

Generic Cover Letter

Form File Name	Purpose and Contents
Generic CoverLetter-Participant Copy FINAL *mm-dd-yy*	cover letter for sending enrollment forms (HIPAA and IC)
Location: *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies*	

LTFU Expansion Cohort (Case) Informed Consent and LTFU HIPAA

Form File Name	Purpose and Contents
Baseline Expansion Minnesota Over_Under 18 *mm-dd-yy*_Participant Copy	MINNESOTA ALIVE case participant copy *contains a copy of the appropriate consent form and LTFU HIPAA*
Baseline Expansion Minnesota_Deceased *mm-dd-yy*_Participant Copy	MINNESOTA EXPIRED case participant copy *contains a copy of the appropriate consent form*
Consent and LTFUHIPAA Baseline Expansion *mm-dd-yy*__Participant Copy	NON-Minnesota ALIVE case participant copy *contains a copy of the appropriate consent form and LTFU HIPAA*
Consent Baseline Expansion_Deceased *mm-dd-yy*__Participant Copy	NON-Minnesota and NON-Dana Farber EXPIRED case participant copy - *contains a copy of the appropriate consent form*
Baseline Expansion Dana Farber Deceased *mm-dd-yy*__ParticipantCopy	DANA FARBER EXPIRED case participant copy - *contains a copy of the appropriate consent form*
LTFU HIPAA-ParticipantCopy *mm-dd-yy*	LTFU HIPAA form used for ANY case ANY institution ANY vital status
Location: *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\PARTICIPANT COPIES*	

LTFU Expansion Cohort (Sibling) Informed Consent and HIPAA

Form File Name	Purpose and Contents
Sibling-Baseline_Over-Under 18-Living *mm-dd-yy*	ALIVE sibling participant copy *contains a copy of the appropriate consent form and LTFU HIPAA*
Sibling-Baseline_Deceased *mm-dd-yy*	EXPIRED sibling participant copy *contains a copy of the appropriate consent form*
Sibling-LTFU HIPAA *mm-yy-dd*	LTFU HIPAA form used for ANY sibling ANY vital status
Location: *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\Participant Copies*	

2. **Identify the case or sibling participants** that need a paper copy of the informed consent by reviewing requests in the "Needs Consent" folder of the file cabinet A.

3. **Prepare the materials**:
   A. Collect or print a copy of the **Generic CoverLetter-Participant Copy FINAL *mm-dd-yy*** on St. Jude letterhead stationery (see step 1, above, for location).
   B. Locate the appropriate version of the participant copy needed for each recipient:
      i. For cases, identify the treating institution by reviewing the CCSSID. See the SOP titled **Decoding CCSSID** for details.
      ii. Determine whether the *living* or *deceased* version is needed.
      iii. If you do not have a preprinted stockpile of the copy you need, print the participant copy from the server document (see above for location) to a COLOR printer.
      *NOTE: Please do NOT use participant copies with poor color resolution.
      *NOTE: Always print participant copies with 2-sided printing for multi-page consent forms.
   C. Assemble the materials by stacking the cover letter on top of the participant copy. Clip the copies together, and identify the CCSSID or SIBID with a Post-It note on the front.

4. Once weekly, (either on Tuesday afternoon or Wednesday morning):
   A. For baseline surveys, check the **Thank you Sent** field in the Baseline tab (for cases) or the Sib Baseline tab (for siblings) of the Expansion Tracking database to determine if the thank-you card for the survey in question has already been sent. If the field is blank, the card has not been sent.
   B. For FU5 surveys, check the **Date Thank You Letter Sent** field in the FU5 Tracking tab (for cases and siblings) of the LTFU Participant database to determine if the thank-you card for the survey in question has already been sent. If the field is blank, the card has not been sent.

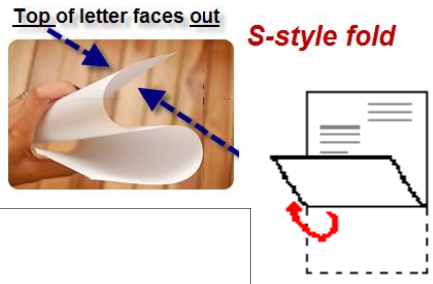
C. If the thank-you card *has not* been sent AND the **Date Survey Returned** field on the same tab is populated with a date, take the assembled materials to the CRAII right away for inclusion with the survey thank-you cards.

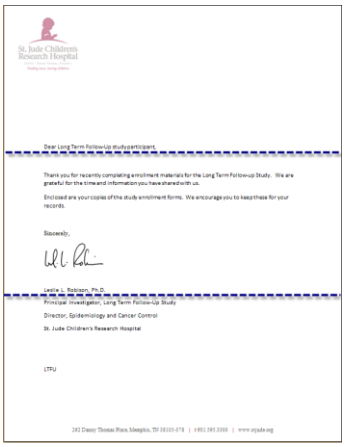
D. If the thank-you card *has* already been sent OR if the **Date Survey Returned** field on the same tab is blank:

i. **Prepare the envelope**:

1. Go to *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies* and open the **Envelope** document.
2. Type in the participant's name, address, and CCSSID/SIBID in the format pre-defined in the document. For minors, the envelope should be addressed to "The Parents of" the participant; for deceased participants, the envelope should be addressed to "The Family of" the participant.
3. Print the envelope using St. Jude logo envelopes.
4. Close the **Envelope** document without saving your changes.

ii. **Fold the documents**: Remove the paper clip and Post-It note. Hold the 2 documents together, and then fold in thirds. In the second fold, the top of the letter with the letterhead should face outwards. (See the illustrated example for this S-style fold.)





iii. **Insert the documents into the envelope** with the letterhead facing up and facing the back of the envelope. Seal.

iv. **Put the envelope in the outgoing mail** to send the copy to the participant.

5. Continue to the section of this document titled *Documenting the Sent Participant Copy*.

Preparing Emailed Copies

1. The needed files are located in *Z:\SJShare\SJCOMMON\ECC\CCSS* as follows:

Generic Cover Letter

Form File Name	Purpose and Contents
Generic CoverLetter-Participant Copy FINAL *mm-dd-yy*	cover letter for sending enrollment forms (HIPAA and IC)
Location: *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies*	

LTFU Expansion Cohort (Cases) Informed Consent and LTFU HIPAA

Form File Name	Purpose and Contents
Baseline Expansion Minnesota Over_Under 18 *mm-dd-yy*_Participant Copy	MINNESOTA ALIVE case participant copy *contains a copy of the appropriate consent form and LTFU HIPAA*
Baseline Expansion Minnesota_Deceased *mm-dd-yy*_Participant Copy	MINNESOTA EXPIRED case participant copy *contains a copy of the appropriate consent form*
Consent and LTFUHIPAA Baseline Expansion *mm-dd-yy*__Participant Copy	NON-Minnesota ALIVE case participant copy *contains a copy of the appropriate consent form and LTFU HIPAA*
Consent Baseline Expansion_Deceased *mm-dd-yy*__Participant Copy	NON-Minnesota and NON-Dana Farber EXPIRED case participant copy *contains a copy of the appropriate consent form*
Baseline Expansion Dana Farber Deceased *mm-dd-yy*__ParticipantCopy	DANA FARBER EXPIRED case participant copy - *contains a copy of the appropriate consent form*
LTFU HIPAA-ParticipantCopy *mm-dd-yy*	LTFU HIPAA form used for ANY case ANY institution ANY vital status
Location: *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\PARTICIPANT COPIES*	

LTFU Expansion Cohort (Sibling) Informed Consent and HIPAA

Form File Name	Purpose and Contents
Sibling-Baseline_Over-Under 18-Living *mm-dd-yy*	ALIVE sibling participant copy *contains a copy of the appropriate consent form and LTFU HIPAA*
Sibling-Baseline_Deceased *mm-dd-yy*	EXPIRED sibling participant copy *contains a copy of the appropriate consent form*
Sibling-LTFU HIPAA *mm-yy-dd*	LTFU HIPAA form used for ANY sibling ANY vital status
Location: *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\Participant Copies*	

2. **Identify the case or sibling participants** that need an emailed copy of the informed consent by reviewing requests in the "Needs Consent" folder of the file cabinet A.

3. **Prepare the email**:
   A. Open a new email in MS Outlook.
   B. In the **Subject:** field, type "Long Term Follow-Up Study" without quotation marks.

C. Open the document titled **Generic CoverLetter-Participant Copy FINAL *mm-dd-yy*** (see above for location). Copy the body of the document and paste it into the body of the new email, replacing your email signature if present.
D. Attach the appropriate version of the participant copy for each recipient (see above):
    i. For cases, identify the treating institution by reviewing the CCSSID. See the SOP titled **Decoding CCSSID** for details.
    ii. Determine whether the *living* or *deceased* version is needed.
E. Copy the participant's email address, and paste it into the **To:** field of the email.
    i. For baseline surveys, the email address is found in the Quest tab (for cases) or Sib Info tab (for siblings) of the Expansion Tracking database.
    ii. For FU5 surveys, the email address is found in the Participant tab (for cases and siblings) of the LTFU Participant database.

4. Click the **Send** button to **send the email** and informed consent copy to the participant.

5. Continue to the section of this document titled *Documenting the Sent Participant Copy*.

Documenting the Sent Participant Copy

1. **Update the database** for each CCSSID or SIBID that received a participant copy of the informed consent, whether via hard copy or email:
    A. For baseline surveys:
        i. Open the blue case record or the green sibling record in the Expansion Tracking database.
        ii. In the **Tracking Comments** field of the Baseline tab (for cases) or Sib Baseline tab (for siblings), log a dated note with SI ID indicating that the informed consent was either (1) submitted to the CRAII for inclusion with the thank-you card or (2) sent via hard copy or email.
    B. For FU5 surveys:
        i. Open the case or sibling record in the LTFU Participant database.
        ii. In the **Notes** field of the FU5 Tracking tab, log a dated note with SI ID indicating that the informed consent was either (1) submitted to the CRAII for inclusion with the thank-you card or (2) sent via hard copy or email.
2. **Update the informed consent form** by documenting your SI ID and the date of completion in the **Participant Copy Sent** boxes.
3. **File the informed consent form** appropriately:
    A. For completed surveys, indicated on the informed consent form by *populated* **Survey Completed** boxes, file the form in the appropriate folder in file cabinet 2.
    B. For partial surveys, indicated on the informed consent form by *blank* **Survey Completed** boxes, file the form numerically in the "Partially completed surveys" folder in the bottom drawer of file cabinet A.

Revision Record Printed 12/11/2014 1:33 PM

Current Filename: [269]		Sending Participant Copies of the LTFU Informed Consent ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	4/19/2014	D. Rinehart, R. Massey	Initial Development
1.1	12/8/14	R. Massey	Content Revision: updated doc titles, removed *IC Copy Request Log*/replaced with new procedure on IC form, added LTFU Pt db

Sending Participant Copies to Verbal HIPAA Cases

Background

Survey interviewers (SIs) who obtain a verbal HIPAA will determine whether a participant copy of the HIPAA needs to be sent and will post the determination along with the requested format, if applicable, in the **Resend Request** field on the Recruitment database's Tracking tab. A Lead Survey Interviewer (LSI) or the Coordinator's designee then processes the participant copy request on the next weekday (Monday – Friday).

Procedure

Identifying Cases/Participant Copies to Be Processed

1. Open the CCSS Call Center Admin Database, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI\Tech\CCSS Call Center Admin DB*.
2. Click the **Retrieve HIPAA Copies** button. – Each record in this form represents a HIPAA participant copy determination that needs to be processed. Access the first case's record in the CCSS Recruitment Database (located at *https://departments.stjude.org/sites/ECC /DatabasesandSystems/Lists/Databases/AllItems.aspx*), and review the **Resend Request** field on the Tracking tab to determine the type of participant copy needed, if any.
   A. Code 5 – A participant copy is needed, and the requested format is paper.
   B. Code 6 – A participant copy is needed, and the requested format is paper. The participant also requested that the Spanish version is sent.
   C. Code 7 – A participant copy is needed, and the requested format is email.
   D. Code 8 – A participant copy is needed, and the requested format is email. The participant also requested that the Spanish version is sent.
   E. Code 9 – No participant copy is needed.

Preparing Mailed Copies

For participants that requested a paper copy of the HIPAA, denoted by a code 5 or 6 in the **Resend Request** field of the CCSS Recruitment Database:

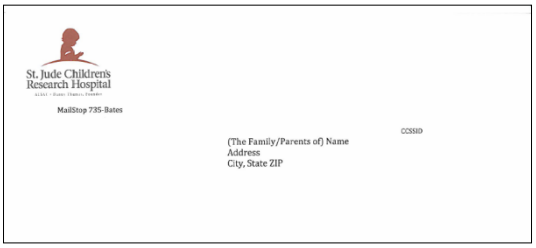
1. Prepare the materials:
   A. Gather the appropriate **participant copy of the institutional HIPAA** from the bottom drawer of file cabinet A:
      i. Treating Institution – Use the CCSSID to identify which institution's HIPAA should be sent. See the SOP titled **Decoding CCSSID** for details.
      ii. Vital Status – Use the case's record in the Recruitment database to determine whether the living or deceased version is needed.
      iii. Spanish – Use the **Resend Request** field in the case's Recruitment database record to determine if the Spanish version is needed.

a. When the Spanish version is requested, *send both the Spanish and English versions*.
b. If a Spanish version is needed but is not in the institution's folder, see your supervisor for assistance.

iv. If there is not a preprinted stock of the correct institutional HIPAA, print the copy from *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies* to a COLOR printer.
a. Always print participant copies with 2-sided printing for multi-page HIPAAs.
b. Do not use participant copies with poor color resolution.

B. Gather the **cover letter** from the bottom drawer of file cabinet A.
i. If there is not a preprinted stock of **Generic CoverLetter-Participant Copy FINAL *mm-dd-yy***, print a copy from *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies* onto St Jude letterhead.
ii. NOTE: If the survey has been completed and the thank-you card not yet processed, the cover letter and HIPAA should now be secured with a paperclip and taken to the CRA2 for inclusion with the thank-you card (no envelope). After delivering the documents, continue to the section of this procedure titled *Updating the Databases*.

C. Prepare the **mailing envelope**.
i. Open the **Envelope** document at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies*
ii. Type the participant's name, address, and CCSSID into the formatted envelope.



a. For minors, the envelope should be addressed to "The Parents of" the case.
b. For deceased cases, the envelope should be addressed to "The Family of" the case.

iii. Print the envelope using a St. Jude envelope.
iv. Close the **Envelope** document without saving it.

2. **Assemble**:

A. Stack the cover letter on top followed by the Spanish version of the HIPAA (if applicable) and then the English version of the HIPAA.

B. Hold the documents together, and then fold them in thirds using an S-style fold. See the image of the letter for the approximate locations of the 2 folds. Folded correctly, the paper will only have 2 folds and will fit neatly in the envelope.

i. First, fold the BOTTOM of the documents, taken together, along the lower dotted line UP to the top dotted line.
ii. Then fold along the TOP dotted line, BACK so that that top third of the letter, with the letterhead, is facing outwards.
iii. Insert the documents into the envelope with the letterhead facing up and out of the envelope.
iv. Seal.

3. **Put the envelope in the outgoing mail** to send the copy to the participant.

4. Continue to the section of this document titled *Updating the Databases*.

Preparing Emailed Copies

For participants that requested an emailed copy of the HIPAA, denoted by a code 7 or 8 in the **Resend Request** field of the CCSS Recruitment Database:

1. **Prepare the email**:
   A. Open a new email in MS Outlook.
   B. In the subject line, type "Long Term Follow-Up Study" without quotation marks.
   C. Open the document titled **Generic CoverLetter-Participant Copy FINAL *mm-dd-yy*** (located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies*). Copy the contents of the document and paste it into the body of the new email, replacing your email signature if present.
   D. Attach the appropriate institutional HIPAA copy (located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Recruiting\!!ParticipantCopies*):
      i. Treating Institution – Use the CCSSID to identify which institution's HIPAA should be attached. See the SOP titled **Decoding CCSSID** for details.
      ii. Vital Status – Use the case's record in the Recruitment database to determine whether the living or deceased version is needed.
      iii. Spanish – Use the **Resend Request** field in the case's Recruitment database record to determine if the Spanish version is needed.
         a. When the Spanish version is requested, *send both the Spanish and English versions*.
         b. If a Spanish version is needed but is not in the institution's folder, see your supervisor for assistance.
   E. Copy the participant's email address from the Quest tab of the Recruitment database, and paste it into the **To:** bar of the email.

2. Click the **Send** button to **send the email** and HIPAA copy to the participant.

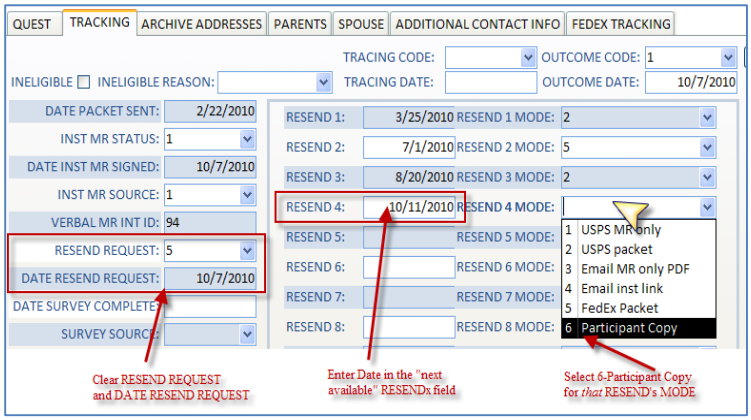
3. Continue to the section of this document titled *Updating the Databases*.

Updating the Databases

For each participant, regardless of whether or not a participant copy of the HIPAA was needed:

1. **Update the Recruitment database** for each CCSSID:
   A. Open the case's record in the Recruitment database.
   B. If a participant copy was mailed, emailed, or delivered to the CRA2:
      i. **Resend #** (Tracking tab) – In the next available field, enter the date the HIPAA was sent.
      ii. **Resend # Mode** (Tracking tab) – In the corresponding field, select 6-Participant Copy.

iii. When the participant copy was mailed or emailed, add a record to the contact log indicating so. In the **Contact Mode** field, choose 5-Mail or 2-Email.



C. Clear the **Resend Request** and **Date Resend Request** fields**.**

D. In the **Recruit Notes** field, enter a dated note documenting:

i. If a participant copy was mailed/e-mailed, if a copy was delivered to the CRA2, or if no copy was needed

ii. The changes made to the **Resend Request** and **Date Resend Request** fields

2. **Update the Expansion Tracking database** (located at *https://departments.stjude.org/sites/ECC /DatabasesandSystems/Lists/Databases/AllItems.aspx*):

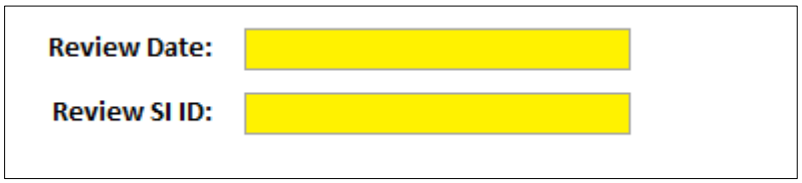
A. Determine if the **Outcome** of the verbal HIPAA call is set to 12-Verbal HIPAA-Sent Link. If yes, the SI emailed the survey link to the participant at the time of the verbal HIPAA.

B. If the link was emailed, document the email in the Expansion Tracking database. See the SOP titled **Expansion Baseline Survey Calls** for instructions.

3. **Update the CCSS Call Center Admin database**. When all above steps have been completed for the record in question:

A. **Review Date** – Enter the current date.

B. **Review SI ID** – Enter your SI ID, and then move to a new field.



C. Press F5 to refresh the form.

D. Repeat entire SOP until all records in the form have been processed.

Revision Record — Printed 9/3/2015 3:22 PM

[15] Current Filename:		Sending Participant Copies to Verbal HIPAA Cases ver 3_4.docx	
Revision No.	Date	Responsible Author	Change Description
1	10/11/10	J. Bates	Initial Development
1.1	11/2/2010	J. Bates	Revised letter content
2.0	6/29/2011	J. Bates	Copies are mailed by survey interviewers
3.0	2/22/12	J. Bates	Illustrated folding instructions
3.1	5/7/12	J. Bates	Merge 2 documents
3.2	12/3/13	R. Massey	Content Revision: specify 2-sided copies, add email instr, formatting
3.3	12/9/14	R. Massey	Content Revision: new process for gathering and documenting HIPAA requests, assign cases for baseline, document survey links sent
3.4	8/12/15	R. Massey	Content Revision: added directive to document in contact log, removed directive to assign Baseline follow-up

Sending Spanish Thank You Notes

Background

The LTFU Study regularly sends pre-printed thank you notes to participants upon receipt of completed baseline and follow-up surveys. Surveys from participants requiring or preferring Spanish are completed via telephone with a Survey Interviewer (SI), and the thank you notes for these participants include a personalized Spanish note inside the English preprinted note card.

The SI obtaining the Spanish language survey creates the personalized Spanish note either by hand-writing it on the inside of a blank thank you card or by printing it on plain paper trimmed to fit inside the thank you card. The note is prepared the same day the survey is obtained and then forwarded to the CRA2. The CRA2 completes the mailing, adding incentive gifts when appropriate.

Procedure

1. The *same day* the survey is submitted:
    A. **Email the CRA2** that a survey was completed with a participant in Spanish and that a personalized note is being prepared in Spanish to be sent with the thank you card. Indicate the CCSSID/SIBID, participant name, and date the survey was completed.
    B. **Compose** a personalized note *IN SPANISH*. Either hand-write the note inside a standard thank you note card, or prepare a computer-printed note in MS Word to be used as an insert.
        i. For a hand-written note inside a thank you card, paper clip a post-it note to the card with the CCSSID/SIBID, the full name of the participant, the date the survey was obtained, and the SI's name.
        ii. For a computer-printed insert/note:
            a. Include the CCSSID/SIBID on the insert.
            b. A sample note, titled **SAMPLE SPANISH THANK YOU NOTE_ao**, is located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Spanish*. If using this template, replace the following with the appropriate values:
                1) Salutation
                2) Surname
                3) "your health" vs. "your child's health" in the body of the note
            c. Neatly trim the printed insert to fit inside the thank you note without having to be folded. 5.25" wide x 4" tall will fit without folding.
    C. **Deliver** the hand-written thank you card with post-it note or the printed thank you insert to the project CRA2. The CRA2 saves the note/insert for the regularly scheduled thank you mailing when the incentive gift card will be added, if appropriate.

2. Ensure:
    A. The call log documenting the survey completed in Spanish has the **DB Change** field populated with "Spanish Survey Completed".

B. The Spanish status field is properly updated in the relevant database.

Revision Record Printed 1/15/2015 9:04 AM

66 Current Filename:		Sending Spanish Thank You Notes ver3_2.docx	
Revision No.	Date	Responsible Author	Change Description
1	3/31/11	J. Bates	Initial Development
2	7/18/11	J. Bates	More explicit: note is written in SPANISH
3	12/12/12	J. Bates	Major change due to incentive enclosures
3.1	1/22/13	J. Bates	Computer-printed option; Inst 01 exception
3.2	12/27/14	R. Massey, A. Oyuela	Content Revision: include siblings, include FU surveys, removed non-incentive language for inst 01

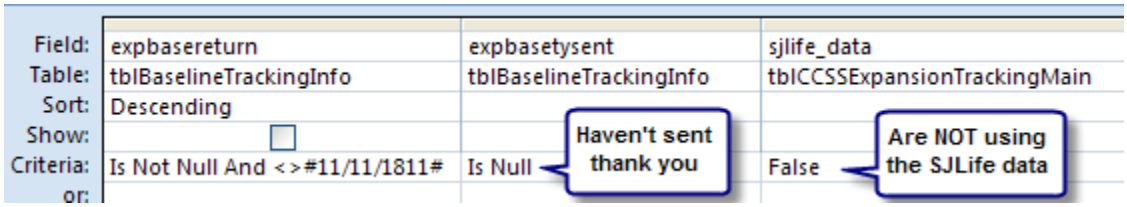
Sending Thank You Notes

Background

On a regularly scheduled monthly basis (the last Monday of the month, for instance), we send Thank You notes to participants who returned surveys. Using the appropriate database, we produce a data file used in create mailing labels using the mailmerge procedure in Word.

***Expansion:* Baseline**

1. Open the Expansion database
2. Find qryThankyouCases
3. Open the query in design view
    a. We need to see CCSSID, name, sendaddr, sendcity, sendstate, zipsort, sendcountry
    b. For these criteria:
    c. Run the query. NOTE how many records occur.

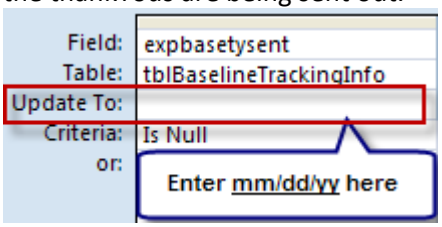


    d. Export the file to Excel (External Data/Export/Excel) and put it on the Z: Drive (…***\ECC\CCSS\Expansion Baseline\Exp Thank yous***) with a file name identifying the query date (e.g., ThankYou Cases mm-dd-yy).
        i. In the excel file, double check SendCareOf variable. If needed, edit in the excel file BEFORE merging the file to labels.
            1. For Alive=2 (deceased), be sure sendcareof says The Family of
            2. For other sendcod values, be sure "The Parents of" does not repeat itself in the sendcareof column.

    e. Update 12/29/10: built-in function to create the "sendcareof" variable. Query displays values for sendcod (as well as the Alive variable). This replaces the 9/7/10 "fix" for deceased cases.
        i. If the sendcod is null or 1 (self), then sendcareof is the individual
        ii. if it is "5", then use Family of (pt is deceased)
        iii. Otherwide, use The Parents of
        iv. SQL: sendcareof: IIf([sendcod] Is Null Or [sendcod]="1",[name],IIf([sendcod]="5","The Family of " & [name],"The Parents of " & [name]))
4. Use the spreadsheet to create the mailing labels.
    a. Affix the labels to the stuffed/sealed thank yous, and mail

5. Now update the records with the date these thank yous were sent. Do this with an Update query:
    a. Change the query to an Update query

b. In the "update to" space for expbaseTYsent field on the query design, key in the date the thankYous are being sent out.



c.
d. View the query results and double-check that the same number of records will be updated as you noted were in the query in the first place! Once confirmed, run the query.
e. Now change the query back to a Select query.
f. Double check by rerunning the select query….you should get 0 records.

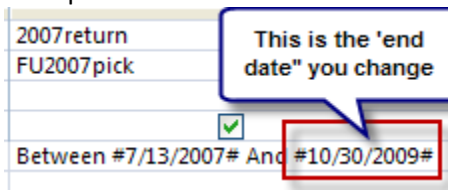
Expansion: Siblings

Once sibling surveys are produced for the expansion cohort, a query will need to be set up for generating the thank you list for that group of participants.

Original Cohort: Cases

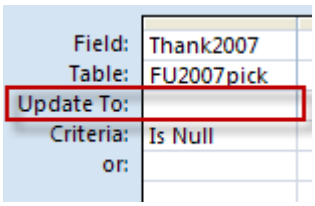
1. Open Registration database
2. Open query list

3. Click on qryjoThankYousFU2007
   a. Open in design view
   b. In criteria for the 2007Return field (in the FU2007Pick table), change the *end date* to 2 days ago (if we inserted today's date, then surveys completed yesterday may not have updated addresses in the database)



   c. Run the query
   d. NOTE how many records will be included.
   e. Send to Excel (Tools/Analyze with ...)
   f. Save Excel file to S:Drive (for example)
      i. ***…\ECC\CCSS\2007FU Cases\Thank you notes*** [Filename: CaseThankYou_mm-dd-yy]

4. Use spreadsheet to create mailing labels
   a. Affix labels and mail



5. Change qryjoThankYousFU2007 query to an *update* query
   a. In the UpdateTo row for the Thank2007 field, key in the date the Thank you notes will be sent

b. Click the Run button… before you give the final OK, double check – be sure it matches the number of records that were in the first select query (if not, cancel the update query!)
c. Once the update query gives the correct number of records, OK to run the query.

6. Change *back to a select query*
   a. Rerun the query. At this point, you should get 0 records

Original Cohort: Siblings

1. Same as above except use gryjosib2007Thankyou
   a. We need to see the ID, sendname, address, city, state, zip, and country in the query output.
   b. Conditions: Thank2007Sib NOT filled in; and interviewerID blank; and 2007returnSib between earliest possible date and the date you are running the query; and the 2007SenddateSib is between earliest and latest possible.
   c. Save the query output to …***\ECC\CCSS\2007Sibling\Thank you Sibs*** [Filename: Sib DThankYou mm-dd-yy-USA or CANADA]

2007SenddateSib	2007returnSib	Thank2007Sib	IntIDSib
SibFU2007Pick	SibFU2007Pick	SibFU2007Pick	SibFU2007Pick
☐	☐	☐	☐
Between #7/2/2008# And #8/25/2009#	Between #7/2/2008# And #10/30/2009#	Is Null	Is Null

Revision Record Printed 7/9/2012 10:36 AM

Current Filename:		Sending Thank You Notes ver 3_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	8/27/09	A. McDonald	Initial Development
2	10/30/09	J.Bates	Expansion details
3	9/7/10	J.Bates	Deceased
3.1	12/29/10	J.Bates	“smart” query to build sendcareof value

Sending Updated SN Confirmation Data to the Biostatistical Center

Background

There are occasions when information regarding a subsequent neoplasm (SN) in the frozen SN project dataset needs to be modified (e.g. upgraded confirmation circumstances from self-report to histologically validated, updated diagnosis date based on newly obtained records, or corrected coding). After the changes to the confirmation record and/or **Pursue Status** fields are documented in detail in the SNT database and the **Record Updated** field is populated with the date of the changes, we must notify the biostatistics team at Fred Hutchinson Cancer Center of the required changes.

This procedure describes the process for using the **Record Updated** flag to periodically alert the biostatistics team to needed changes to the frozen dataset.

Procedures

1. Run the query **qry_SN_UpdateSeattle_RM**.
2. Export the results as an Excel sheet.
    A. Save the results to *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Seattle\Confirmed SN Updates*.
    B. Append the current date to the query name in mmddyy format (e.g. qry_SN_UpdateSeattle_RM 032618).
3. Resave the sheet in the same location with the suffix "-Revised" on the file name (e.g. qry_SN_UpdateSeattle_RM 032618-Revised).
4. Move the original download's Excel file to the Archive folder *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Seattle\Confirmed SN Updates\Archive*.
5. In the –Revised Excel file, update the column headers to more clearly reflect what the data in each column are.
6. Add a second worksheet to the workbook, and name it "Data Legend." Create a data legend in this worksheet to explain the values for the variable in each column, as appropriate.
7. Add a column between the condition number column and the source column.
    A. Title the added column "What Changed."
    B. Highlight this column header.
8. In the "What Changed" column, add a comment for each row explaining in detail what has changed. Clearly state what the value is in the frozen dataset and what it should be changed to.
9. When the workbook is complete, log it in the **Confirmed SN Updates** section of the Excel workbook titled **Seattle Submission Tracking**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Seattle*.
10. When ready to send to Seattle:

A. Open the Excel workbook titled **Seattle Submission Tracking**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Seattle*.
B. Review the **Confirmed SN Updates** section of the workbook. This displays all Excel workbooks created from database queries to report confirmed SNs that (1) have been updated since their original submission to the biostatistics team and (2) are ready to be sent to update the biostatistics team. The list includes the name of the workbooks that are ready for submission to Seattle, their location on the network, the date they became ready for submission, and, when applicable, the date the information was sent to the biostatistics team.
C. For any worksheet without a Date Sent in **Seattle Submission Tracking**, ensure there is a Data Legend worksheet to explain the values for the variable in each column of the query worksheet, as appropriate.

11. Send the worksheets containing the updates to the biostatistics team at Fred Hutchinson Cancer Center in Seattle. If the worksheets amount to less than 5MB of data, send them via encrypted email. If the worksheets amount to more than 5MB of data, send them via the St. Jude File Transfer Application (FTA). In either case, include a reminder to the biostatistics team that there is a legend sheet in the workbook.
12. After the updates have been successfully sent to the biostatisticians:
    A. Move the workbook(s) from *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Seattle\Confirmed SN Updates* to *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Seattle\Confirmed SN Updates\Sent*.
    B. Document the Date Sent in the Excel workbook titled **Seattle Submission Tracking**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\Seattle*.
    C. Manually access each participant's applicable condition record.
        i. Manually clear the **Record Updated** field.
        ii. Manually update the **Date Sent to Seattle** field to the date the change was sent.
        iii. Document the changes to these 2 fields in a dated note with initials in the **Condition Notes** field.

Revision Record Printed 3/27/2018 11:12 AM

Current Filename:		Sending Updated SN Confirmation Data to the Biostatistical Center v1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	3/27/2018	R. Massey	Initial Development

Shipping Recruitment via Fed Ex

Background

When recruitment packets are sent to potential recipients via FedEx, the sender of the package needs to display as the institution where the patient was identified as eligible. This procedure outlines the settings we use when shipping these packets by FedEx, requiring indirect signature. Requiring signature gives us more confirmation that the package was actually received by a human being.

Procedure

In the FedEx online system, enter items as shown below:

Sender fields

Enter the FROM information:	Shows up on the Return address on the label in this order
1. Company (35 char) 2. Contact name (35 char) 3. Address 1 (35 char) 4. Address 2 (35 char) 5. City 6. State 7. Zip 8. PhoneNumber	Contact name (35 char) Company (35 char) Address 1 (35 char) Address 2 (35 char) City, State Zip The phone number is where FedEx will call when it can't deliver. This was one of our admins…..
e.g. (**WE** USED) Memorial Sloan Kettering Charles Sklar, MD c/o Long Term Follow-Up Center 262 Danny Thomas Place Memphis, TN 38105	 Charles Sklar, MD Memorial Sloan Kettering c/o Long Term Follow-Up Center 262 Danny Thomas Place Memphis, TN 38105

Service type: FedEx Express Saver (3 business days)

Delivery address type: RESIDENCE (can deliver up to 7 pm)

Signature options: we used indirect signature (anyone at the address can sign)

Email notifications: select as many options as desired.

- ☐ Shipped
  - *The Shipped notification will contain the recipient name, which helps when you are trying to find the tracking number for a returned package….so you can see how many attempts were made, and sometimes the reason for the return.*
- ☐ exception (e.g., delays)
  - *I did not find this all that useful. However, it did tell me when they were reattempting delivery. If I had to do this again, I would NOT check notification on exceptions*

Lead CRA

- ☐ Delivery
  - *This gives a link to the airbill number, which I used to verify the signature name. Could not always go by what the driver keyed into the system….seeing the actual image was useful. Other times, the signature image was just a scribble, and we had no choice but to go by what the driver keyed.*
  - *Sometimes delivery notice indicates "Signature release on file." This means the resident at the address has signed a document with FedEx, allowing FedEx to leave the document without a signature, should no one be available to sign.*

Email notification addresses: can give up to 3 email addresses. I set my Outlook up with rules to drop the incoming messages into a folder I set up for this….helped with filing….

Revision Record Printed 7/6/2012 8:49 AM

Current Filename:		Shipping Recruitment via Fed Ex ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/21/10	J.Bates	Initial Development

Sibling Baseline Survey Data File and Posting

Background

Once we obtain permission to contact the sibling of an Expansion cohort participant, we send the sibling baseline questionnaire and other study materials to living adults and minors. This procedure describes (1) identifying the send list volume and record integrity, (2) generating participant mailing lists, (3) updating the database, (4) filing the production files, and (5) notifying the fourth floor team once the surveys are in the mail. The CRA2 is responsible for this process.

This document identifies the queries to use to produce the mailing lists and the necessary steps for the expansion sibling baseline survey production. For more detailed information concerning the queries utilized, refer to the query documentation Queries for Baseline Survey Production (in Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\Query Documentation).

Procedure 1: Identify List Volume and Record Integrity

Query Mechanics: The parent query (qry_JB_IdentifyResendSibBaseline) identifies the list of siblings who need to have a survey mailed. This query selects living English-speaking siblings where we (a) have NOT yet received a completed survey; and (b) DO have permission to contact (and a valid date of birth); and (c) DO have a valid address (i.e. do have an address and it is not in 13,18, or 81 tracing). (Note that deceased and Spanish-speaking surveys are handled by the LSI team and are therefore excluded.)

From this group, the query selects those siblings who EITHER (d) have *not yet been mailed* a survey; OR (e) *have an explicit resend code*; OR (f) *have* been sent a survey over 90 days ago but have not yet been sent a second copy.

1. Run the query **qry_JB_IdentifyResendSibBaseline**.
2. Scroll through records to find anomalies (e.g. concerns about address; issues with sib name; etc.).
    a. Take necessary action(s) to correct issues in individual records. Use the form interface.
    b. After corrections are made to the data, rerun the query.
3. Export to a temporary folder on your U drive.
4. You will use this Excel file later when you post the baseline mailings to the database.

Procedure 2: Generating Adult and Minor Production Files

Query Mechanics: This pair of queries uses the parent query to split the list into ADULTS (those 18 and over OR will be 18 in two weeks) and MINORS (those 17 and under and still 17 in 2 weeks). These two queries also construct fields needed for two different mail merge cover letters (sibProperName, SibProperFirst) and the mailing label (LabelName).

1. Run both: **qry_JB_SibBaselineADULT** and **qry_JB_SibBaselineMINOR**.
2. Export each file to Excel in a temporary folder on your U drive.
3. Create the production assignments/schedule.
    a. A template can be found here: Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\BASELINE MAILINGS
    b. Include the mailing date and the date to be used on the cover letter.
4. Distribute to the production team.

Procedure 3: Updating the Database

1. After the surveys have been mailed, open the saved Excel datafile from the parent query that you saved on your local drive (qry_JB_IdentifyResendSibBaseline).
2. Copy the **SIBID** column (not the SIB_ID column) and paste on a new sheet. Name the new sheet **_TEMP_SibSendList**.
3. Save the excel file and close it.

4. Open the **!!JB-POSTING TABLES_ExpansionTracking Resend Tables** database (currently located on the server in **Z:\SJShare\SJCOMMON\ECC\CCSS\Jerry\LOCAL COPY-DATABASES**)
5. Import the "_TEMP_SibSendList" sheet from the Excel file into a new table. When prompted that this table already exists, click yes to replace it.

6. Locate and view **qry_Post_TEMP_SibSendList** to be sure you have all the records in the production job. Be sure you are using the CORRECT posting query, as the database has several different ones (for other purposes).
    a. Determine which is the "largest" resend date field you will need to use.
    b. E.g., View expbasedate_SIB, expbaseresend_SIB, expbase2ndresend_SIB, expbase3rdresend_SIB, (through 10th resend) to see which is the largest resend number you will need. (Put another way, who has had the MOST mailings so far? From that individual, determine which mailing this one will be. If there's already been a 3rd resend to this person, THIS mailing will be the 4th resend. So the 4th resend field is the largest resend number you will need.)

7. Change the posting query to design view. In design view, set criteria to select records where you need to post the "highest" resend date
    a. E.g., Modify the query with criteria so that expbasedate_SIB and each resend date field IS NOT NULL, and the largest resend you need IS NULL.
        i. Note how many records meet the criteria. Note the number on the production schedule for historical reference. E.g., Resend #4: 5
        ii. In design view, change the query to an update query. Set the Update To value to the mailout date *on the largest resend field you needed*. Run the update.
        iii. **Clear the update to values**, and then change the query back to a select query (do NOT save the query as an Update query).
    b. Modify the criteria again so that both the largest *and the one before it* are IS NULL. View to see how many records match. Note number on the schedule. E.g., Resend #3: 2
        i. If there are any records that match the revised criteria, in design view change to an update query, set the Update To value to the mailout date on the applicable resend field (in this example, Resend3). NOTE: Update only ONE resend field. Run the update.
        ii. **Clear the update to values**, and then change the query back to a select query.
    c. Continue to modify the query working backwards from the largest resend field needed back to the initial mailing (expbasedate_SIB).

8. Use the query to clear the addresscode_SIB and TracingDate_SIB:
    a. In Design view, clear all the criteria left from the date posting (the "IS NOT NULL/IS NULL" criteria on the date fields).
    b. Set the criteria for addresscode_SIB = 82. View the results.

c. Change the query to an update query for records where addresscode_SIB = 82.
   i. Update addresscode_SIB to NULL and TracingDate_SIB to NULL.
   ii. NOTE: you do NOT want to update any other addresscode values!
   iii. Run the update query
   iv. Clear the criteria
d. Clear the criteria and change the query back to a select query.

9. Spot check the results. No record should have an 82 value in TracingDate_SIB. Every record should have the currently posted mailing date in ONE and ONLY ONE of the send fields.

10. Be sure you change the query to a select query and remove all criteria before saving and closing.

11. Create the ARCHIVE reference table from the _TEMP_SibSendList table:
    a. From the list of tables in Posting Table database, COPY the _TEMP_SibSendList table.
    b. Then RENAME the copy by adding the date using the posted date (format mm-dd-yy) to the end of the table name.

Procedure 4: Filing the Data Files

1. Add the mailing date to the end of each Excel production data file (saved on your U drive).
2. Copy the data files and the production schedule to the server: Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\BASELINE MAILINGS.
3. Archive the originals and the production schedule on your user drive.

Procedure 5: Notifying the Call Center

1. Email a list of SIBIDs included in the mailing to the call center coordinator and lead SIs to facilitate follow-up call scheduling.

Revision Record Printed 6/28/2013 9:28 AM

[249] Current filename		Sibling Baseline Survey Data File and Posting ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/5/13	J. Bates, L. Harrison, J. Ford	Initial Release
1.1	6/27/13	Ford, Harrison, Bates	Simplified queries

Sibling Permission Initial Data File Preparation

Background

The CRA production team generates the sibling permission letters and forms using the data file prepared by the Lead CRA. This data file begins with a set of queries run from the Expansion Tracking database used to identify which permission letter (and form) to use, based on case age, vital status, and reconsent status, as well as known conditions about the potential sibling. The query file is output to Excel where it is then further processed as outlined in this procedure, in order to generate the data file presented to the production team who will merge the letters and forms. This document is the procedure used for the INITIAL run of the Sibling permission data files. For subsequent permission production, refer to **Sibling Permission Subsequent Data File Preparation**.

Procedures

Parent Query and Child Query

The Parent query **qry_JB_SiblingPermission00** constructs a wide range of variables subsequently used to decide which letter is needed. The query also pulls the fields ultimately needed for mail merging the letter, the form, and the mailing label. To help you decide which permission letter(s) need to be put into production, review the parent query to establish the remaining volume by letter type. Simplify the production process by putting only one type of permission letter into production at a time.

After you decide which permission letter to put into production, run the child query for that letter (e.g., **qry_JB_SiblingPermission01_Ltr{A1 A2 B1 B1missing B2 D1}** and export it to Excel. At this point, the data file will contain EVERYBODY who fits that letter's specifications, including those already sent, those refusing, those ineligible, those in tracing, those with resend requests, and those on hold.

Processing the Initial Excel Data File

In excel, make a copy of the FULL set of records (so you keep the original group intact in the data file), then HIDE the original group.

1. In this tab, remove **records that should NOT be mailed**:
    a. The **case** is in tracing: Addresscode is 13, 18, or 81
    b. The **case** is ineligible (outcome = 10)
    c. The **case** is "on hold": CCSSonHold is not null (check CCSSonHoldDate to see if case is scheduled to come off hold)
    d. **Case** needs Spanish (SpanishStatus=1)
    e. **Permission outcome** obtained: (Outcome_Permission not null: obtained, refused, ineligible, jail, on hold)
    f. Those already sent (Date_Sent_Permission not null AND ElevenEleven IS NULL) but who do NOT have a Permission resend request (e.g., Tracing_Status_Permission = 82).
        - NOTE ElevenEleven field flags instances where date sent was 11/11/1811 which does NOT translate in Excel. 11/11/1811 indicates the letter was "as good as sent" (as when Spanish permission was sent to immediate call assignment).

2. Of the REMAINING records, check to see if ANY cases **have a newer address on file** than the one we currently have in the Sibling Permission dataset:
    a. Look for "NewerAddress" in the column of that same name
    b. Then get SIBID for that record, go to Sibling form in database, and search for that sibling.
    c. For that sibling, go to his/her "Case" tab. This will give you the CURRENT address we have for the case. We need to use the Case's CURRENT address information. Therefore:
        - On the PERMISSION tab, update case's address, including Addr Date and Source
        - In EXCEL FILE, replace the old address with the new address.
        - DOUBLE-CHECK the data entry

3. **Name Checks: Parentheses**
    a. First check for **any case names that have parentheses**, suggesting data entry error for the case name. E.g., if there is a Mary (Smith) Jones, this probably needs attention. Look up the case in the database to determine what the name should be. Most likely, it should be Mary Jones (with Smith being the maiden name).
    b. If you determine the case name needs to be corrected:
        - Make the correction first in the case tracking system
        - Then go to the Permission tab and correct "To Whom Letter Sent" value
        - Finally, fix the name in the excel data file.

4. **Case Name Formatting check:** we need to check the formatting of the case name, so that the capitalization functions in the mail merge will not produce non-standard output. Make these changes ONLY in the Excel data file (not in the database). Specifically:
    a. Last names with O'LASTNAME: insert a blank space after the apostrophe (e.g., O' Lastname)
    b. Last names with II, III, IV: add a blank space before Roman numerals, and then insert a single blank space between each figure in the numeral.
    E.g., "Jones III" becomes "Jones I I I"
    c. Hyphenated last names: need to add a blank space after the hypen (before the second last name). E.g., "Jones-Smith" should become "Jones- Smith"
    d. Last names that start with "Mc" or Mac": insert a space after the Mc or Mac. Note that this is NOT a wholesale change. E.g., "McDonald" and "MacDonald" become "Mc Donald" or "Mac Donald" respectively. But "Macbeth" would stay "Macbeth".

5. POSTPONEMENT WINDOW for Deceased cases and/or siblings
    a. Letters A2, B2, and D1 are used in situations where either case or sibling may be deceased. We do not send permission letters around death date anniversary.
    b. The "postponement window" is a 3 month period around the death anniversary: The month before, month of, and month following the month in which the individual died.

c. **RIPmonthCASE** and **RIPmonthSIB** present the month of death date. Inspect both of these RIPmonth fields for records occurring within the window. Note that if both are deceased, there will be a window for the case and another for the sibling.
d. If the current month is within the Postponement window, remove the record from the production; it will need to be picked up at a later date.

6. REMOVING EXTRA FIELDS in DATA FILE

a. The excel data file contains columns NOT needed by the production team. Delete these columns before distributing the file to them.
b. **ALL** letters (forms/labels) NEED these COLUMNS

• *LtrSub (built at the CHILD qry level)*	• Name_Sib_Permission
• CCSSID	• Care_of_Permission
• SIBID	• Address_Permission
• SibInitials	• CIty_Permission
• SIBLINGDOB	• State_Permission
• *ExactLetter (built at CHILD qry level)*	• Zip_Permission
• *Letter (built at CHILD qry level)*	• Country_Permission
• *Form (built at CHILD qry level)*	

c. In addition, letters **A2, B1, B2, and D1** ALSO NEED **Name_Sib2** *(built at CHILD qry level)* and **CaseFirstName**
d. Check for Name_Sib2 fields that may have a double "The Parents of The Parents of" and make the correction in the data file only.

7. **Final data file preparation**

a. **Volume exceeds daily mailing cap**. If the remaining number of records exceeds the daily mailing volume cap, delete the excess records. They will need to be captured in a later production run.
b. **Different "Sub" letters**. If the production included different "sub" letters, separate the records onto separate tabs in the data production file.
c. **Rename each data tab** with the value from the Exact Letter column (E.g., LtrA1.1, LtrA1.2, LtrA1.4)
d. **Color coding**. It may be useful to differentiate the group of records assigned to different production team members by using a different text color for each assigned set of records.
e. After the data file preparation and color coded assignments, distribute the data file with the production schedule.

Lead CRA

PARENT QUERY FIELDS

PARENT QUERY FIELDS:

A. CCSSID
B. Date_Sent_Permission
C. ElevenEleven
D. Outcome_Permission
E. Outcome_Date_Permission
F. Tracing_Status_Permission
G. Tracing_Date_Permission
H. addresscode
I. TracingDate
J. CaseTracing
K. NewerAddress
L. CCSSonHold
M. CCSSonHoldDate
N. Addr_Date_Permission
O. ADDRDATE
P. INELIGIBLE
Q. outcome
R. OutcomeDate
S. CaseDOB
T. Age_Return
U. Age_Now
V. ReconsentNeeded
W. ReconsentOutcome
X. Alive
Y. DeathDate
Z. CASEdeceased
AA. RIPmonthCASE
BB. RIPmonthSIB
CC. SpanishStatus
DD. SurveyType
EE. SIBID
FF. SibInitials
GG. SIBLINGDOB
HH. SIbAgeToday
II. SIBLING_STATUS
JJ. SIBLINGDOD
KK. SibDeceased
LL. Name_Sib_Permission
MM. CaseFirstName
NN. Care_of_Permission
OO. Address_Permission
PP. CIty_Permission
QQ. State_Permission
RR. Zip_Permission
SS. Country_Permission
TT. LetterType
UU. FormType
VV. Send_Permission_To

Name_Sib2 is built at child query level for B1, B2, and D1

Revision Record

Printed 7/1/2013 8:09 AM

[237] Current Filename:		Sibling Permission Initial Data File Preparation ver 1_2.docx	
Revision No.	Date	Responsible Author	Change Description
1	5/13/13	Bates/Harrison	Initial Development
1.1	6/7/13	J.Bates	Production file fields; correction re 11/11/1811 (Spanish)
1.2	7/1/13	J.Bates	Used for INITIAL data runs; cross reference “re” send SOP

Sibling Permission Subsequent Data File Preparation

Background

The CRA production team generates the sibling permission letters and forms using the data file prepared by the Lead CRA. This data file begins with a set of queries run from the Expansion Tracking database used to identify which permission letter (and form) to use, based on case age, vital status, and reconsent status, as well as known conditions about the potential sibling. The parent query used for "subsequent" data file preparation (1) *excludes* those already having a permission outcome as well as those whose CCSS case is on hold; and (2) *includes* those not yet sent where the case is not in tracing as well as those previously sent but now having a resend request. Child queries based on this parent query subdivide the group according to letter types. The queries are output to Excel where they are further processed as outlined in this procedure, in order to generate the data files presented to the production team who will merge the letters and forms.

Procedures

Check for Expired Hold Codes

1. Run **qry_JB_SiblingPermission99_SibCaseHold** first, to see if any HOLD code for either the case or the sibling has expired. The query calculates when the hold expires based on the type of hold code and the hold date.

   (OffHold1 is for Case hold; OffHold2 is for sibling hold). The flag TakeOFFhold displays either "not yet" or "TAKE OFF HOLD", after interpreting these dates.

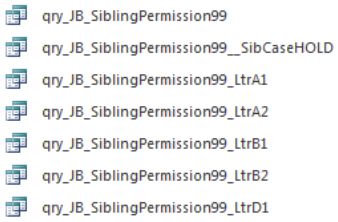
2. *IF ANY HOLD HAS EXPIRED,* go to the respective record (Case or sibling), document that you are releasing the hold, and clear the hold code and date.

qry_JB_SiblingPermission99__SibCaseHOLD

OFFHOLD1	OFFHOLD2	takeOFFhold
12/25/2013		not yet
12/13/2013		not yet
2/13/2014		not yet
6/7/2014	3/4/2014	not yet
	9/4/2013	not yet
	9/4/2013	not yet
	12/17/2013	not yet

Identify Permissions to Send (Parent Query)

1. Run the Parent query **qry_JB_SiblingPermission99** to identify sibling permissions that need to be sent, due either to an active permission resend code or to an initial letter not yet having been sent. (For technical detail on query mechanics, refer to Sibling Permission Resend Queries in the Query Documentation folder.)



2. Check the **address status** flags, investigate flagged records, and reconcile those address variances if possible.
   a. "CaseTracing" displays "RecheckAddress" if the address on file for the case is in tracing. If the permission is an explicit resend request, the address for the sibling permission may be newer than the address on file for the case. Refer to the "NewerAddress" flag to see if this is so.
   b. If it is, check the case address to see if you may update it with the newer address subsequently obtained for the sibling permission.

3. **Name Checks: Parentheses**
    a. First check for **any case names that have parentheses**, suggesting data entry error for the case name. E.g., if there is a Mary (Smith) Jones, this probably needs attention. Look up the case in the database to determine what the name should be. Most likely, it should be Mary Jones (with Smith being the maiden name).
    b. If you determine the case name needs to be corrected:
        i. Make the correction first in the case tracking system
        ii. Then go to the Permission tab and correct "To Whom Letter Sent" value

4. **Case Name Formatting check:** Check the formatting of the case name, so the capitalization functions in the mail merge can produce grammatically correct output. Make these changes in the Excel data file (although you may also elect to change the database on Permission tab for sibling, and then rerun the query). Specifically:
    a. Last names with O'LASTNAME: insert a blank space after the apostrophe
    (e.g., O' Lastname)
    b. Last names with II, III, IV: add a blank space before Roman numerals, and then insert a single blank space between each figure in the numeral.
    E.g., "Jones III" becomes "Jones I I I"
    c. Hyphenated last names: need to add a blank space after the hypen (before the second last name). E.g., "Jones-Smith" should become "Jones- Smith"
    d. Last names that start with "Mc" or Mac": insert a space after the Mc or Mac. Note that this is NOT a wholesale change. E.g., "McDonald" and "MacDonald" become "Mc Donald" or "Mac Donald" respectively. But "Macbeth" would stay "Macbeth".

5. Export the parent query to Excel, storing it in your local production work folder. You will use it again later to post the mailings.

Run Child Queries to Generate Data Files for Individual Letter Types

1. Run each of the child queries below.

2. For the queries where either the case or the sibling may be deceased (i.e., all EXCEPT LtrA1), inspect the query to see if there ARE any records that can be mailed at this time. To make this determination, see whether the death month of the case (RIPmonthCASE) or the sibling (RIPmonthSIB) was last month, this month, or next month.
    a. If NO records can be mailed, then do not export the data file.
    b. If at least ONE of the records can be mailed, export the data file. Then in the Excel file, delete the records that we cannot mail at this time.
3. Child queries
    a. Qry_JB_SiblingPermission99_LtrA1 (Letters going to Living Adult cases with Form A)
    b. Qry_JB_SiblingPermission99_LtrA2 (Letters going to Cases with Form D)
    c. Qry_JB_SiblingPermission99_LtrB1 (Letters going to Parents with Form B)
    d. Qry_JB_SiblingPermission99_LtrB2 (Letters going to Parents with Form D)
    e. Qry_JB_SiblingPermission99_LtrD1 (Letters going to Parents with Form B)

Lead CRA

Final Preparation of Production Data File(s)

1. For all data files except LtrA1, delete any records that cannot be mailed at this time. I.e. where the month from RIPmonthCASE or RIPmonthSIB is last month, this month, or next month.
2. Your exported Excel files for each of the Letter types contain columns the mail merge jobs do NOT need. You may delete these from the excel file if you wish.
    a. If you choose to delete them, it is best to do so BEFORE splitting the records into separate tabs according to the "LtrSub" groups (outlined below)
    b. The columns that you DO need are

CCSSID	Care_of_Permission	***Needed ONLY for A2, B1, B2, and D1***	***NOTE: these Fields built in the CHILD query:***
SIBID	Address_Permission	CaseFirstName	*LtrSub*
SibInitials	CIty_Permission		*ExactLetter*
SIBLINGDOB	State_Permission	***Needed ONLY for B1, B2, and D1***	*Letter*
Name_Sib_Permission	Zip_Permission	**Name_Sib2**	*Form*
	Country_Permission		

    c. See if any **Name_Sib2** fields have a double "The Parents of The Parents of". Make the correction in the data file only.

3. For each Excel file that has more than one LtrSub value, group and separare them onto separate tabs in the excel file so the production team can mail merge the appropriate sub version of the letter.
    a. Name each tab appropriately (See table below for recommended names)

LtrSub 1 (initials & DOB)	LtrSub2 (Initials only)	LtrSub3 (DOB only)	LtrSub4 (neither)
LtrA1.1	LtrA1.2	LtrA1.3	LtrA1.4
LtrA2.1	LtrA2.2	LtrA2.3	LtrA2.4
LtrB1.1	LtrB1.2	LtrB1.3	LtrB1.4
LtrB2.1	LtrB2.2	LtrB2.3	LtrB2.4
LtrD1.1	LtrD1.2	LtrD1.3	LtrD1.4

PARENT QUERY FIELDS (RED = needed in mail merge)

A. CCSSID
B. Date_Sent_Permission
C. ElevenEleven
D. Outcome_Permission
E. Outcome_Date_Permission
F. Tracing_Status_Permission
G. Tracing_Date_Permission
H. addresscode
I. TracingDate
J. CaseTracing
K. NewerAddress
L. CCSSonHold
M. CCSSonHoldDate
N. Addr_Date_Permission
O. ADDRDATE
P. INELIGIBLE
Q. outcome
R. OutcomeDate
S. CaseDOB
T. Age_Return
U. Age_Now
V. ReconsentNeeded
W. ReconsentOutcome
X. Alive
Y. DeathDate
Z. CASEdeceased
AA. RIPmonthCASE
BB. RIPmonthSIB
CC. SpanishStatus
DD. SurveyType
EE. SIBID
FF. SibInitials
GG. SIBLINGDOB
HH. SIbAgeToday
II. SIBLING_STATUS
JJ. SIBLINGDOD
KK. SibDeceased
LL. Name_Sib_Permission
MM. CaseFirstName
NN. Care_of_Permission
OO. Address_Permission
PP. CIty_Permission
QQ. State_Permission
RR. Zip_Permission
SS. Country_Permission
TT. LetterType
UU. FormType
VV. Send_Permission_To
Name_Sib2 is built at child query level for B1, B2, and D1

Revision Record Printed 7/1/2013 12:19 PM

[250] Current Filename:		Sibling Permission Subsequent Data File Preparation ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/1/13	J.Bates	Initial Development: spl version for the 99 queries

Sibling Recruitment Permission Stage

Background

The first step in recruiting siblings for the LTFU study is to obtain permission to contact the potential sibling participant or their designated proxy/LAR. The potential sibling is the full-blood sibling who would be "closest in age" to the case. A deceased sibling may be the appropriate sibling, so long as the sibling lived to be at least five years old.

We seek permission by mailing a letter either to the participating survivor (18 or over when consented to the study and still alive) or to parents of the case (deceased or case was a minor when consented and has not been re-consented via the age of majority process). We initially use the address we have on file for the case. The letter inserts the initials and date of birth of the potential sibling recruit, as long as we were able to obtain them from the case's baseline survey. The letter asks the recipient to find out if the "closest in age" sibling (or parents of minor or deceased sibling) would be interested in participating, and then return a completed response form to indicate the sibling's interest, name, vital status, birth date (and death date if applicable), and address of either the sibling or the parents of the minor or deceased sibling.

The permission process is tracked in Sibling section of the Expansion Tracking database on the **Permission** tab. When permission is obtained, we enter sibling's information into the database on the **Sib Info** tab. Thereafter, we introduce the study to siblings while sending the sibling baseline questionnaire (tracked on the **Sib Baseline** tab).

Procedures

Sending Permission Letters and Forms

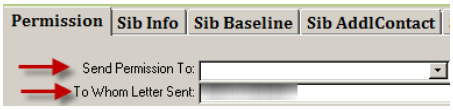
1. The CRA2 generates batch data files needed to mail merge pertinent permission letters and forms. We consider *case hold* status and *proximity to death dates, which may delay sending the letter and form*. We initially used the mailing address of the participating case imported from expansion tracking case record in early March 2013, but permission queries check for updated case addresses and modify permission mailing address accordingly.

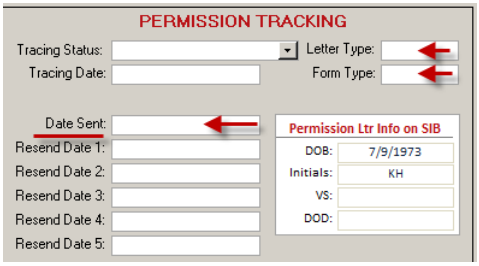
2. Mail merge letters, forms and labels are separate folders in **Z:\SJShare\SJCOMMON\ ECC\CCSS\Expansion Recruiting SIBLING\IRB Approved Letters and Forms** (*A Letters and Forms*; *B Letters and Forms*; *D Letters and Forms*)
    a. Letters need to be merged for editing and then individually reviewed *before being printed*.
    b. Review merged letters to identify incomplete references (sibling initials and/or date of birth) or other unforeseen situations (especially for the B and D letters). The A1 and B1 letters have already taken this into consideration by presenting different "exact letter" versions of A1/B1 merge letter (e.g., A1.1, A1.2, B1.1, B1.2, etc).
    c. When letter by letter review is needed, review sentences for incomplete references (e.g. Based on your survey, we believe your closest in age brother/sister has the initials ___ and date of birth ___.)

Everyone

Recording Sent Permission Forms (see **Posting Sibling Permission Letter Mailings** for complete procedure)

1. When permission letters are mailed, the CRA2:
   a. Posts the appropriate values in **Send Permission To**, in the main part of **Permission** tab.
   b. Updates **To Whom Letter Sent** field to include "The Parents of " (e.g., "**The Parents of John Doe**") *when letter is sent to PARENTS of the case*.
   c. Posts **Date Sent, Letter Type,** and **Form Type** which will display on **PERMISSION TRACKING** portion of **Permission** tab. (Review the **Letter and Form Guide** at the end of this document for information about the types used.





2. The PERMISSION TRACKING section also displays expected sibling's DOB, initials, vital status and DOD when available. This information came from the case baseline survey, and is inserted into the permission letter. (This is for reference only)
3. Subsequent resend dates are recorded in **Resend Date #** fields. If a change in letter/form type is necessary in a resend, based on new findings about the case and/or prospective sibling, the CRA2 documents original type sent in **Comments** field, and then updates the letter/form type to show the most recently mailed versions.

Spanish-Speaking Cases

1. We put cases coded as Spanish-speaking into immediate call rotation to obtain permission, instead of mailing a permission letter.
2. The CRA2 documents this in Permission tab **Comments**, posts "11/11/1811" in **Date Sent**, and records the appropriate values in **Send Permission to**, **To Whom Letter Sent**, **Letter Type**, and **Form Type**.

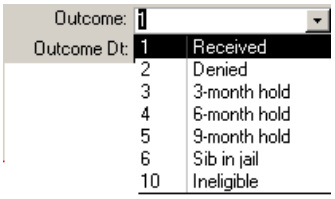
Undeliverable Permissions returned to Sender; Tracing

1. When undeliverable permissions are returned to sender, the CRA 2 sets **Permission** tab **Tracing Status** to 18 and adds the **Tracing Date**
2. In addition, go to the Case tab to check the current address and tracing status for the case. If appropriate, put the case into tracing by going to the Quest tab for the case, entering the tracing status/date, and documenting that tracing code originated because sibling permission letter was returned to sender.
3. The Lead SI's will put the case into tracing queue.
4. When tracing is successful, the SI responsible will
   a. Change tracing status/date to *82-Resend Permission* (current date) on **Permission** tab
   b. Document tracing outcome in the built-in tracing log
   c. On **Permission** tab, update mailing address, source, and date (adding phone number if applicable). (There is currently NO archive address function on the Permission tab.)
   d. If address change relates to the case, check information about the Case.
      i. Copy the case's CCSSID from the Case tab
      ii. Go to the database Main Menu, select Cases, then search for the Case's CCSSID.
      iii. ARCHIVE then UPDATE the Case mailing address (Note that having updated the address on the Permission tab did NOT change the case address)
      iv. Go back to the sibling's record
      v. On the Case tab, click the Refresh button to refresh the displayed case address/date.

e. If the tracing effort results in a phone contact with the person from whom permission is being sought, the permission process may be transferred to a SI in order to obtain verbal permission, after relevant information is obtained, or the tracer may pursue the permission as applicable.

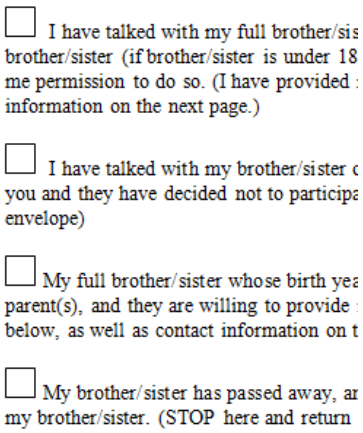
Processing Permission Status Returned by Mail or Obtained by Phone

1. The **PERMISSION TRACKING** panel of the **Permission** tab is where we record the Permission **Outcome**.
   a. Outcome codes 1 and 2 are "final/terminal" outcome codes: permission granted or denied (note – although these codes are terminal from a permission pursuit perspective, participants can always change their mind)



   b. Outcome code 10 is also a final outcome code, which indicates the sibling is ineligible. This determination is made by the CRA2. A sibling may be declared ineligible even if permission has already been obtained.
   c. Four other outcome codes are temporary.
      i. Three (3, 4, 5) are available to put the permission process "on hold" for a designated period of time. The LSI/CRA2 will canvass the database using the OutcomeDt to determine when a hold code can be released. When clearing a hold **outcome** code (and **Outcome Dt**), the LSI will put the case back into call rotation.
      ii. The final temporary outcome code (6) is Sib in Jail. If we know the anticipated release date, use the most appropriate hold code instead, documenting the reason in Permission Comments (e.g., "***m/d/y: incarcerated sib due for release m/d/y per … [##]***").

2. When we receive a permission form in the mail, the form will either indicate we DO have permission to contact the sibling or we do NOT have permission to do so. The data entry that ensues depends on whether or not permission is granted.
   a. If the form indicates incarceration or the need for a hold, refer the case to the CRA2 for appropriate coding and data entry.
   b. If we already have a permission outcome on file in the database (look for an Outcome code in the Permission Tracking section of the Permission tab), refer the case to the CRA2 who will decide how to code (or recode) the permission status.
   c. Otherwise, review the check boxes on the front of the returned form to determine the status of the permission:
      i. Sibling (or parents of minor sibling) gave permission to release contact information (granted)
      ii. Sibling does not want to participate (<u>denied/refused</u>)
      iii. Sibling closest in age is deceased and parents ARE willing to participate (granted)
      iv. Sibling closest in age is deceased and parents do NOT want to participate (<u>denied/refused</u>)


☐ I have talked with my full brother/sis
brother/sister (if brother/sister is under 18
me permission to do so. (I have provided
information on the next page.)

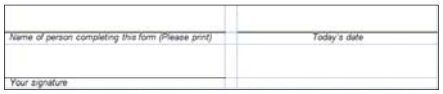
☐ I have talked with my brother/sister c
you and they have decided not to particip
envelope)

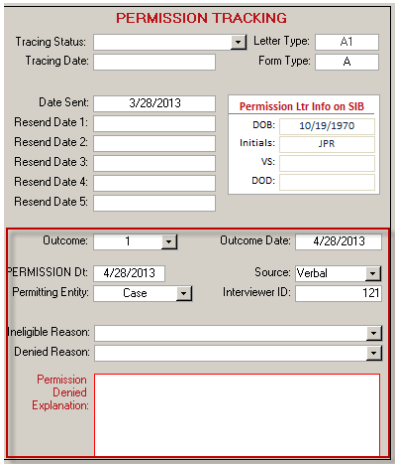
☐ My full brother/sister whose birth yea
parent(s), and they are willing to provide
below, as well as contact information on t

☐ My brother/sister has passed away, ar
my brother/sister. (STOP here and return

Everyone

3. <u>If permission IS **GRANTED** (and no other permission outcome already on file)</u>
   a. If the respondent did NOT fill in the date on the returned form, date-stamp the Date area on the form with the current date.





   b. Select Permission **Outcome** 1 ("Received")
   c. Enter the current date in **Outcome Date**.
   d. Record the date filled in on the form in **PERMISSION Dt**. (For verbal permission, record the current date)
   e. Record **Source** (paper, verbal). Use "verbal" Source for permission obtained by SI.
   f. If response is obtained by phone (by survey interviewer), record the SI's ID# in **Interviewer ID.**
   g. Select the appropriate **Permitting Entity** (Case, Parent, LAR, Other) from the dropdown.

4. <u>If permission IS **DENIED** (no permission outcome on file)</u>
   a. Select **Outcome** 2 (Denied) from the dropdown box
   b. Enter the current date in **Outcome Date**
   c. Leave **PERMISSION Dt** <u>blank</u>
   d. Record **Source** (paper, verbal). Use "verbal" Source for refusal obtained by SI; use "paper" for a refusal that was received in the mail.
   e. Leave **Permitting Entity** <u>blank</u> because no one provided permission (we do not use Permitting Entity to record who denied us the permission)
   f. If refusal is obtained by phone (by survey interviewer), record the SI's ID# in **Interviewer ID**
   g. Select the code for the most appropriate **Denied Reason** based on check box description on returned form.

1	Sibling does not want to join study
2	Parent denied permission to contact sibling
3	Adult case denied permission to contact adult sibling
9	Other

   h. Provide additional explanation in **Permission Denied Explanation** using standard comment format. Specifically, indicate name/relationship of person who denied permission; for a paper denial, if the form was dated, indicate the signature date.
   i. *If any other sibling info is obtained (name, DOB, address),* record it in the Comments area of the Permission tab, but **DO NOT record it in the Header or the Sib Info** tab.

<u>Recording Sibling Name, DOB, Gender, and Spanish Status in the HEADER AREA</u>

When permission <u>is *granted*</u> to contact a sibling, we obtain sibling's name and date of birth. We may also know Gender and Spanish Status. Record this information using the **Edit Header** button which opens the **<u>Edit Sibling Record</u>** form. On the Edit Sibling Record form, enter:

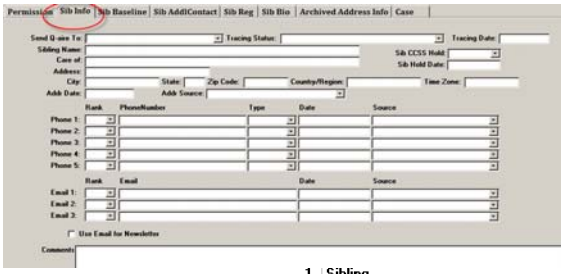
1. **First**, **middle**, **last name** of actual SIBLING identified as closest in age.
1. **SIBINITIALS** (optional)
2. **Date of Birth** of SIBLING; sibling **Gender** (only if known)
3. As **Gender** and **Race** information becomes available from baseline surveys, we will update Gender (1=Male; 2=Female), and Race with appropriate codes.
4. If **Spanish Status** is known, record it.
5. Note - the form displays the Password (**PW**) (read only). Do not modify this field.
6. **SAVE and CLOSE** the form.

Everyone

Recording Remainder of Sib Info

When permission is *granted* to contact the sibling, enter the sibling's CONTACT information from the permission form onto the **Sib Info** tab. (*Do **NOT** record this on the Permission tab!*)

1. *After updating the Header information*, enter the following information on the Sib Info tab:
   a. Sibling's first and last name (in **Sibling Name**)
   b. Mailing **address**, **phone(s)**, **email** (as provided on the returned form), entering **date**, **source**, **type**, **ranks** as appropriate.
   c. If there is the name of a "Care of" person, enter it in **Care of** (as *C/O* followed by name).
   d. Depending on Sib vital status (from the permission form) and sibling's current age (calculated and displayed in the header area), select appropriate value for **Send Q-aire To**. Generally speaking:
      i. If sibling is 18 or over and living, select **1**-Sibling
      ii. If sibling is deceased, select **5**-Parent
      iii. If sibling is under 18, select **2**, **3**, or **4**, depending on who provided permission
      iv. If sibling is 18 or over, but clearly has a guardian or legal representative, then select **6**.

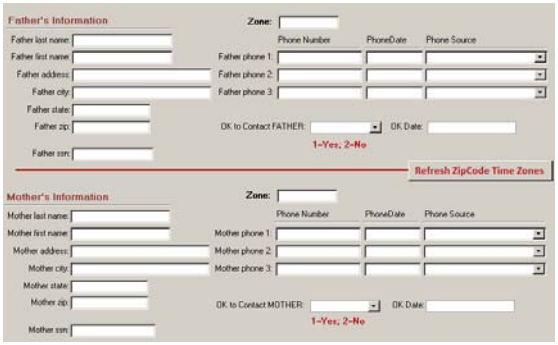


1	Sibling
2	Mother(sib under 18)
3	Father(sib under 18)
4	Both(sib under 18)
5	Parent(sib has died)
6	Parent(Eventhough sib over 18)

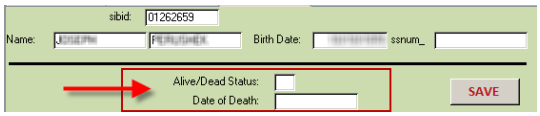
2. After completing the data entry, move the cursor to another field. Then click the **Save** icon on the ribbon.

3. Click the **Update Sibling Print Table** button. (Wait to do this until AFTER updating the header, entering the Sib Info and clicking the Save icon.)

4. If permission form contains address information about a PARENT, enter it on **Sib Reg** tab. Also check parent information we have on file for related case, but do not automatically assume sibling and case still have the same parents. (Refer to ***Looking up the Sibling's Case*** below for how to easily access the sibling's case record.) If it is clear that the case and the sibling have the same parents, then update the case's parents' information too.



5. ***If Sibling is DECEASED***
   a. *CAUTION: Do NOT open the Death Data form UNLESS sibling is DECEASED!*
   b. Click **Death Data Form** button (on Sib Info) to open Deathdata form
   c. In **Alive/Dead Status**, enter 2
   d. If Date of Death is known, enter it in **Date of Death**.
   e. No other data entry is needed on this form. Click the **SAVE** button then close the form. The **Survival Status** (and **Death Dt** if entered) will be displayed in the Header area.



Everyone

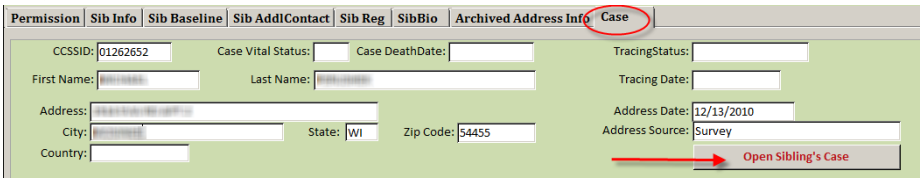
Changing Sibling's Vital Status from Deceased to Alive

If the database currently shows the sibling to be deceased (Survival Status displays '2'), and we learn the sibling is NOT DECEASED, send the pertinent information to the CRA2 who will process the change in vital status.

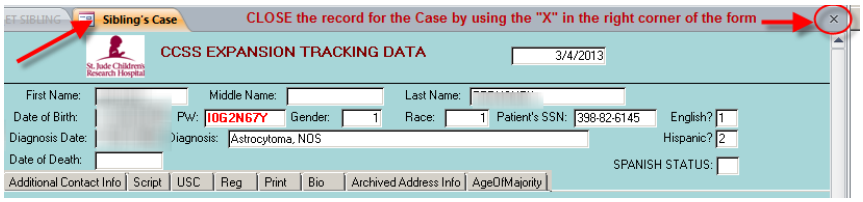
Looking up the Sibling's "Case"

The CCSS SIBLING TRACKING DATA form allows access to tracking information about the CCSSID related to the sibling, without having to go through the Main Menu. (To edit case information, however, you DO need to go through the Main Menu so you can archive the information before updating it.).

1. Click on the **Case** tab. This provides the CCSSID, current information (read-only) for: vital status, death date, name, address (date and source), and tracing status of the case.



2. To go to the full record for the case related to the current sibling, use the **Open Sibling's Case** button.
   a. You have full access to all tabs (Quest, Baseline, Reg, etc) for that specific case, restricted to the single case. Note that on this restricted form, the Archive Contact Info button does not work.



   b. You can also use this to check parent information we have for the case (on the Reg tab).
   c. When finished with the case, be sure to CLOSE the **Sibling's Case** tab by using the "X" box in the upper right corner of the Sibling's Case tab.

3. To Archive the case information (before updating it), you must go back to the database Main Menu and select the Case section. Then search for the case by CCSSID. Then use the Archive Contact Info button on the Quest tab, *before* updating the case address information.

4. NOTE: Updating information about a specific CCSSID Case does NOT change any information that we have on file about the Sibling. Similarly, changing the Tracing status of a sibling (at any level) has no effect on the tracing status of the case.

5. NOTE: Since a sibling and the related CCSSID case are supposed to be full blood siblings, they *should* have had the same parents at conception. (The Reg tab displays parent information.) As time passes, it is possible that the recognized parents of either the case or the sibling change (adoption, divorce, etc.). For this reason, parent information for the case and the sibling are maintained separately, but a manual comparison is recommended when new information is obtained about the sibling's parents, to see if the case parent information needs to be updated.

Letter and Form Guide

The following lists the different Letters and Forms used in obtaining Permission to contact a sibling.

Letter	Sent to	FORM	When CASE CONDITION is	And Sibling condition is
A1	case	A	Living now & GT17 @ enrollment (or reconsented)	adult/minor/not KNOWN deceased
A2	case	D	Living now & GT17 @ enrollment (or reconsented)	thought to be deceased
B1	parent	B	• LT18 @ enrollment, not reconsented; OR • Deceased @ enrollment	adult/minor/not KNOWN deceased
B2	parent	D	• LT18 @ enrollment, NOT reconsented; OR • Deceased @ enrollment	thought to be deceased
D1	parent	B	Deceased now but Living Adult @ enrollment	adult/minor/not KNOWN deceased

Revision Record Printed 6/24/2013 12:21 PM

(233) Current Filename:		Sibling Permission ver 1_5.docx	
Revision No.	Date	Responsible Author	Change Description
1	3/6/13	J.Bates	Initial Development
1.1	3/11/13	J.Bates	SI responsibility
1.2	3/25/13	J.Bates	Update db screens; ltr inits/dob; case VS
1.3	3/27/13	J.Bates	Update Ltr/Form guide; Spanish status 1
1.4	5/10/13	J.Bates	Reorganize for clarity; record sib death status ONLY WHEN deceased
1.5	6/5/13	J.Bates	Clarify Dt Response; archiving case; other clarifications/refinements
1.6	6/24/13	J.Bates	Screen shot update perm tracking; data entry sequence

Skin Cancer Study Key Informant Recruitment Calls

Background

The Key Information Interview (Kii) study is a small study that is being conducted in order to prepare for a larger Skin Cancer ancillary study which will be conducted by the Harvard School of Public Health (HSPH). The purpose of the Kii study is to collect information from a small, select group of LTFU participants regarding educational materials and communication tools to improve early detection of skin cancers. The Coordinating Center is recruiting LTFU Study participants to participate in interviewers to ensure that the education materials (website, text messages, and literature) are effective, relevant, and useful

Prior to the recruitment phone calls, the CRA mails introductory packets to a selected group of 16-20 LTFU participants and notifies the Coordinator of the Survey Interviewers (CSI). Approximately two weeks after the invitation packets are mailed, the Survey Interviewer (SI) will begin follow up calls to the non-responders. Cases determined to have outdated contact information will be placed in tracing.

Tools the Survey Interviewer will need to support this study:
(NOTE: The location of each tool can be found at the end of this document.)

1. **Skin Cancer Study Key Informant Recruitment Calls** SOP
2. **KII Recruitment Tracking Log**
3. REG database
4. Original Cohort MS Word **Phone Contact Log**
5. **CCSS Skin Cancer Material Review Recruitment Script**
6. **Skin Cancer Study Kii Recruitment Call Assignments Workbook**

Procedures

Pre-Call Mailing of Intro Packet

CCSS Coordinating Center (CC) mails the introductory packet (cover letter, informed consent form, contact information update form, postage paid business reply envelope) to 16-20 randomly selected CCSS participants.

1. If packets are returned and the participant consents to participate in the interview:
    A. The CRA updates the **Kii Recruitment Tracking Log**.
    B. The CRA forwards the participant name, phone number(s), and best time to call to the HSPH study team.
    C. A HSPH interviewer contacts the participant and conducts the key informant phone interview.
    D. HSPH notifies the CRA when an interview is completed.
    E. The CRA mails a thank you gift card and updates the **Kii Recruitment Tracking Log**.
2. If packets are returned to sender:
    A. The CRA updates the **Outcome** and **Outcome Date** in the **Kii Recruitment Tracking Log**.
    B. The CRA emails a tracing request to the CSI. See the section of this document titled *The Tracing Process*, below.
    C. Following successful tracing, the CRA resends the introductory packet to the participant.

SI Phone Follow-up Calls

The Survey Interviewer (SI) will call non-responders two weeks after mailing.

Pre-Call Review

1. Review the **Skin Cancer Study Kii Recruitment Call Assignments Workbook** to determine who needs to be called based on information in the **Begin calls** and **Pending Status** fields on the Call Assignments tab.
2. Review the **Kii Recruitment Tracking Log** to determine:

a. If a packet has been sent to the participant and when
b. The date of the last resend to the participant
c. If there is a terminal outcome for the participant

3. Review the following in the REG database:
   a. Name, DOB, **Sex**, **Alive** status in the record header
   b. The **outcome** field on the Page 3 tab should be blank.
   c. Page 1 tab:
      i. All phone contact numbers available to call
      ii. All additional phone numbers on all tabs after clicking the **Edit Reg** button
      iii. **Tracing Status** and **Tracing Date** fields
      iv. The dates and sources of all contact information
      v. Any relevant notes in the **Tracing History** field
      vi. Any relevant information found after clicking the **Sibling** button
      vii. Any relevant information found after clicking the **FU2007** button
   d. All phone contact numbers available to call on the Contact Info tab
4. Review the MS Word **Phone Contact Log**.
   a. Review the call history and all notes.
   b. If the log indicates the case is a participant in an ancillary study, access the database for the indicated study to review the telephone number ranking.
      NOTE: If access to the ancillary database is restricted, email the LSI team and cc the CSI for assistance.
   c. If no log exists, create one. See the SOPs titled **Using and Creating Participant Call Logs (Phone Contact Log)** and **Updating Original CCSS Cohort Contact Information**, located in the SOP library.
      NOTE: Begin all comments/notes in the log with "Skin Cancer Study:".

During the Call

If contact *IS* made, use the **CCSS Skin Cancer Material Review Recruitment Script** and:

1. Explain the study and answer questions.
2. Gain commitment to participate, refusal, or agreement to receive a resend. (If a resend is necessary, see the section of this document titled *Requesting a Resend*, below.) If commitment to participate is gained:
   a. Complete the informed consent form and eligibility questions (preferably), or ask them to sign and return the forms.
      NOTE: If the participant reports a skin cancer or any other cancer, email Lynn Harrison and "cc" Olivia, the LSI team, and the Coordinator.
   b. Acquire the best phone number, day of week, and time of day for the HSPH study team to contact the participant for the KII interview.
3. Verify all contact and additional contact information. Note any new contact information for the participant and additional contact.
4. If the participant is found to be deceased, complete the **Expired Participant Information Sheet**.

If contact *is NOT* made:

1. The SI will leave a call-back message when appropriate and follow up, or the SI will put the case in tracing.
2. If tracing is needed, the SI will email the CSI who will add the case to the tracer's workbook.
3. The Tracers will trace the participant and try to reestablish contact and commitment to the LTFU Study.
4. The SI will call the participant and process the case.

After the Call

1. Update the MS Word **Phone Contact Log**. If contact information changed, add detailed notes regarding changes in the **Comments** column *and* make appropriate changes in the header of the document.

2. Log requests to update the Header section (name, DOB, **Sex**, **Alive** status) of the REG database in the **Call Outcomes Log**, email Olivia, and "cc" Lynn, the LSI team, and the Coordinator.
3. Update the REG database:

Case Contact Information

frmQuestTab, Page 1 tab:

a. Mailing address:
   i. Archive the current address by making a dated note in the **Tracing History** field with your SI ID. The note should include the updated address.
   EXAMPLE: *11/6/2013: Pt updated mailing address from 123 Fourth Street, Anywhere, TN 39001 to 234 Fifth Avenue, Anywhere, AZ, 21002. [89]*
   ii. Make the appropriate changes in the address fields in the Page 1 tab of the case's record. See the SOP titled **Use of Care of Field** for guidance on the **Care of/For** field.
   iii. Update the **addrdate** and **Address Source** fields.

b. Telephone number:
   i. Do NOT remove disconnected numbers, wrong numbers, or Do Not Call numbers unless absolutely necessary to record new, valid numbers. Doing so can negatively impact documentation in ancillary databases.
   ii. Add any new telephone numbers to the first empty row. If there is no empty row:
      1. Use the rankings from the ancillary database in step 4b of the section of this document titled *Pre-Call Review*, if applicable, to determine which number should be moved to the **Tracing history** field to make room for the new number. Refer to **Handling Additional Phone Numbers** if needed.
      2. Choose the phone number to move using the following priority: duplicate numbers as first priority to move, then numbers ranked 9-Disconnected in the ancillary database, then numbers ranked 37-Do Not Call. If no ancillary database rankings are available as guidance, use information gained from the case and/or information documented from previous calls to determine the number to move, based on the priority above.
      3. Archive the appropriate phone number in a dated note in the **Tracing history** field with your SI ID. Include the updated phone number. EX: *11/6/2013: Pt updated phone contact number from 901-222-3333 to 901-333-4444.[89]*
      4. Update *only* the chosen phone number's row with the newly obtained number, even if the other rows also contain "bad" numbers.
      5. Update the **Phone # Date** and **Phone # Date** fields.

Additional Contact Information

frmQuestTab, Contact Info tab:

a. If the additional contact is a party other than a parent or sibling CCSS participant, and the contact IS NOT already listed in the Contact Info tab, add the contact information to the Contact Info tab.
b. If the additional contact is any party other than a parent or sibling CCSS participant, and the contact IS already listed in the Contact Info tab:
   i. If the address and/or telephone number for the party HAS NOT changed:
      1. Update the **Information last updated on** field with the date.
      2. For spouses, go to the Page 1 tab, click on the **Edit Reg** button, and ensure the spouse's name is entered on the Page 2 tab for frmReg.
   ii. If the address and/or telephone number for the part HAS changed:

1. Make a note of the outdated address and/or phone number from the Contact Info tab. This will be used to archive the data.
2. Update the address and/or **Phone** fields on the Contact Info tab.
3. Archive the outdated address and/or phone by entering a dated note in the Tracing History field of the Page 1 tab with your SI ID. Include the updated address.
4. For spouses, go to the Page 1 tab, click on the **Edit Reg** button, and ensure the spouse's name is entered on the Page 2 tab of frmReg.
5. Move to a new field and save using the Save icon on the Home tab of Access ribbon.

c. If the participant specifies their parent or sibling CCSS participant as an additional contact:
   i. If they ARE NOT already listed in the Contact Info tab:
      1. Do not add them in the Contact Info tab.
      2. On the Page 1 tab, add a note to the **Tracing history** box indicating the participant has specified the parent or CCSS sibling as an additional contact.
      3. Follow procedures below for frmReg and frmSibling to document information.
   ii. If they ARE already listed in the Contact Info tab:
      1. Archive the data currently in the Contact Info tab by making a dated note in the **Tracing history** box (Page 1 tab) that includes all data, including the date, from Contact Info. Include your SI ID.
      2. Add a note to the **Tracing history** box indicating the participant specified the parent or sibling as an additional contact.
      3. Enter the current contact information in frmReg or frmSibling using the appropriate button on the Page 1 tab. See instructions below.

Parent Contact Information

frmReg, Page 2 tab:

a. If the parent's information is missing from the Page 2 tab, add it, then close frmReg.
b. If the parent's confirmed information is already in the Page 2 tab, simply close the frmReg tab.
c. If outdated parent information is in the Page 2 tab:
   i. Archive the outdated address and/or phone by entering a dated note in the **Notes** field with your SI ID. Include the updated address.
   EXAMPLE: *11/6/2013: Updated parent's mailing address from 123 Fourth Street, Anywhere, TN 39001 to 234 Fifth Avenue, Anywhere, AZ, 21002. Updated phone from 901-222-3333 to 901-333-4444. [89]*
   ii. Update the address and/or phone fields.
   iii. Copy the note in the **Notes** field, then close the frmReg form.
   iv. Paste the note into the **Tracing history** field of the Page 1 tab, frmQuestTab.
   v. Move to a new field and save using the Save icon on the Home tab of Access ribbon.

Spouse Name

frmReg tab, Page 2 tab:

a. If the spouse name fields are blank, populate them with the spouse's name.
b. If the spouse's name is already in the Page 2 tab, simply close frmReg.
c. If an outdated spouse name is in the Page 2 tab:
   i. Archive the outdated name by entering a dated note in the **Notes** field with your SI ID. Include the updated name. EXAMPLE: *11/6/2013: Updated spouse name from Robert John Smith to Maxwell S. Hammer. [89]*
   ii. Update the first (and if applicable, middle) name in the **SpousFN** field, and update the spouse's last name in the **SpousLN** field.

iii. Copy the note in the **Notes** field, then close the frmReg form.
iv. Paste the note into the **Tracing history** field of the Page 1 tab, frmQuestTab.
v. Move to a new field and save using the Save icon on the Home tab of Access ribbon.

Sibling CCSS Participant Contact Information

frmSibling, Sib Permission tab

a. If the sibling's documented contact information IS correct, simply update the **saddrdate**, **saddrsource**, **sphonedate**, and/or **sphonesource** fields, as appropriate.
b. If the sibling's documented contact information IS NOT correct:
   i. Archive the outdated information by making a dated note in the **Notes** field of the Sib Permission tab with your SI ID. Include the new address or phone number in your note.
   ii. Enter the new contact information in the appropriate fields.
   iii. Update the **saddrdate**, **saddrsource**, **sphonedate**, and/or **sphonesource** fields, as appropriate.

4. Update the **Skin Cancer Study Kii Recruitment Call Assignments Workbook**.
   a. On the Call Assignments tab, update the **Pending Status** column with each call.
   b. Update the **Date** column.
   c. Update the call outcome fields for each call (**O1a**, **O1b**, etc.), using the Outcome Code Legend on the Pending Status, Outcome CodeLG tab.
      NOTE: If you make more than 4 outgoing calls in one day, skip over the next Date cell, leaving it blank, and then enter the outcome in the next available outcome cell.
   d. Enter your SI ID number in the **SI** column.
5. File completed forms in drawer A of the file cabinet by the Call Center printer, if applicable:
   a. File the **CCSS Skin Cancer Material Review Recruitment Script** in the "Skin Cancer Worksheets – Completed" hanging file.
   b. File the **Expired Participant Information Sheet** in the "Refusals and Deceased" hanging file.
6. Email the CRA and "cc" the Lead Survey Interviewer (LSI) team and the CSI, if applicable:
   a. Include the study name and CCSSID in the Subject bar and body of the email.
   b. Indicate the outcome of the call and that the **CCSS Skin Cancer Material Review Recruitment Script** has been completed and filed.
   c. Include the participant's name and preferred phone number(s).
      Note: The LSI will review the file daily and deliver the worksheets to the CRA. The CRA will update the **Kii Recruitment Tracking Log**.

Requesting a Resend

Email the CRA:

1. Include the study name and CCSSID in the Subject bar and body of the email.
2. Indicate whether the request is for an initial packet to be mailed or a resend. The CRA will update the **Kii Recruitment Tracking Log**.

The Tracing Process

1. The CRA or SI updates the REG database **Tracing Status** and **Tracing Date** fields and notifies the CSI via email to place the case in tracing.
2. The CSI adds the case in the **All Others Tracer's Workbook mm-dd-yyyy** tracing workbook and emails the tracer to begin working the case.
3. The tracer will trace the participant and:
   a. If contact is made:

i. Reintroduce the participant to the LTFU Study.
ii. Obtain updated contact information for the case and additional contacts
iii. Use a blank **CCSS Skin Cancer Material Review Recruitment Script** to explain the Skin Cancer Pilot study and attempt to gain commitment, refusal, request a resend or set an appointment for an SI to follow up OR
iv. Transfer the call to the assigned Skin Cancer Pilot SI.

b. If commitment is gained:
i. File the completed **CCSS Skin Cancer Material Review Recruitment Script**in the file "Skin Cancer Worksheets – Completed" hanging file in drawer A of the file cabinet by the Call Center printer, if applicable.
ii. Update the REG database. See steps 2a – 2b of the section titled *After the Call*, above.
iii. Email the SI and "cc" the LSI team, the CSI, and the CRA.

c. If contact is not made, the Tracer will:
i. Continue to work the case per standard tracing procedures.
ii. Email the SI any new "possible" unconfirmed contact numbers for the SI to continue follow up.

d. Update the MS Word **Phone Contact Log**.

Any questions should be emailed to the CRA, CSI or LSI team.

The tools the Survey Interviewer will need to support this study can be found at the following locations:

SI Calling Tool	Location
Skin Cancer Study Key Informant Recruitment Calls SOP	***CCSS SOP Library***, *http://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
KII Recruitment Tracking Log	***Qualitative Study folder***, *Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Skin Cancer (Gellar & Mertens)\Qualitative Study*
REG database	***St Jude Intranet Sharepoint***, *http://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*
Original Cohort MS Word **Phone Contact Log**	***Interviewers folder***, *Z:\SJShare\SJCOMMON\ECC\Interviewers\Original Cohort Call Logs - Reg db*
CCSS Skin Cancer Material Review Recruitment Script	***Skin Cancer Study folder***, *Z:\SJShare\SJCOMMON\ECC\Interviewers\Skin Cancer Study\Scripts*
Skin Cancer Study Kii Recruitment Call Assignments Workbook	***Skin Cancer Study folder***, *Z:\SJShare\SJCOMMON\ECC\Interviewers\Skin Cancer Study\Assignments*
Pre-Post Checklist - Skin Cancer KII Pilot Calls	***CCSS SOP Library***, *http://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx*

Revision Record Printed 11/13/2013 9:55 AM

[ ] Current Filename:		Skin Cancer Study Key Informant Recruitment Calls ver 1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	9/19/2013	D. Rinehart	Initial Development
1.1	11/5/2013	D. Rinehart, R. Massey	Content revision
1.2	11/12/2013	D. Rinehart , D. Jackson, R. Massey	Content revision

Solid Tracing Phone Lead Follow-Up Calls

Background:

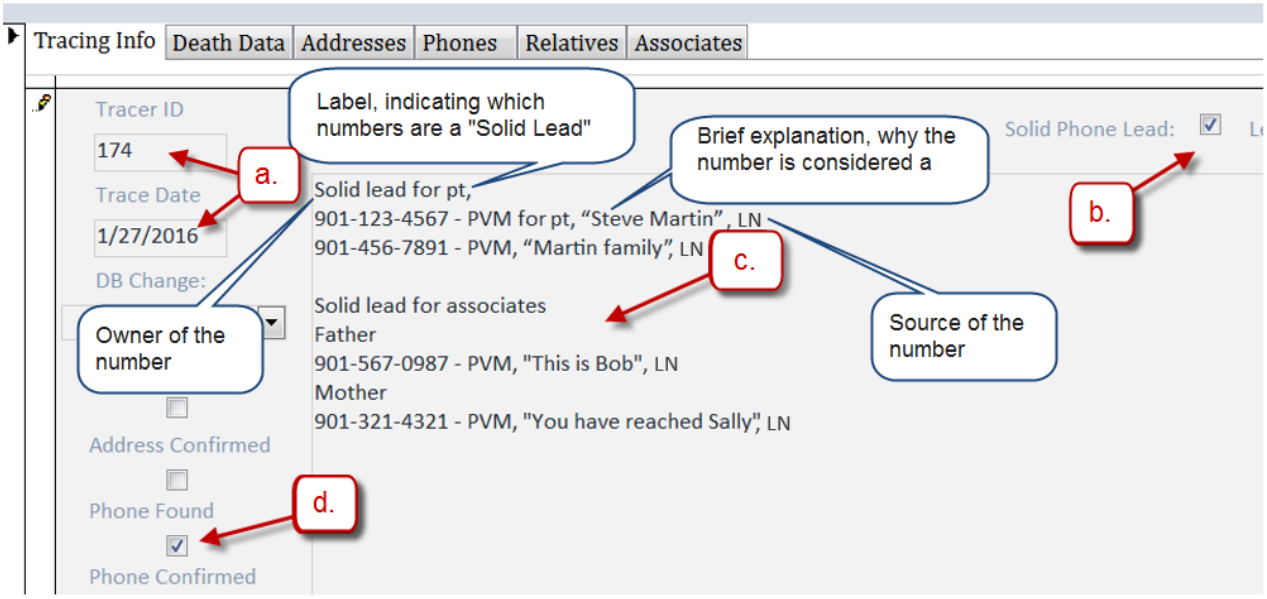
When an un-confirmed phone number for a participant in the **CCSS Tracing** database has been called and logged in the parent database **Trace Log**, if strong evidence exists (e.g., the participant's full name is included in the recorded voicemail greeting) that number will be marked as a "**Solid Lead**" both in the parent database **Trace Log** and in the **CCSS Tracing** database. Calls will continue to these numbers until someone answers and confirms whether the number is valid for the participant or not.

Tools:

1. **CCSS Survey Interviewer Assignments Database**
2. **CCSS Tracing Database**
3. **Current SOP for updating the applicable "Parent" database**
4. **Applicable "Parent" Database**
5. **Phone Message Guidance_Rev 5-30-2014.docx**

Solid Phone Lead Tracing Event:

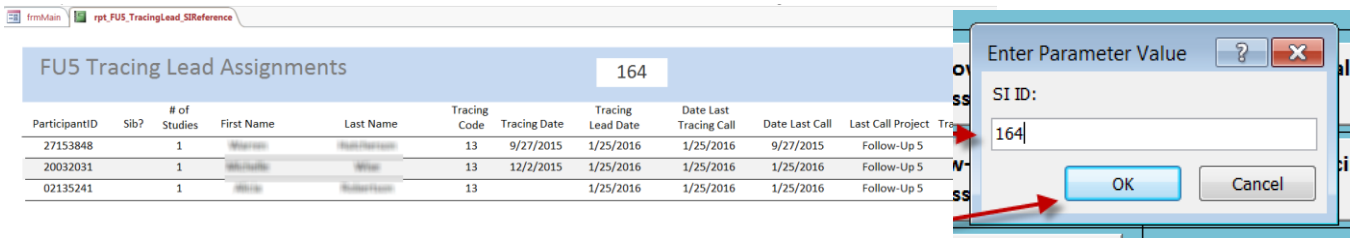
1. Tracers will call all numbers in the **CCSS Tracing** database for the Pt, as well as any relatives and associates linked to the Case or Sibling participant (for more information, see the SOP, **Tracing Lost Participants**).
2. When a Tracer determines a phone number is valid for the pt or associate, but cannot confirm the phone number, they will:
    a. Enter SI ID in the **Tracer ID** field and enter the current date in the **Trace Date** field
    b. Check the "**Solid Phone Lead**" box
    c. In the **Tracer Comments** field**,** add the unconfirmed phone number(s) with a brief note, indicating:
        i. Label, "Solid Lead"
        ii. The number believed to be a "Solid Lead"
        iii. Short explanation why the number is believed to be a "Solid Lead" (e.g., personalized voice mail (PVM) with the pt's full name, family's last name, etc.)
        iv. The source of the number (e.g., online tracing, LN, parent database, etc.)
        v. The owner of the number (e.g., pt, associate, LAR/Proxy, etc.)
    d. Check the "**Phone Found**" box



3. Pts with the "**Solid Phone Lead**" box checked will be added to the project specific "**Tracing Leads**" assignments, in the **CCSS Survey Interviewer Assignments** database for SI's to follow-up.

Outgoing "Solid Phone Lead" Follow-Up Calls

1. Open the **CCSS Survey Interviewer Assignments Database**
2. Left-click the project specific **"Tracing Leads"** button
3. Enter the SI ID and left-click OK.



4. Open the **CCSS Tracing Database**
5. Locate the pt record.
6. On the **Tracing Info tab,** review the notes in the **Tracer Comments field**
7. Cautiously call all the contact numbers that have been identified as a "**Solid Phone Lead**".

After the Call*: If Contact is Not Made*

Parent Database (see the current SOP for updating the parent database)

1. Log the call in the **TRACE Log**
2. Enter a note in the **Notes** field of the New Trace Log indicating that the number called was a "**Solid Phone Lead"**, with the phone number and person called.
3. Move on to the next "**Solid Phone Lead**" assignment. No need to add a note in the **CCSS Tracing** database.

After the Call: *If Contact is Made*

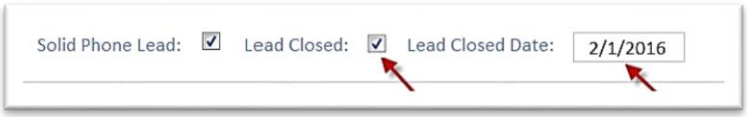
Parent Database (see the current SOP for updating the parent database)

1. Log the call in the **TRACE Log**
2. Enter a "**Solid Phone Lead"** note in the **Notes** field of the New Trace Log. Example*: "Called Solid Phone Lead number for pt, 901-346-1234"*
3. Click the "**Add Record to Contact Log**" button in the **New Trace Log.**
4. Update the applicable fields in the pt record.

CCSS Tracing database

Note: If new contact information is gained for the pt, the "**Solid Phone Lead**" needs to be closed. If no contact has been made with anyone after calling the unconfirmed numbers five times, the "**Solid Phone Lead**" needs to be closed.

1. Check the "**Lead Closed**" box.
2. Enter the current date in the "**Lead Closed Date**" field.



3. Enter a clear, concise dated note with SI ID in the **"Tracer Comments"** field, indicating that the **"Solid Phone Lead"** has been closed.
   For example, "*3/1/2016: Participant's contact info confirmed. Closed "Solid Phone Lead". [156]*"

Note: When in doubt, after reviewing the SOPs, send all questions to the LSIs via email.

Revision Record

Printed 4/5/2018 2:16 PM

Current Filename:		Solid Tracing Phone Lead Follow-Up Calls ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	4/3/18	D. Rinehart, A. Cobble, D. Daniels, K. Rothammer, D. Davis	Initial Development

Spanish Cover Letters and Authorization Forms - Merging

Background

Generating **Spanish cover letters** and **Spanish authorization forms** for recruitment packets uses the same data file you use for the English cover letter. This data file now contains an additional column "SpPkt". People whose recruiting packet is to ALSO INCLUDE the Spanish packet will have "SpanPacket" in this column. Those who do NOT get the Spanish packet will be blank. E.g.,

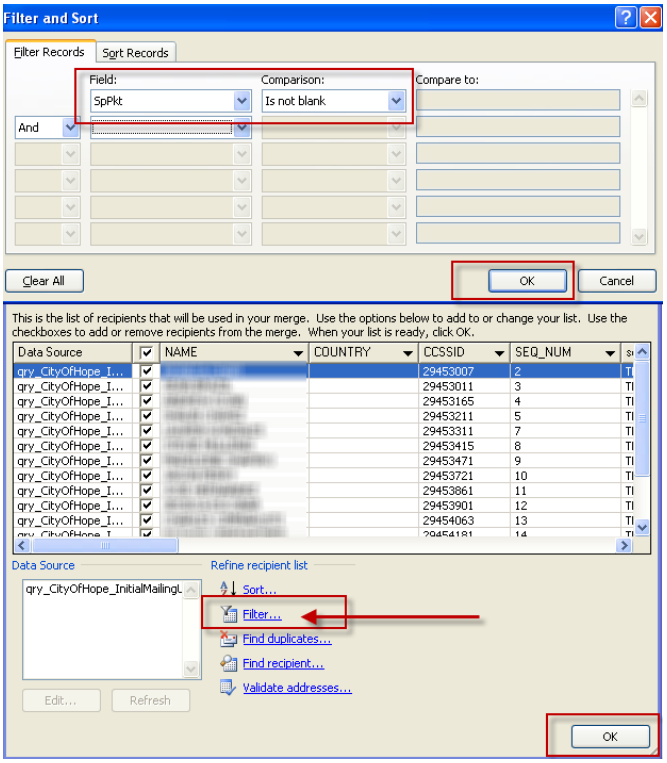
	A	B	C	
1	CCSSID	SEQ_NUM	SpPkt	sendcareof
2	29453007	2	SpanPacket	THE PARENT OF M
3	29453011	3		THE PARENTS OF
4	29453165	4		THE PARENTS OF
5	29453211	5		THE PARENTS OF

	A	B	C	
1	CCSSID	SEQ_NUM	SpPkt	sendcareof
2	29416723	1		THE FAMILY OF
3	29416851	2		THE FAMILY OF
4	29451022	3		THE FAMILY OF
5	29451723	4		THE FAMILY OF
6	29451791	5		THE FAMILY OF
7	29451981	6		THE FAMILY OF
8	29452021	7		THE FAMILY OF
9	29452671	8		THE FAMILY OF
10	29452768	9		THE FAMILY OF
11	29452801	10	SpanPacket	THE FAMILY OF
12	29452921	11		THE FAMILY OF
13	29453081	12		THE FAMILY OF

Procedure

When you use this data file to produce the Spanish cover letter and the Spanish authorization forms, use the **filter** feature to filter for records where SpPkt is not blank:

1. Select the Excel data source.
2. In the **Filter and Sort** dialog, refine the recipient list using the FILTER feature:
   a. In **Filter Records**, from the **Field:** dropdown, select SpPkt.
   b. In **Comparison**: dropdown, select "Is not blank"
   c. Click **OK**.
3. Double-check this against the data file, just to be sure.



Revision Record Printed 7/6/2012 8:08 AM

Current Filename:		Spanish Cover Letters Authorization Forms-Merging ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/18/10	J.Bates	Initial Development

Spanish Packet Recruitment Materials

Background

We enclose a Spanish packet of materials when recruiting individuals whom we believe do not speak English. These individuals receive a "Spanish packet" IN ADDITION TO regular English recruitment materials. As with other recruitment materials, there are separate documents for adults, minors, and deceased. The Spanish packet contains the following documents translated into SPANISH:

1. Introductory letter
2. Authorization forms (i.e., institutional HIPAA, LTFU consent, LTFU HIPAA, for mailings with full survey booklet; for "HIPAAonly" mailings, only the institutional HIPAA). Separate forms for living and for deceased.
3. Participant copy (either living or deceased)
4. NOTE: for HIPAAonly Spanish packets, some institutions use the same HIPAA authorization form (and participant copy) for both living and deceased.

Place Spanish materials in a 9x12 white labeled envelope indicating Spanish materials are enclosed.

Procedure

Note that people receiving the Spanish packet ALSO RECEIVE the English recruiting packet. This process ADDS the following to the production/assembly process. The data file includes a NEW column "SpPkt". If the individual is to receive a Spanish packet, the column will say "SpanPacket."

FOR *THESE* CASES:

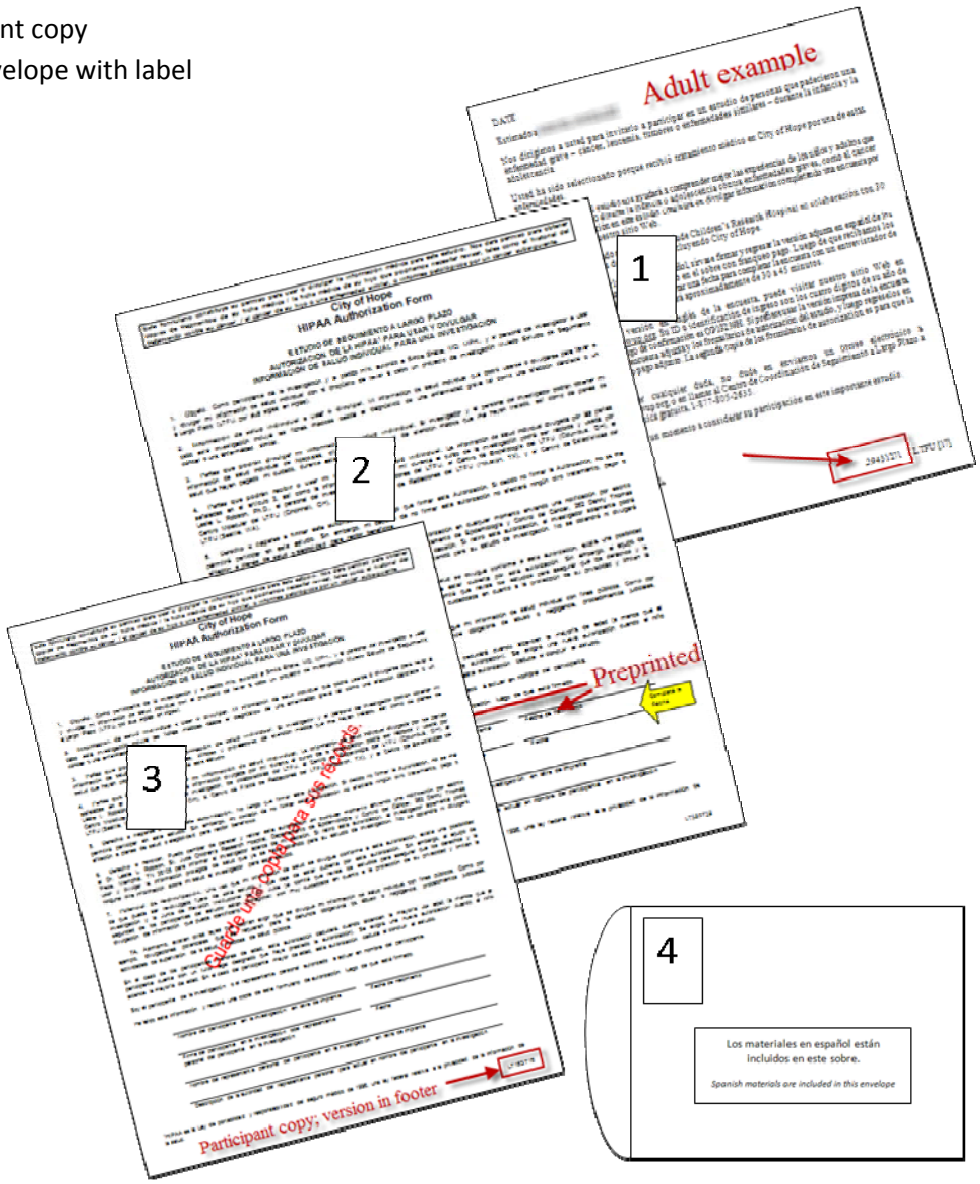
1. Mail merge appropriate introductory SPANISH letter with data file. (e.g., adult, minor, deceased)
    a. Spanish letters are located in the **IRB-approved letters** folder.
    b. Filter the data file to include those where SpPkt is not blank.
2. Mail merge appropriate SPANISH HIPAAonly document with data file. (e.g., living or deceased)
    a. Spanish HIPAAs for merging are in same folder as English HIPAAs (**InstHIPAA**)
    b. As with letters, filter data file to include those where SpPkt is not blank.
3. Print the appropriate participant copy-SPANISH (living or deceased). Found in the institution's main folder. (Some institutions use the SAME HIPAA for living and deceased.)
4. Paper clip Spanish materials together, with 9x12 white envelope with Spanish label
5. Find the Recruitment packet for the case.
    a. Insert Spanish materials into 9x12 white Spanish envelope. Tuck flap inside (do not seal).
    b. Insert Spanish envelope into the white 10x13 mailing envelope
6. During QA: double-check to be sure the Spanish packet is in the correct recruitment envelope.

CRA

Sample assembly: Spanish Packet

Adult, City of Hope example

1. Introductory cover letter
2. Authorization forms
3. Participant copy
4. 9x12 envelope with label



Revision Record

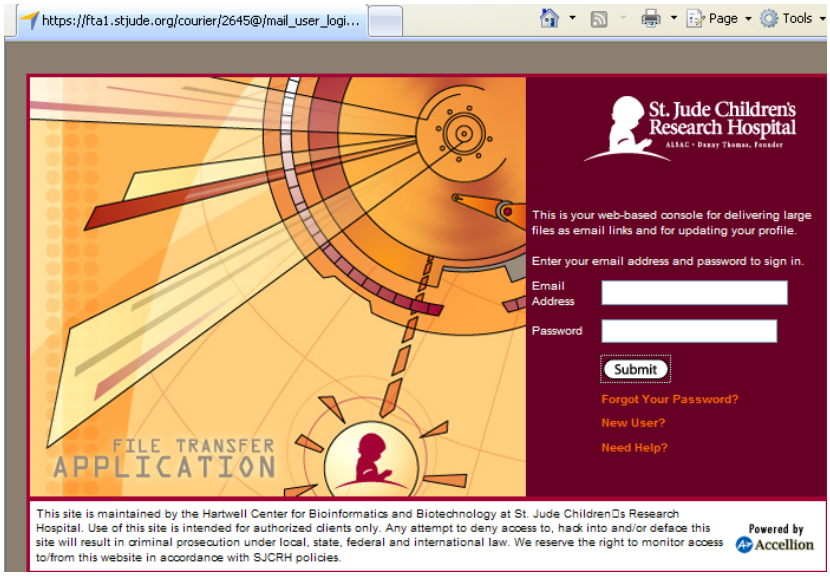
Printed 7/6/2012 8:06 AM

Current Filename:		Spanish Packets Recruitment Materials ver 2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/18/10	J.Bates	Initial Development
2	3/20/11	J.Bates	HIPAA only packet

St Jude FTA

(Secure File Transfer Application)

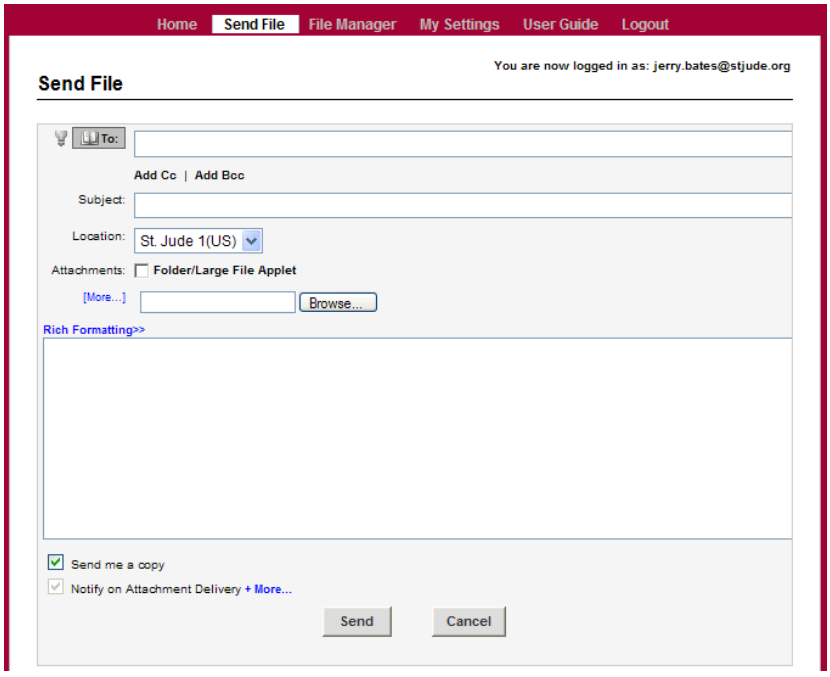
Access the St. Jude File Transfer Application (http://fta.stjude.org) and then log in with your St. Jude username and password.



(Non-St. Jude individuals will need to set up a username and password. Use the New User? link to do this.)

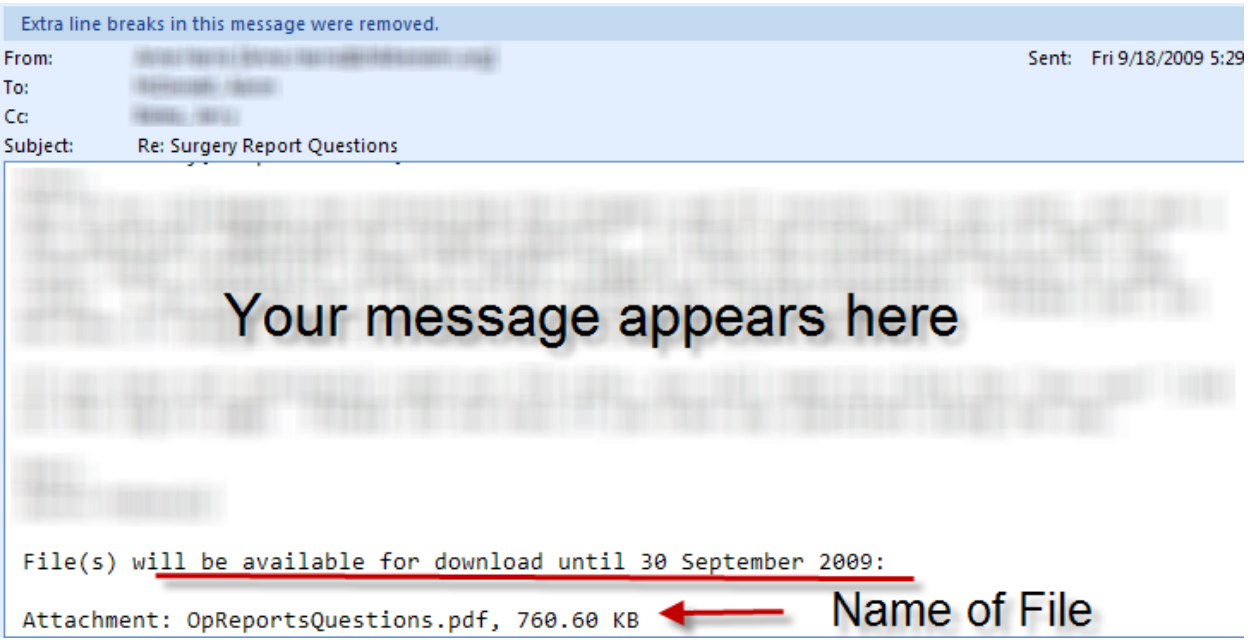
After logging in, you may upload the file(s) and notify the recipient.

1. Enter the recipient's email address. If needed, you may Add cc (and/or) Add Bcc.
2. Complete the Subject line.
3. Browse for the attachment(s)
4. As needed, key in a message for the transmitting email.
5. Check Send me a Copy.
6. Click Send.



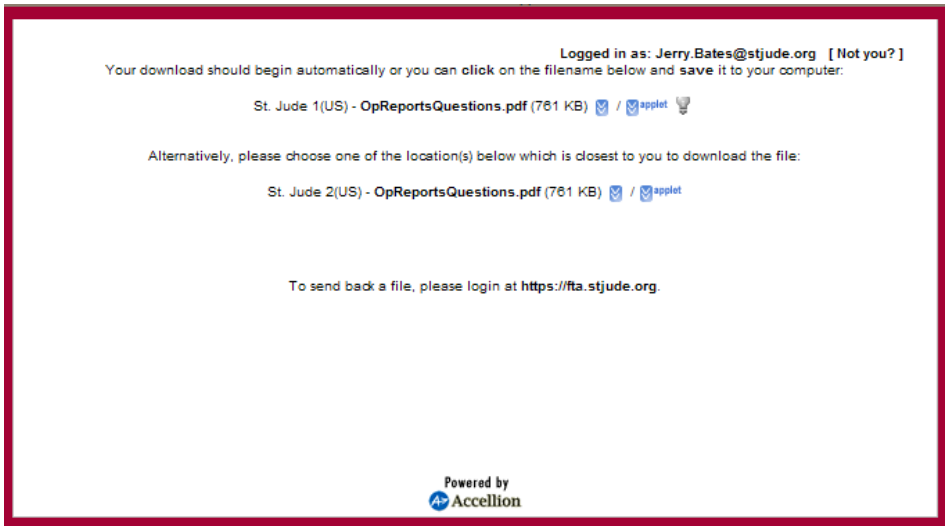
Everyone

Your recipient(s) will receive an email message which includes a hyperlink to the uploaded file (beneath the file name).



On connecting to the link in the email, the download process information page displays.

(If you are not logged in to the St. Jude system, or if you are not a St. Jude employee, you will be prompted to log in to the FTA program.)



Revision Record

Printed 7/9/2012 2:25 PM

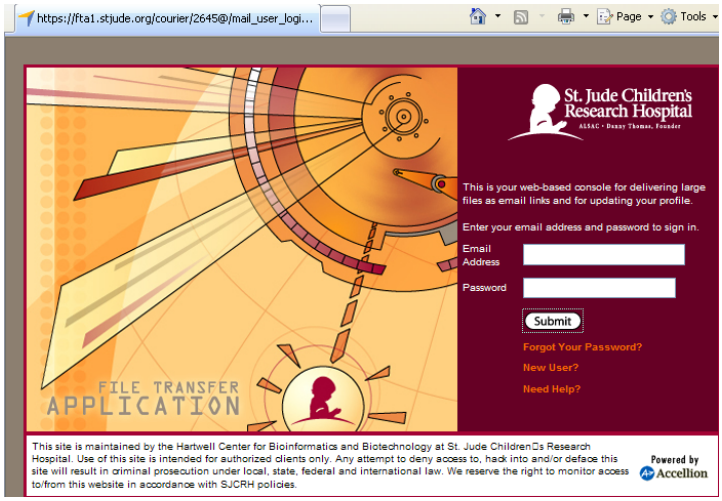
Current Filename:		St Jude FTA ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/6/09	J.Bates	Initial Development

St Jude FTA – External Parties

(Secure File Transfer Application—information for external parties)

Certain large and/or confidential files may be sent to you via St. Jude's secure File Transfer Application. In order to retrieve the files, you will first need to establish your account.

To establish your account,



- Go to the St. Jude File Transfer Application (http://fta.stjude.org).
- Click the **New User?** link.
- Enter your **EMAIL address**.
- A temporary password will be emailed to you.
- Once you receive the password, return to the site and log in with it. (Logging in involves entering **your email address** and the **password**. You will need to change the temporary password. Follow the prompts to do so.)

When your correspondent from St Jude sends you a file via the StJude FTA, you will receive an email notification. The notification contains a hyperlink to use to take you to the file. Notice that the message also indicates how long the file will be available for download.

Click the hyperlink. You will be prompted to log in to the FTA site. Log in using the email address and password associated with your FTA account.

Save the document to your local storage device. FTA will notify your St Jude correspondent when you have downloaded the file.

Revision Record

Printed 7/9/2012 2:27 PM

Current Filename:		St Jude FTA-outside users ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/3/10	J.Bates	Initial Development

St. Jude Life CCSS Appointments

Background

Of patients currently enrolled in the St. Jude Life (SJL) study, some are also enrolled in CCSS, some are eligible for CCSS, while others are not. For those SJL participants who return to St. Jude for an individualized health evaluation, the coordinating center must identify whether these former St. Jude patients are

- eligible for CCSS but not yet enrolled;
- enrolled in CCSS and eligible for the Saliva study (i.e. have not refused the saliva study or provided a saliva/blood sample within the previous 12 months);
- enrolled in CCSS and have not signed a LTFU HIPAA; or
- enrolled in CCSS as a minor but are now 18 or older and need to be reconsented into CCSS.

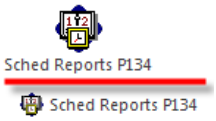
If any of these apply, a qualified representative of CCSS will meet with the participant during the participant's St. Jude visit and document the outcome of the appointment. This document outlines the procedures surrounding the SJL participant's CCSS Appointment. We use a query repeatedly in the following procedure sets to identify what we need for each identified case.

Procedure Step 1: *Identify former St. Jude patients who are 18 or Older*

Each month, we identify former St. Jude patients who are 18 or older, eligible for or enrolled in CCSS, and for whom we need a Childhood Cancer Survivor Study Research appointment scheduled during their SJL visit for one reason or another. (*Note: Not all these CCSS eligible/enrolled participants are enrolled in SJL.*) The project manager runs a query, save it into a master Excel list, and gives it to the SJL nurses responsible for scheduling the CCSS appointment.

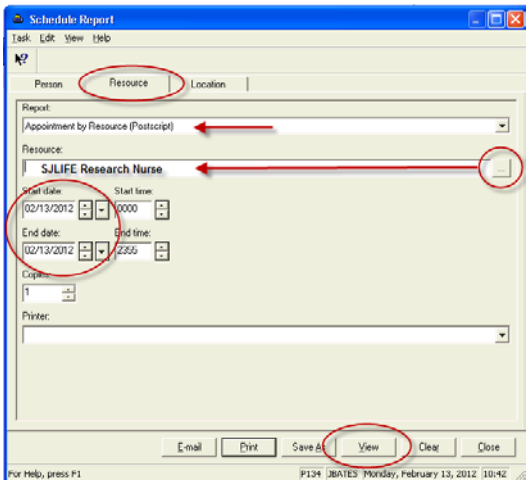
1. Open the **CCSS DNA Tracking** database.
2. Run the following query: **qry_SJLEligibleforConsent_DNA_HIPAA**
   a. Identifies former St. Jude patients who fall into one of the following categories:
      i. Have not signed a St. Jude HIPAA, CCSS consent/completed the baseline survey, and LTFU HIPAA.
      ii. Signed a St. Jude HIPAA but have not signed a CCSS consent/completed the baseline survey and LTFU HIPAA.
      iii. Need reconsenting (i.e., a minor at the time of study enrollment)
      iv. Have not refused the saliva study or previously provided a saliva sample
3. Export the query and save file as: **n**[X] **date** [XX-XX-XX]" here:
   \\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Consents - CCSS exp\SJL_CCSS Eligible for Recruitment and_or DNA\SJL_CCSS Pts Eligible for Recruitment and_or Saliva for 2018
4. Send the master list to Cobble, Tabitha, Zazzara, Terry, Young, Rachel, and Zelinka, Katherine the SJL nurses responsible for making appointments. Ask that a "Childhood Cancer Survivor Study Research" appointment be scheduled for any of these participants that return to St. Jude for a SJL visit.

Procedure Step 2: *Identify SJL participants scheduled for a campus visit*



Prior to the beginning of each week, generate a list of SJL participants scheduled for an individualized health examination *for the upcoming month*. Create the list using the Milli Scheduling Program:

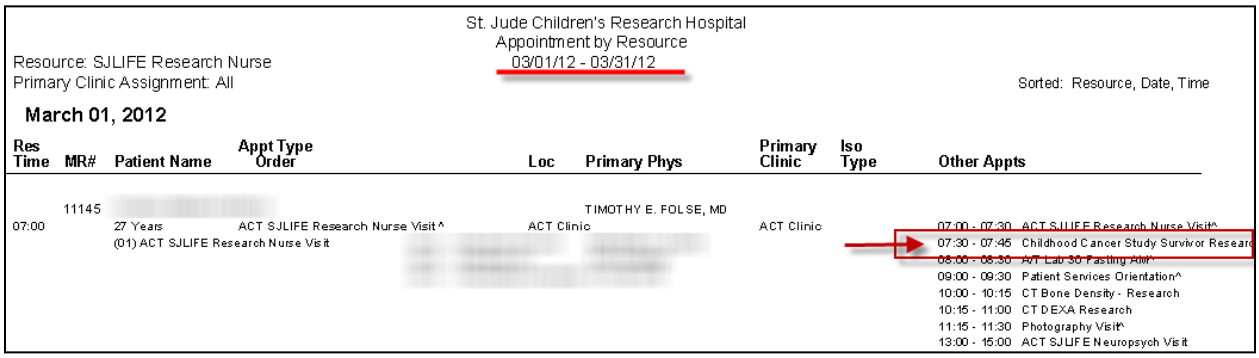
1. In MILLI, open the Application **Sched Reports** (call the help desk if you don't have access to this program)
2. On the Schedule Report screen, click the **Resource** tab
3. Under **Report**, select Appointment by Resource (Postscript)
4. Under **Resource**, click the ellipsis button and select Epidemiology CRA
5. Using the DATE RANGE that covers the entire upcoming week, enter **Start date** and **End date**
6. Click the **View** button
7. On the Report Output screen, you can rotate the orientation using View Orientation and page through the report using the Previous/Next icons or the keyboard page Up/Page Down keys.
8. Use the Printer icon to **print copy of the report.**
9. Repeat process selecting SJLIFE Research Nurse under **Resource**



Procedure Step 3: Determine NEED for CCSS appointment (upcoming SJL visit cases)

Compare the reports you printed for the upcoming week to the following query to see which cases will need a CCSS appointment.

1. Open the **CCSS DNA Tracking database**
2. Run the following query (for up-to-date results) **qry_SJLEligibleforConsent_DNA_HIPAA**
3. For each MR# listed in the *Scheduling Report*, search the above query
   a. If the MR# is NOT IN any of the queries, then an appointment is NOT NEEDED.
      v. If the MR# is NOT IN the query BUT there IS a *Childhood Cancer Study Survivor Research Visit* listed under **Other Appts** in the printed report, contact Cobble, Tabitha, Zazzara, Terry, Young, Rachel, and Zelinka, Katherine to inform them that the appointment is **not** needed
   b. If the MR# IS in any of the queries, then an appointment IS NEEDED. Verify there IS an appointment for *Childhood Cancer Study Survivor Research Visit* in **Other Appts**.
      i. If appointment is NOT scheduled (i.e. *Childhood Cancer Study Survivor Research Visit* not listed in **Other Appts**), contact Michelle Fite-Weatherford to request one
      ii. NOTE: Orders for the CCSS Research visit are grouped under Consults/Follow-ups in the Orders section of Power Chart.



St. Jude Children's Research Hospital
Appointment by Resource
03/01/12 - 03/31/12

Resource: SJLIFE Research Nurse
Primary Clinic Assignment: All

Sorted: Resource, Date, Time

March 01, 2012

Res Time	MR#	Patient Name	Appt Type Order	Loc	Primary Phys	Primary Clinic	Iso Type	Other Appts
07:00	11145	27 Years	ACT SJLIFE Research Nurse Visit^	ACT Clinic	TIMOTHY E. FOLSE, MD	ACT Clinic		07:00 - 07:30 ACT SJLIFE Research Nurse Visit^
		(01) ACT SJLIFE Research Nurse Visit						07:30 - 07:45 Childhood Cancer Study Survivor Researc
								08:00 - 08:30 A/T Lab 30 Fasting AM^
								09:00 - 09:30 Patient Services Orientation^
								10:00 - 10:15 CT Bone Density - Research
								10:15 - 11:00 CT DEXA Research
								11:15 - 11:30 Photography Visit^
								13:00 - 15:00 ACT SJLIFE Neuropsych Visit

CRA

Procedure Step 4: *Determine the MATERIALS needed for the CCSS appointment*

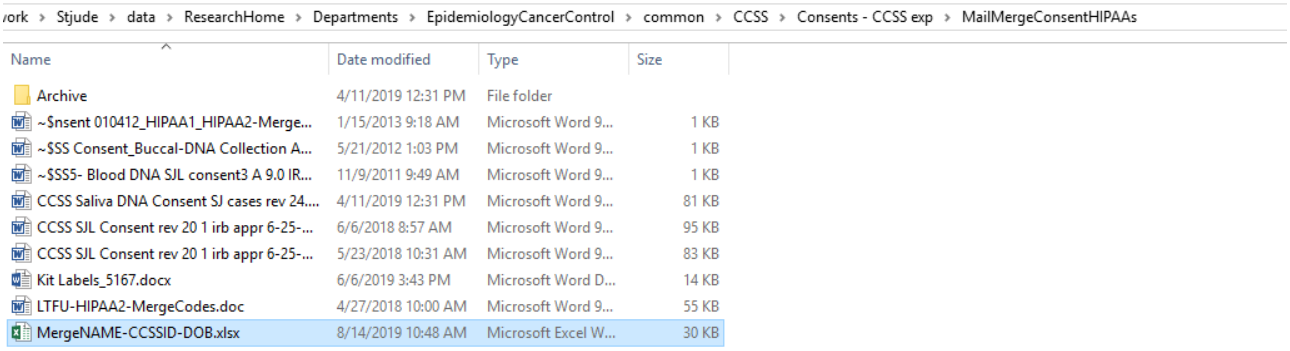
After identifying participants who need a CCSS appointment, determine the materials needed for the appointment. Do this no later than FRIDAY of each week, in order to prepare for upcoming week.

1. Open the **CCSS DNA Tracking** database. Run the following query: **qry_SJLEligibleforConsent_DNA_HIPAA**
2. Search the query for each MR# listed in the "Scheduling Report" (Remember to add/cancel appointments as need; see *Determine NEED for CCSS appointment*)
3. Determine what type of materials you will need for the CCSS appointment, based on the values in the **Needs** columns of the query. E.g.

Needs SJ-HIPAA	Needs LTFU-HIPAA	Needs Consent	Needs RECONSENT	Needs Saliva
N	N	N	N	Y
Y	Y	Y	Y	Y
N	Y	N	Y	Y
N	Y	N	N	N
N	Y	N	Y	N

   a. If *Needs SJ-HIPAA* equals **Y**, then always print a SJ-HIPAA
   b. If *Needs LTFU-HIPAA* equals **Y**, then always print a LTFU-HIPAA
   c. If *Needs Consent* Equals **Y**, then always print a LTFU Consent form
   d. If *Needs RECONSENT* equals **Y**, then always print a LTFU Consent form.
   e. If *Needs Saliva* equals **Y**, then always print a Saliva Consent form.

4. Open the file **MergeNAME-CCSSID-DOB**, located:
   DATA\\STJUDE)(Z)\ResearchHome\Departments\ECC\common\CCSS\Consents - CCSS exp\MailMergeConsentHIPAAs



   a. Do not remove the first row of the file but DO copy the rows containing previous participant information to the sheet Completed in the file and then delete the previous participant information.
   b. For participants that need an appointment (for any reason), copy the participant info from the query and paste it into the file **MergeNAME-CCSSID-DOB**
   c. After updating the document, save it so you can use it for the mail merge.

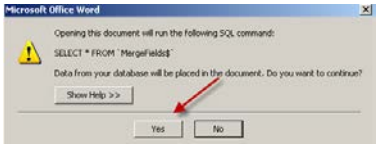
Procedure Step 5: *Prepare MATERIALS for CCSS Appointment*

(1) CCSS CONSENT/SJ HIPAA/LTFU HIPAA; (2) CCSS RECONSENT; (4) LTFU HIPAA; (4) CURRENT ADDRESS MATERIALS.

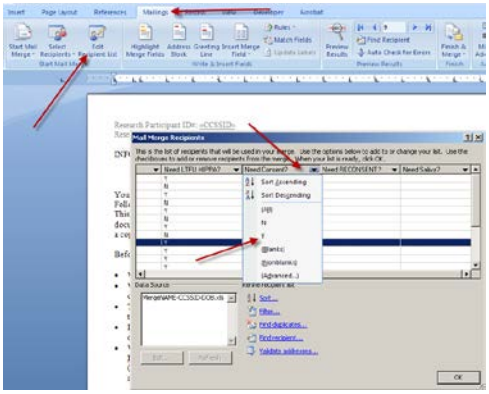
For participants that we will pursue for the CCSS study (Needs Consent, Needs RECONSENT, LTFU HIPAA = Y), prepare materials as follows, no later than Friday of each week.

(1) CCSS Consent/SJ HIPAA/LTFU HIPAA (and Participant Copy)

1. Open the file *CCSS SJL Consent rev 20 1 irb appr6-25-14_HIPAA1_LTFU-HIPAA2-MergeCodes.doc* located here: **DATA(\\STJUDE)(Z)\ResearchHome\Departments\ECC\common\CCSS\Consents - CCSS exp\MailMergeConsentHIPAAs** (Note: ALWAYS select "Yes" when you receive the *Do you want to continue?* Message….)

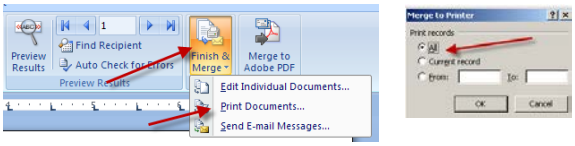


2. Go to **Mailings** on the tool bar, select **Edit Recipient List**, click on **Need Consent?** and select **Y** (by doing this, you limit the list to those participants eligible for CCSS)



3. Select **Finish & Merge** from the toolbar, click **Print Documents…,** and select **All**

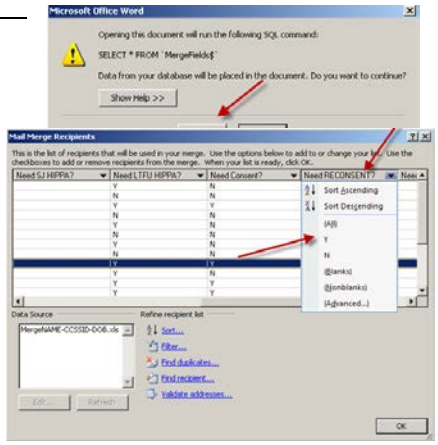
4. Print <u>2-sided</u>



5. Close document but **<u>do not save</u>** <u>the changes</u>

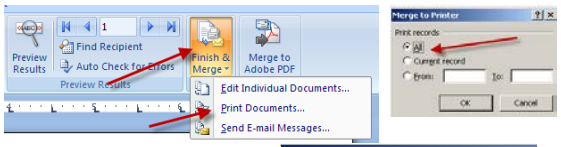
6. <u>For participant copies</u>: Open CCSS SJL Consent rev 20 1 irb appr 6-25-14_HIPAA1_LTFU-HIPAA2-ParticipantCopy.pdf and print appropriate # of participant copies (Document located here: **DATA\\STJUDE)(Z)\ResearchHome\Departments\ECC\common\CCSS\Consents - CCSS exp\ParticipantCopies**

(2) Reconsent (and Participant Copy)



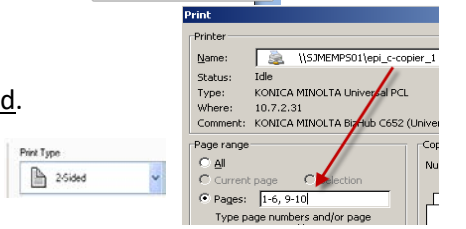
1. Open the file: CCSS SJL Consent rev 20 1 irb appr 6-25-14_LTFU-HIPAA2-MergeCodes.doc located here: **DATA(\\STJUDE)(Z)\ResearchHome\Departments\ECC\common\CCSS\Consents - CCSS exp\MailMergeConsentHIPAAs** (Note: ALWAYS select "Yes" when you will receive the *Do you want to continue?* Message….)

2. Go to **Mailings** on the tool bar, select **Edit Recipient List**, click on **Need RECONSENT?,** and select **Y** (by doing this, you limit the list to those participants who need reconsenting)



3. Select **Finish & Merge** from the toolbar, click **Print Documents…,** and select **All**

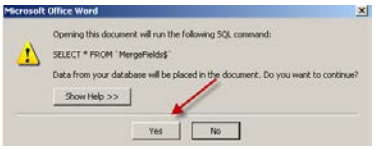
4. From Print menu,
   a. Select **Pages:** and enter **1-6, 9-10**
   b. From Printer Properties/Layout, specify printing 2-sided.



5. Close document but **do not save** the changes

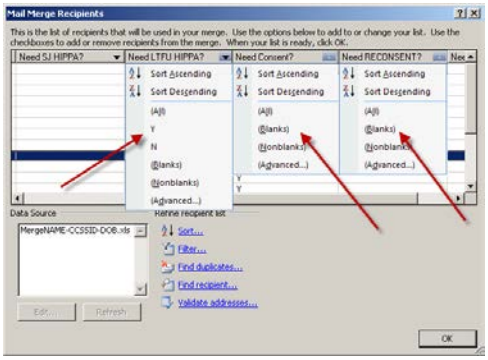
6. For participant copies: Open *2.Consent 010412_LTFU-HIPAA2-ParticipantCopy* and print appropriate # of participant copies (Document located here: **DATA(\\STJUDE)(Z)\ResearchHome\Departments\ECC\common\CCSS\Consents - CCSS exp\MailMergeConsentHIPAAs\ParticipantCopies**

(3) LTFU HIPAA (and Participant Copy)

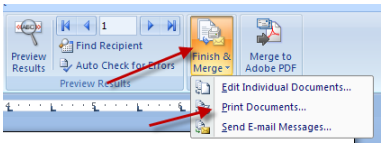


1. Open the file LTFU-HIPAA2-MergeCodes.doc located here: **DATA(\\STJUDE)(Z)\ResearchHome\Departments\ECC\common\CCSS\Consents - CCSS exp\MailMergeConsentHIPAAs**
(Note: ALWAYS select "Yes" when you receive the *Do you want to continue?* Message….)

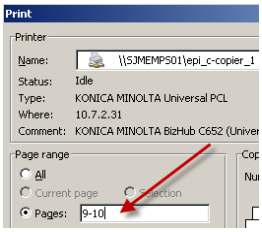
2. Go to **Mailings** on the tool bar, select **Edit Recipient List**, click on **Needs LTFU-HIPAA?,** and select **Y** first, then click on **Needs RECONSENT & Needs Consent** and select **N** (by doing this, you limit the list to those participants who do not need consenting/reconsenting but do need a LTFU HIPAA)



3. Select **Finish & Merge** from the toolbar, click **Print Documents…,** and select **All**



4. From Print menu,
    1. Select **Pages:** and enter **9-10**
    2. From Printer Properties/Layout, specify printing 2-sided.

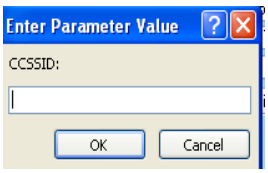


5. Close document but **do not save** the changes

7. For Participant Copies: Open *1.LTFU-HIPAA2-ParticipantCopy* and print appropriate # of participant copies (Document located here: **DATA(\\STJUDE)(Z)\ResearchHome\Departments\ECC\common\CCSS\Consents - CCSS exp\MailMergeConsentHIPAAs\ParticipantCopies**

(4) Current Address Sheet

In addition to the imprinted consent and HIPAA forms, you need an Address sheet with the patient's and associate's information: current address, phone, and email for the participant to make corrections. Generate this sheet from the appropriate database.



1. From the database object list, locate **Rpt_ContactInfoSheet_LTFU, Rpt_AssociateInfoSheet_LTFU**.
2. Double-click reports. When prompted, type the CCSSID of the patient you are consenting.
    a. If no data is displayed, then use **Rpt_ContactInfoSheet_Exp, Rpt_AssociateInfoSheet_Exp;** If no data is displayed, then use **Rpt_ContactInfoSheet_Rec, Rpt_AssociateInfoSheet_Rec**
3. Print sheets for the CCSS ID patient's address and patient's associates address sheet.
4. Repeat steps 1-4, if needed, for additional patients.

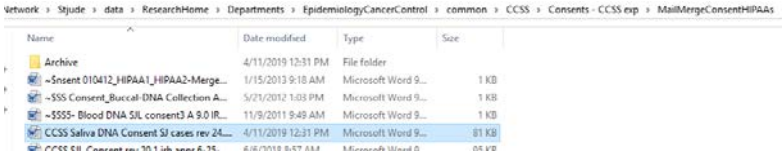
Set aside these documents (e.g., (1) CCSS Consent (2) CCSS Reconsent (3) LTFU HIPAA (4) Current Address), so they can be combined with other consent/kit materials.

***Procedure Step 6**: Saliva Materials*

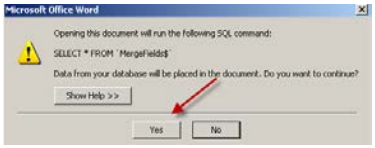
(1) SALIVA INFORMED CONSENT MATERIALS

1. For participants that we will pursue for the saliva study (Needs Saliva = Y), prepare saliva materials as follows, no later than Friday of each week.

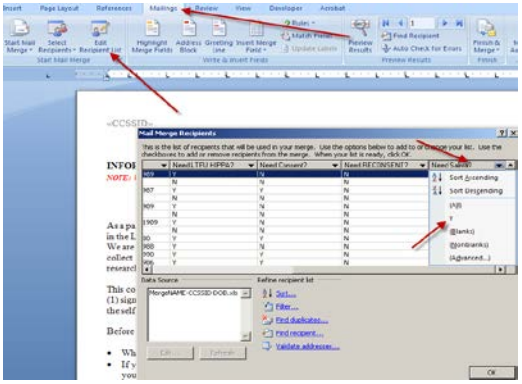
2. Open the file ***CCSS Saliva DNA Consent SJ cases rev 24.3 irb appr 2-20-19 MERGED.doc*** located here:



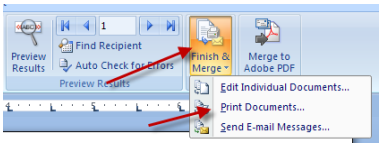
\\Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Consents - CCSS exp\MailMergeConsentHIPAAs (Note: ALWAYS select "Yes" when you receive the Do you want to continue? Message….)



3. Go to **Mailings** on the tool bar, select **Edit Recipient List**, click on **Need Saliva?,** and select **Y** (by doing this, you limit the list to those participants eligible for the saliva study)



5. Select **Finish & Merge** from the toolbar, click **Print Documents…,** and select **All**



6. Print 2-sided
7. Close document but **do NOT save** changes

8. Open **4. CCSS Saliva DNA Consent SJ cases rev 24.3 irb appr 2-20-19-ParticipantCopy.pdf** and print appropriate # of participant copies
    i. Document located here:
    \Stjude\data\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Consents - CCSS exp\ParticipantCopies
9. Create an Address sheet (if not previously printed; see section above *Current Address Sheet*)
10. Set aside Saliva Consent documents, so they can be combined with other consent/kit materials

(2) SALIVA KIT MATERIALS

1. An adequate supply of Saliva Kit materials will be kept in the storage room. The bulk of the saliva kits are housed in the basement cage.
2. Gather enough saliva kits, biohazard bags, and swab kits for the entire week.
   a. While collecting saliva kits, be sure to note the **Box #** from which you pulled the kit (so you can maintain an accurate count of our inventory; see *Maintaining Saliva Kit Inventory*.)

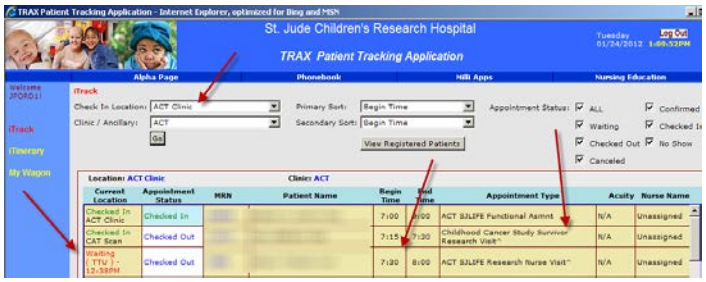
3. Create a 5167 label with participant's CCSSID#. Attach it to the bottom of a specimen container.

4. For ease and accuracy, mail merge the labels with the MergeNAME-CCSSID-DOB document using the same method as the earlier *Saliva Informed Consent Materials* section.

Procedure Step 7: *Conduct the CCSS appointment*

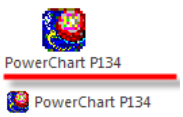
For participants for whom we need the CCSS appointment, use the following process. (Be sure that all appropriate materials are in hand, depending on the nature of the CCSS appointment.)

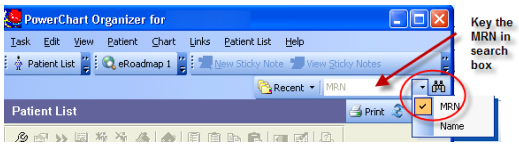
1. Report to the TTU building ACT Clinic Charting Room at least 5 or 10 minutes prior to the appointment. (NOTE: If you have access to TRAX, you can wait until the participant is "Waiting" at the TTU building for the CCSS appointment.)

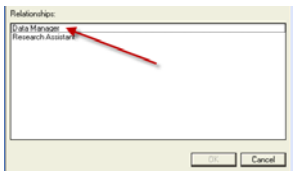


2. Check with SJL and ACT nurses, who are in the Clinic Charting Room, to determine which TTU clinic room to use for your appointment.

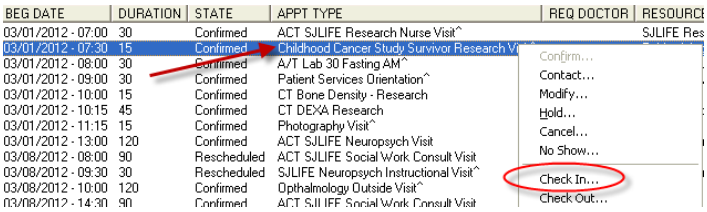
3. 'Check-in' the participant for his/her appointment (If you need assistance, SJL and ACT nurses are happy to help)
   a. Open **PowerChart**
   b. In Patient List, search for participant by **MRN.** Click on participant's name (if more than one name is associated with an MRN, be sure to select the correct participant name).
   c. For Relationship, select **Data Manager** then click **Ok.**
   d. From the left menu, click **Patient Schedule**





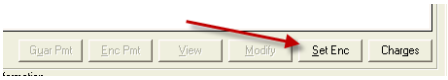


e. Find the *Childhood Cancer Study Survivor Research Visit* appointment, right click the mouse, and select **Check In…**



f. Click **Set Enc**

g. Select **Ok** (the participant is now "Checked In")



4. Find and escort participant to assigned clinic room

5. For participants needing the **CCSS CONSENT OR RECONSENT AND/OR LTFU HIPAA:**
   a. Read and discuss the consent and/or HIPAA form(s).
   b. Obtain signature on the necessary forms
   c. Give participant a copy of each of the forms)
   d. Have them verify their current contact information
   e. Continue with Saliva Kit process, if necessary (below)

6. For participants needing the **SALIVA KIT:**
   a. Read and discuss the Saliva Study Consent form. (Reminder: if the participant needs to be consented/reconsented to the CCSS study or we simply need a signed LTFU HIPAA, be sure to complete that process BEFORE consenting them to the saliva study.)
   b. If the participant **refuses** the saliva study, politely inquire as to why and update your physical copy of the *SJL In Clinic Saliva Tracking Sheet*
   c. If the participant **consents** to the saliva study, provide the participant with a copy of the consent form, saliva kit, saliva kit instruction sheet, and biohazard bag
      i. *NOTE: Reserve the swab kit for situations when a participant is unable to provide enough saliva*
      ii. Ask the participant to place the saliva sample inside the biohazard bag and seal it
      iii. Wait **outside** the room for participant to provide you with the *sealed* biohazard bag

   d. If the participant is *unable to provide an adequate sample*, provide him or her with a swab kit and briefly describe the instructions, which are included inside of the swab kit. *BE SURE TO document* this in a NOTE on your hard copy of the *SJL In Clinic Saliva Tracking Sheet*.

   e. After the participant provides you with a specimen sample, walk the specimen over to the Technologists in the TTU lab.

   f. Using Power Chart, **Check Out** the participant

Procedure Step 8: *Perform post-appointment data entry*

1. **CURRENT ADDRESS INFORMATION:** Unless the participant refuses to update his or her contact information, all name, address, phone, and email information must be updated in the appropriate database.
2. Open CCSS LTFU Participants Database
    a. Search by CCSSID
    b. If **Tracing Status** is **13**, **18**, **19**, **20**, or **81**, remove the code and the **Tracing Date**
    c. If you have any **corrected name or address information**, click the **Archive Contact Info** button
    d. If the participant indicated a **name or DOB change**, notify the appropriate CRA2
    e. Enter any corrected or new name, address, phone, and email information
    f. Enter appropriate **Address Date/Source**, **Phone** type (e.g. Cell, Home, etc), **Date**, and **Source**, and **Email Date/Source**
    g. Enter appropriate **Phone/Email Rank** info (e.g. 1 is preferred, 9 is disconnected, 11 is invalid/inactive, 37 is do not call/use)
3. **CCSS CONSENT/RECONSENT/LTFU HIPAA CASES:**
    a. For participants that needed CCSS/LTFU consenting or reconsenting, and/or LTFU HIPAA process in the database *no later than the day after* the consent is obtained.
    b. For information on how to record CONSENTS in the database, refer to ***Processing St Jude Life In-Hospital Recruits***.
    c. For information on how to record RE-CONSENTS (originally consented to LTFU as a minor) as well as original parental refusals and ongoing guardianship, refer to ***Reconsenting St Jude Life Cases to LTFU*****.** In this document, begin with the section RECRUITED to LTFU as a MINOR. Also note the Exceptions on handling Guardians and Refusals.
4. **Record the receipt of a signed LTFU HIPAA**
    a. Open the CCSS LTFU Participants Database
    b. Search by CCSSID
    c. Go to HIPAA Participation History tab
    d. If there is any HIPAA info, archive the old info before entering new info
    e. Enter **Date HIPAA Received** [Enter current date]**, Date HIPAA Signed [**Date participant signed]**, HIPAA Source** [SJL visit]**, HIPAA status**[Complete or Refused]**.**
5. **SALIVA STUDY CASES:**
    - For those participants who consented to or refused the saliva study, follow the procedures in ***Processing Returned Saliva Samples and Maintaining Saliva Kit Inventory***.
    - All forms should be scanned into pdf format and then saved to the following location (see *Scanning Saliva/Blood Consent Forms* as a quick reference **Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\Saliva\Scanned Consent Forms**. Scan and save file as the CCSSID on the consent form.
        - **NOTE**: If a file *already exists* for the CCSSID you just scanned, save the current document as the CCSSID# on the consent and add the following info to the end of the file "c2" or "c3" and so on
    - Staple the pages together, insert signed consent into a manila file folder (attach CCSSID label), and file in CCSSID order in saliva consent file cabinet.

Revision Record Printed 8/20/2019 2:11 PM

(28) Current Filename:		St Jude Life CCSS Appointments ver 3_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	1/31/2012	J.Ford	Initial Development
1.1	2/13/12	J.Bates	Formatting
2.0	2/20/12	J.Ford	Incorporate related procedures
2.1	2/22/12	J.Bates	REconsenting former minors
3.0	1/23/13	J.Ford	Saliva; reconsent AOM; necessary documents
3.1	10/23/13	J.Ford	Address report revised
3.2	12/12/13	J.Ford	Additional contact report added to procedure
3.3	8/20/19	R. Vejandla, J. Ford	Network and database changes

St. Jude Life Food Frequency Questionnaires

Background

Participants complete an online Food Frequency Questionnaire (FFQ) as part of their St. Jude Life visit. Currently, Janna Lipford (CRA) has the primary responsibility of adding the appointment to her Outlook calendar based on what is in MILLI, creating/maintaining weekly FFQ spreadsheets, finding the patient in clinic, setting up the survey on a computer, and following the login instructions for each participant. If she is unable to cover an appointment, then she emails Aaron McDonald who ensures a staff member can provide necessary coverage. The assigned staff member is then directed to the FFQ folder located in the path Z:\SJShare\SJCOMMON\ECC\CCSS\FFQ Appointments to access the appointment that requires attention as well as the correct log-in information. Be sure to obtain the correct user ID before the scheduled appointment. In most cases, the staff member is not required to stay with the participant as he or she completes the questionnaire, but should confirm the participant has finished the survey in the recommended time frame.

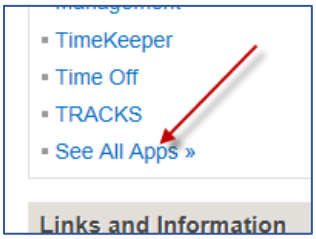
Occasionally, the participants need help reading the questionnaire or they have limited computer skills. In these cases, the staff member will help the participant complete the questionnaire by reading each question and then entering the response into the online questionnaire.

The participants will be in the After Completion Therapy Clinic (ACT).

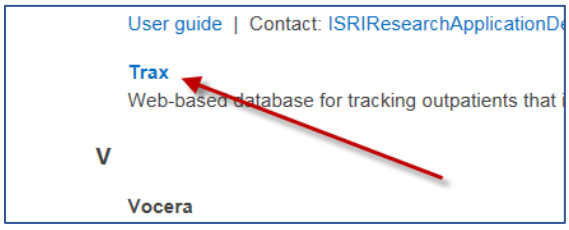
Procedure

Note – remember to obtain correct user ID from the spreadsheet located here:
Z:\SJShare\SJCOMMON\ECC\CCSS\FFQ Appointments

1. Finding your patient
   A. Check the patient's status in MILLI before the scheduled appointment time.
   B. Go to clinic a few minutes before the scheduled appointment time. In general, there are two methods to find your patient using MILLI:
      i. If you HAVE access to the **Trax application**, access Trax from the St. Jude homepage through Internet Explorer to locate the patient.
         a. Under the "Popular Tools and Apps" list on the right side of the screen, click See All Apps.



         b. Locate the Trax application, and log in using your user ID and password.
         c. Click iTrack.
         d. Make sure ACT clinic is chosen from the drop down menu for



Check In Location, and ACT is chosen from the drop down menu for Clinic/Ancillary.

e. Click **Go**, and locate the patient with their MRN.

ii. If you don't have access to the Trax application, utilize the **Power Chart P134** icon to locate the patient.

a. Click on Clinical Desktop.
b. Enter your user name and password.
c. Click on Clinical Desktop.
d. Click on the icon for Power Chart P134.
e. Select patient information from the Menu drop down list on the left side of the screen.
f. Locate cell number under the All Addresses tab
g. Ask a TTU nurse if you can use a phone to call the patient.

iii. If you don't have access to either, **check with the patient representative** at any of the ACT information desks at either extension 3658 or 4993.

2. After you locate and confirm the appointment, go to the charting room in the TTU and ask a TTU nurse in the charting room (Room 5774 in ACT clinic) **what room is available**.
   A. If the appointment cannot be confirmed and has been rescheduled, please notify Janna Lipford and Aaron McDonald.
   B. If the room you've been assigned does not have a computer, then request another room. You can tell the nurse that this appointment requires a computer.
   C. If the appointment is not already written on the board in the charting room, reserve the room by writing down the following information:
      i. Room number, Participant's first and last name, FFQ appointment, Appointment time, initials of the person who is covering the appointment
3. Using the computer, **check the person into the FFQ appointment**:
   A. Click on Clinical Desktop from the homepage.
   B. Enter your user name and password.
   C. Click on Clinical Desktop.
   D. Click on the icon for Power Chart P134.
   E. Click "Patient" from the task bar then select Search.
   F. Find the participant by MRN.
   G. Double click the Participant's name.
   H. Select "Research Assistant".
   I. Click **OK**.
   J. When the patient page displays, click on Patient Schedule.
   K. Locate the ACT SJLIFE Food Questionnaire appointment in the patient's schedule. Right-click the appointment. Use the pop-up menu:
      i. To check in, select Check In…
      ii. To check out, select Check Out…

4. If the **patient does not show up for the appointment** (i.e., more than 15 minutes late for the appointment), please notify Jenny Lanctot and Aaron McDonald via email that the patient was a "no show."
5. **Access the Food Questionnaire** on the computer in the room:
   A. Log on to the computer using your login information.
   B. Go to the website: https://www.nutritionquest.com/login/

   Important – The FFQs should be completed using the website. You should rarely, if ever, need to use the paper-based FFQ.
      i. Enter the patient's user name – this is usually the participant's Medical Record Number (MRN) and possibly a visit number.
      ii. Enter password: sjlife
      iii. Enter Group ID:
         a) 245 (For participants 18 and older)
         b) 812 (For participants less than 18)

         NOTE: The patient's username and group ID can be found here Z:\SJShare\SJCOMMON\ECC\CCSS\FFQ Appointments.

   C. If you have problems with your log-in or accessing the internet:
      i. Call the help desk at x2000.
      ii. If the computer will not allow the questionnaire and the help desk cannot fix the problem, then there are paper copies located in the 5th floor storage room and the 4th floor Call Center file cabinet A.
         A. Be sure to choose the correct version.
            a. Adult Version: English or Spanish
            b. Minor Version: English or Spanish

      NOTE: If you are using paper, then please remind the participant to answer *all* questions on the form.
   D. When applicable, read the questions to the patient and type/select their answers when necessary.
   E. Tell the patient that they will receive their results in the mail with all of their St. Jude Life results, and thus, they do not need to print the questionnaire results.
   F. Tell the patient when s/he is finished, s/he should go to the lobby (s/he can check in with the ACT desk if he has any problems or questions)

G. ***NOTE:*** If you do not stay with the participant, then let them know s/he can call you if s/he has questions about the survey. Give your name and phone number to the participant.

6. **Finishing up**
   A. Unless you have another interview or task that presents a conflict, then you need to check on the participant to see if s/he has finished (has moved on the next appointment, not surfing the web on your login, etc.).
   B. Check the patient out of the appointment in MILLI when they are finished with the FFQ.
   C. If you had to complete the paper version of the questionnaire:
      i. Please verify to make sure all the questions have been answered before the patient is released and checked out.
      ii. Give the paper copy to Aaron McDonald.

Points of Contact:

Aaron McDonald x6177	Janna Lipford x7363	Jenny Lanctot x5916	TTU Nurses x3658	Shavon Dale x7521

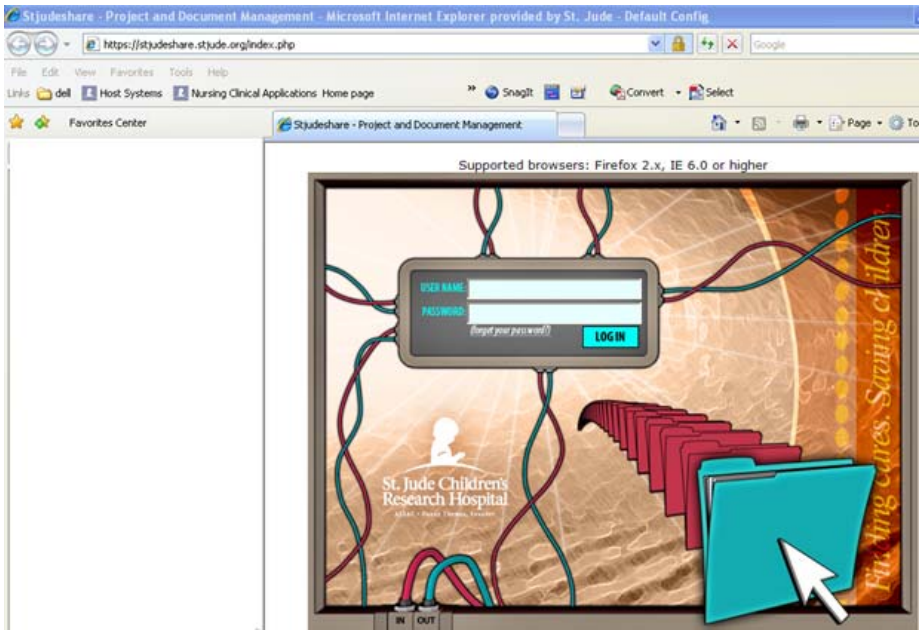
Revision Record Printed 8/06/2015 11:45 AM

(163) Current Filename:		St Jude Life Food Frequency Questionnaires ver 4_8.docx	
Revision No.	Date	Responsible Author	Change Description
4.1	9/10/9	Nina Tinner	Initial Development
4.2	9/20/11	J. Bates	Contact name changes; reference to MILLI appointment SOP
4.3	10/13/11	Nina Tinner	Paper Version Instructions if required
4.4	3/4/13	J. Lipford, A. McDonald	Update points of contact
4.5	3/9/15	J. Lipford, A. McDonald	Update points of contact
4.6	8/6/15	J. Lipford	Content Revision
4.7	5/23/16	L. Bonner, J. Lipford, J. Ford	Added process (creating/maintaining weekly FFQ spreadsheet)
4.8	9/22/2016	J. Lipford	Edit procedure (reserving a room for FFQ)
4.9	8/31/2017	J. Lipford	Edit procedure (update group ID/questionnaire version for minor participants)

StJude Share

Background

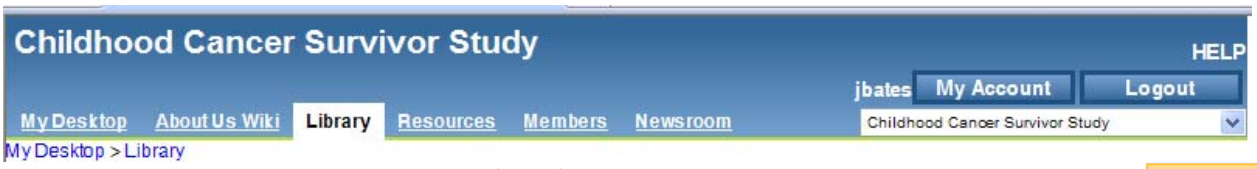
https://stjudeshare.stjude.org/index.php is the link to the St. Jude share site. This is where certain types of information are posted to share with the LTFU Coordinating Center, USC, and various collaborating institutions. Access to the site is through username/password access. Usernames and passwords are generated by the LTFU center in Memphis.



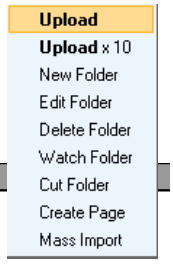
Procedure

To UPLOAD a file to the share site:

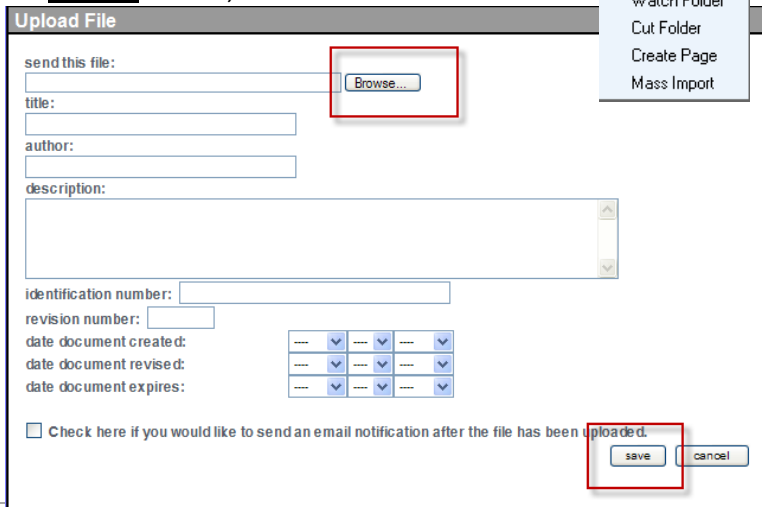
1. Log in to the share site



2. On the Library tab, see a list of the folders to which you have access.
3. Determine WHICH folder you want to upload the file to.
4. Right-click on the folder. From the pop-up menu, select **Upload**



5. In the Upload File dialog box, click the **Browse** button, then locate and click on the name of the file in your computer's file directory system.
6. This fills in the name (and path) to the file.
7. Then click the **Save** button.
8. Exit (**Logout**)



To DOWNLOAD a file from the share site:

1. Log in
2. Locate the file
3. Right-click on the file name
4. Click **Download**
5. In the File Download dialog box, select **Save**
6. In the dialog box that ensues, indicate where (on your computer) you want the file saved.
7. **Logout**

Revision Record

Printed 7/9/2012 2:22 PM

Current Filename:		StJude Share-upload-download for external users ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	12/6/10	J.Bates	Initial Development

Subsequent Neoplasm (SN) Facility Calls

Background

The CCSS subsequent neoplasm (SN) project tracks cancers and tumors that develop in CCSS participants. If a CCSS participant reports a new cancer or tumor, the study may pursue medical records from the doctor or facility where the condition was diagnosed and/or treated to confirm the report.

Survey Interviewers (SIs) call the facilities in the following situations:

1. We do not have enough doctor or facility contact information to request the records.
2. A request for records has been sent, but we have not received the records.
3. A request for records has been sent, and records were received, but the received records are incomplete or otherwise inadequate.
4. The facility may have other special conditions that need to be met before records are released.
5. The Project Manager has specific questions to ask the facility.

These calls are made for both the Original and Expansion Cohort cases and siblings.

This procedure describes how to approach, make, and document these calls to the doctor's office or medical facility. For guidance on making SN project calls to *participants*, please see the SOP titled **Subsequent Neoplasm (SN) Participant Calls**.

Tools Needed:

1. CCSS LTFU Participants Database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
2. SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
3. CCSS SI Assignments database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
4. **LTFU Participant Database Data Entry** SOP, found in the CCSS SOP Library database at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
5. **Subsequent Neoplasm (SN) Participant Calls** SOP, found in the CCSS SOP Library database at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
6. **SENDING A FAX for SN Project mmyydd**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Faxes*
7. **New Facility Contact Information Verification Quick Sheet**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\SMN*
8. Copies of the pathology report request faxed to the facility, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Faxes\SMN Pathology Requests*
9. Online search engine, such as Google

Before The Call:

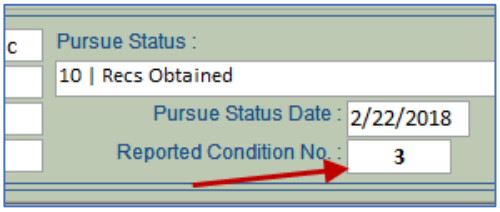
1. Open the SI Assignments database and click the button titled **SNT Case Facility Call Assignments** or **SNT Sibling Facility Call Assignments**, then enter your **SI ID** number to **view the list assigned to you**.

> NOTE: These buttons will display all participants for a given facility together, allowing the SI to address all outstanding pathology requests to the given facility in a single call. To see the list of assignments sorted by the date of the last call instead, use the buttons labeled **SNT Case Facility Call Assignments DLC** or **SNT Sibling Facility Call Assignments DLC**. "DLC" stands for Date Last Call.

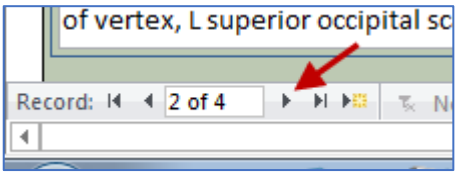
2. **Select a participant to be called**, and consider the main details of the call:
   A. The **ParticipantID** number, **First Name** and **Last Name**
   B. **Condition #** = Indicates which condition requires a call (when the participant has more than one SN…e.g., multiple skin cancers, etc.)
   C. **Facility Name** = The name of the facility to be called - This sometimes helps determine in which time zone the facility is located.
   D. **Date Last Fax** = The most recent date on which a request was faxed to this facility
   E. **Date Last Call** = The most recent date on which a call was made for this participant, regardless of the purpose
   F. **Last Call Project** = The most recent project for which a call was made to/for this participant

3. **Build the call profile from the LTFU database**:
   A. Locate the participant by name or CCSSID number, and open the participant's record.
   B. Review any available information from previous calls to the designated facility by clicking the **Review Contact Log** or **Contact Log History** button.

4. **Continue building the call profile from the SNT database**:
   (Remember the participant may have more than one reported condition, and not all reported conditions are pursued. Additionally, there may be multiple facilities being pursued for a single condition.)
   A. **Locate the condition** in question:
   The **Reported Condition No.** is in the upper right-hand side of the record under the **Pursue Status** and **Pursue Status Date** boxes.

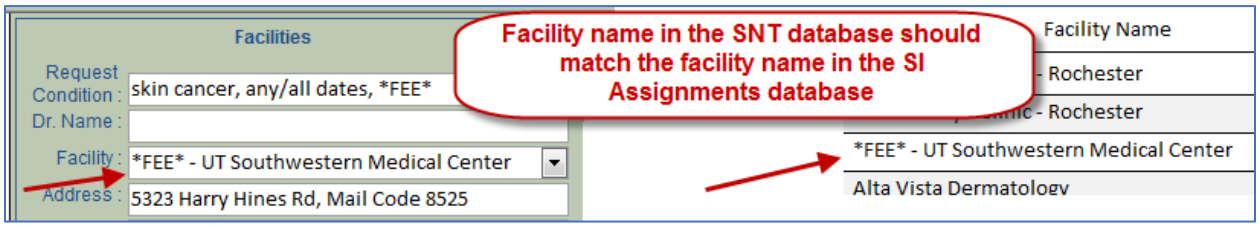


There are forward and back arrows at the very bottom left of the condition record window to navigate from one *condition record* to another for the participant displayed.

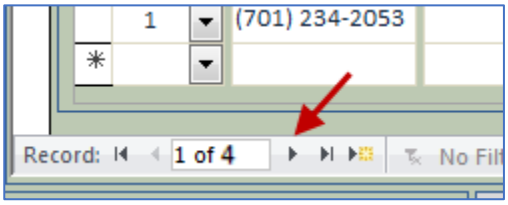


i. The condition should have a **Purse Status** of 4 – Pursue.
ii. Review the **Condition Notes** field along the far left side of the record.

B. **Locate the facility** to be called and determine the purpose of the call:
i. The facility name in the SNT database should match the SI Assignment record.



If the first facility visible is not correct, use the arrows at the bottom of the facility record to navigate between *facility records* for the displayed condition.



ii. Check the **Request Status** field of the designated facility. The status should either be 1-Need Info From Facility or 2-Follow-Up Needed With Facility.
   a. If we **need information from the facility** (The **Request Status** field will be populated with 1-Need Info From Facility.):
      1) Note the information to obtain. There will be a dated note in the **Facility Notes** box stating the specific need. (e.g., *10/6/2017: Please contact the facility for the fax number for requesting medical records.*)
      2) In general, there will be a phone number listed under the facility name and address fields. If there is not, use an online search engine (e.g. Google) for a possible phone number.
   b. If we need to **follow-up with the facility** (The **Request Status** field will be populated with 2-Follow-Up Needed With Facility.), note the follow-up that is needed. There will be a dated note in the **Facility Notes** box for direction. (e.g., *11/15/2017: Faxed request for medical records*. or *4/19/2016: Please contact the facility to see if another department might have the 1/25/16 path report.*)

iii. Review the **Facility Notes** in the center of the Facility record.
iv. Check the **Rank** of the phone numbers listed (if more than one).
v. Check the **Request Date** and **Request Type** fields to the right of the **Facility Notes** box. The most recent fax will appear at the top.

5. It may be necessary and/or helpful to **review the actual faxed request**. See the *Tools Needed* section of this SOP for the network location of the requests. Identify the request by **CCSSID** number, facility name abbreviation, and date of request – all documented in the file name.
   A. Note the name of the facility on the request.
   B. Note the wording of the request:
      i. What is the **name of the participant** on the request? – If a participant has married or divorced or changed their name for any reason, the facility may have records under a different name.
      ii. What is the **diagnosis (dx) name** on the request? If we are requesting records for breast cancer and some other diagnoses (e.g. some brain tumors), then we request imaging reports, office notes, etc., in addition to pathology reports.
      iii. What is the **date range of records** we are requesting? Sometimes our reported dates of service are incorrect and the facility has the desired records under different dates. Be prepared to ask questions.
      iv. Did we **include a signed LTFU HIPAA authorization and/or a signed Facility specific authorization**? If the participant is deceased, we may have sent the request without a signed authorization.

Make The Call:

1. State your name, state that you are calling from St. Jude Children's Research Hospital, and state the purpose of the call (e.g., the status of a records request or questions about records we received). It may be necessary to go through a receptionist or hospital operator and request to be transferred to the medical records department.
2. Once the most appropriate staff person is reached, give the details of your request [e.g., verify the fax number(s) for sending a medical records request, ask if the facility received our request, or ask other specific questions outlined by the project manager (PM)]. Be prepared to give the participant's name and date of birth (DOB).
3. If you are unable to reach the right person, gather as much information about what and when is the best way to reach that person, and follow-up at the designated time/day.
4. If a resend of the request is needed, review contact information and gather details about any necessary revisions to the request.
5. Notate all the information the representative provides.
6. Thank the representative for their assistance.

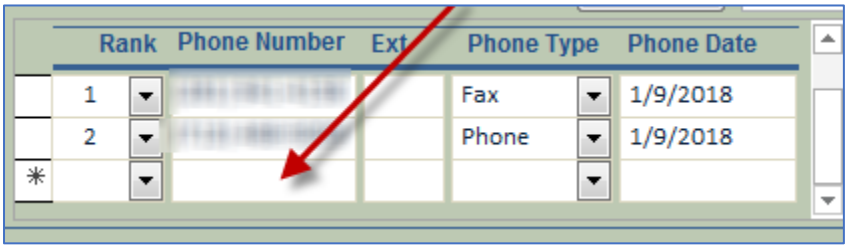
After the Call:

1. **Record the call in the CCSS LTFU Participants database** using the SOP titled **LTFU Participant Database Data Entry**. Use the following guidelines, which are specific to the SN project:
    A. **Contacting** – 11-Facility
    B. **Name** – Type name of the facility as listed in the SNT database
    C. **Project** – 7-SMN
    D. **Contact Reason** – 6-Path Report (for all types of records requests)
    E. Outcome: The most common SNT facility call outcomes are: 5 – Resend, 9 – Will return by mail/online and 10 – Other
    F. **Notes** – Document a clear, concise, and detailed note of the call, its outcome, and the information gathered.

2. **Record the call in the SNT database**.
    A. **Facility Notes** field (appropriate facility record on the appropriate condition record) – Type a concise, clear, and detailed dated note documenting the call, information gathered, and the outcome. End the note with SI ID.
    B. If there are items in the note that are also applicable to the pursuit at the condition level, copy and paste the note into the **Condition Notes** field as well, making any appropriate edits (e.g. removing data that is not applicable at the condition level).

    C. Document other important outcomes in the SNT database:
        i. SI obtains a **new or direct phone or fax number** for the facility's medical records department that is not currently listed in the facility's phone number list:
            a. ***NOTE: This will update the facility record for every participant who has this facility linked to their condition record now or in the future.*** These changes should only be made if the new number is applicable to all requests to this facility for this participant and any other requests or participants in the future.
            b. Locate the appropriate facility record on the participant's condition.
            c. Confirm the phone/fax number is not already listed in the record.
            d. Under the facility's address fields, on the first blank phone number line:

1) **Rank** – Populate with the appropriate rank. If the new number is the first number that should be called/faxed to in all future contacts with the facility for all participants, that



rank should be "1."

2) **Phone Number** – Populate with the new phone number.
3) **Ext** – Populate with the appropriate extension number for the facility's medical records team, if applicable.
4) **Phone Type** – Choose the appropriate phone type from the drop-down menu.
5) **Phone Date** – Enter the date the telephone number was most recently confirmed with the facility as accurate.

Note that each phone type has separate ranking. The best "phone" number should be ranked 1, and the best "fax" number should also be ranked 1.

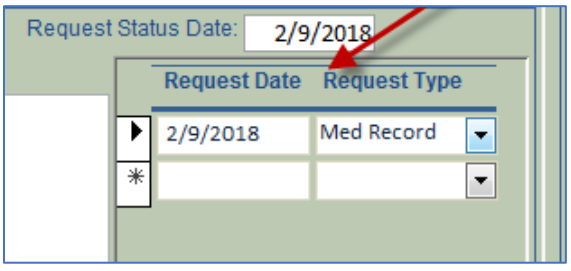
e. It may be necessary to change the **Rank** of other existing numbers. Two numbers with the same phone type (phone vs fax) should not have the same rank.

ii. The facility **asked for a resend of the request and only accepts MAILED requests** (resend will be completed by the PM):
   a. Ensure the fax number with rank "1" is 000-000-0000. This alerts the PM that requests to this facility must be MAILED.
   b. **Resend Request –** Populate with 1-Med Rec Request.
   c. **Resend Request Date –** Populate with the current date.
   d. **Request Status –** Populate with 4-Project Mgr Action Required.
   e. **Request Status Date** – Populate with the current date.
   f. **Facility Notes** – Ensure the call notes clearly document the resend request is needed via mail as well as the changes (to and from) to the Facilities group's fields.
   g. If the request is time-sensitive OR has special considerations, send an email to the PM.

iii. SI determined during the call that a request for the same condition **needs to be sent to a new facility that IS listed in the database facility list**:

NOTE: Never change the Facility name and address fields on an existing record to a new or different facility.

a. Click the Facility record arrows at the bottom of the Facilities group to create a new/blank facility record for the condition.
b. **Facility Notes** (in the newly created facility record's Facilities group) – Make a dated with SI ID note describing how the new facility was identified. *Example: 2/26/2018: Facility identified by medical records representative at MD Anderson (separate facility). [81]*
c. **Request Condition** (in the newly created facility record's Facilities group) – Enter the same condition name used for the previous facilities for this condition.
d. **Dr. Name** (in the newly created facility record's Facilities group) – If known, free-type the provider's name here.
e. **Facility** – Locate the facility in the database using the drop-down arrow or by clicking the **Facilities** button and using the search feature. Select the record to auto-populate the fields. (It may be necessary to scroll forward and back among facility records for the phone and fax numbers to display.)
f. Fax the request using the instructions outlined in the document **SENDING A FAX for SN Project mmyydd**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Faxes*.
    1) Document the fax in the CCSS LTFU Participants database using the directives from the SOP titled **LTFU Participant Database Data Entry**.
    2) **Facility Notes** (in the newly created facility record's Facilities group) – Document the faxed request in your dated note.
    3) **Request Date** (in the newly created facility record's Facilities group) – Populate with the current date.



    4) **Request Type** (in the newly created facility record's Facilities group) – Populate with Med Record.

5) **Request Status** (in the newly created facility record's Facilities group) – Populate with 2-Follow-Up Needed with Facility.

6) **Request Status Date** (in the newly created facility record's Facilities group) – Populate with current date.

iv. SI determined during the call that a request for the same condition **needs to be sent to a new facility that IS NOT listed in the database facility list**:

a. Click the Facility record arrows at the bottom of the Facilities group to create a new/blank facility record for the condition.

b. **Facility Notes** (in the newly created facility record's Facilities group) – Make a dated note with SI ID documenting, (1) how the new facility was identified, (2) the confirmed contact information for medical record requests, (3) that the information was confirmed by phone as accurate for the facility's medical record requests, (4) that the facility is not found in the database, and (5) that an email was sent to the PM to add it. *Example: 2/26/2018: Facility X identified by the medical records clerk at Dr. Smith's ofc (separate facility). Googled Facility X and found address, 123 Fourth Street, Anytown, TN 38123, phone, 901-123-4500, fax, 901-123-4511. Called 901-123-4500, rep at Facility X verified information, and provided medical records direct phone, 901-123-4567, and fax, 901-123-4578. Facility X not found in the database. Emailed PM. [81]*

c. **Request Condition** (in the newly created facility record's Facilities group) – Enter the same condition name used for the previous facilities on this condition.

d. **Dr. Name** (in the newly created facility record's Facilities group) – If known, free-type the provider's name here.

e. **Request Status** (in the newly created facility record's Facilities group) – Populate with 4-Project Mgr Action Required.

f. **Request Status Date** (in the newly created facility record's Facilities group) – Populate with the current date.

g. **Resend Request** NOTE: If no request has ever been sent to the facility, it is not necessary to request a resend to generate the initial request. Resends should only be requested as follow-up to a previous request to the same facility.

h. Use the **New Facility Contact Information Verification Quick Sheet** for documenting the information obtained and for communicating with the PM.

v. SI's professional opinion is that **all possibility of obtaining the needed records from the facility in question is exhausted** (e.g. facility reports they destroyed the needed records):
   a. **Request Status** – Update with 4-Project Mgr Action Required.
   b. **Request Status Date** – Update with the current date.
   c. **Facility Notes** – Ensure documentation with the dated note clearly indicates the SI's opinion and how s/he came to this opinion and the changes (to and from) to the Facilities group's fields.

vi. SI learns the **facility has special or unique requirements for releasing records** (e.g. fees, verbal authorization from the participant, etc.):
   a. **Request Status** – Update with 4-Project Mgr Action Required.
   b. **Request Status Date** – Update with the current date.
   c. **Facility Notes** – Ensure documentation with the dated note clearly indicates the requirements for the PM's evaluation and the changes (from and to) to the Facilities group's fields.

vii. Facility advised the **LTFU HIPAA is not acceptable only because of the signature date** (i.e., a new LTFU HIPAA is required):
   a. **Need New MR** – Populate with 2-LTFU HIPAA.
   b. **Need MR Date** – Populate with the current date.
   c. **Request Status** – Populate with 4-Project Mgr Action Required.
   d. **Request Status Date** – Populate with the current date.
   e. **Facility Notes** – Ensure documentation with the dated note clearly indicates the rejection of the LTFU HIPAA, the reason for the rejection, and the field changes to the Facilities group's fields (from and to).

viii. Facility advises the LTFU HIPAA is not acceptable and **requires their facility-specific medical release form**:
   a. **Need New MR** – Populate with 1-Facility MR.
   b. **Need MR Date** – Populate with the current date.
   c. **Request Status** – Populate with 4-Project Mgr Action Required.
   d. **Request Status Date** – Populate with the current date.
   e. **Facility Notes –** Ensure documentation with the dated note clearly indicates the rejection of the LTFU HIPAA, the reason for the rejection, and the field changes to the facility group's fields (from and to).

3. If the facility asked for a resend of the request, and the facility accepts requests via fax, the SI will re-**fax the request** using the instructions outlined in the document **SENDING A FAX for SN Project mmyydd**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Faxes*.

A. **Record the fax in the LTFU Participant database** using the directives from the SOP titled **LTFU Participant Database Data Entry**. Use the following guidelines, which are specific to the SN project:
   i. **Contacting –** 11-Facility
   ii. **Name** – Type the name of the facility as listed in the SNT database
   iii. **Project** – 7-SMN
   iv. **Contact Reason –** 6-Path Report
   v. **Outcome:** 9-Will return by mail/online or 10-Other
   vi. **Notes** – Document that the request was refaxed and indicate if directed changes were made. (These directives should either be specifically documented in the original call's **Notes** field or here.)

B. **Record the fax in the SNT database**:
   i. **Facility Notes** field (appropriate facility record on the appropriate condition record) – Enter a dated note with SI ID documenting the fax. This can be included in the call notes.
   ii. **Request Date** (appropriate facility record on the appropriate condition record) – Enter the date of the faxed request.
   iii. **Request Type** (appropriate facility record on the appropriate condition record) – Choose Med Rec from the drop-down menu.
   iv. When the facility requests the resend to be sent to a temporarily better or one-time fax number:
      a. **Facilities Notes** – Ensure the dated note documents the fax number used, and explain that the number is not valid for every participant or request linked to this facility. Explain why this number was used for this participant.
      b. Do NOT add the fax number to the phone fields linked to the facility. Doing so would update every participant/condition linked to the facility.

Please contact the PM for all questions regarding unusual circumstances not addressed within this SOP.

Revision Record

Printed 3/16/2018 8:44 AM

Current Filename:		Subsequent Neoplasm (SN) Facility Calls ver2_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/11/2015	D. Rinehart, B. Lewis, P. Davis, N. Marble, R. Massey	Initial Development
2.0	3/5/18	B. Lewis, D. Rinehart, A. Cobble, R. Massey	Update SOP title from "SMN Pathology Report – Treating Institution Calls", SOP overhaul for new SNT database. Content revision.

Subsequent Neoplasm (SN) Participant Calls

Background

If a CCSS participant (case or sibling) reports a subsequent neoplasm (SN) after their original childhood diagnosis, then the CCSS may pursue medical records related to this SN. Facilities cannot release this information without a signed consent/release of information form from the participant, their legally authorized representative (LAR), guardian, or executor of estate. Survey Interviewers call the participant in the following two situations:

1. We do not have a necessary signed LTFU HIPAA or institution-specific medical release form/HIPAA required by the institution where they were treated and/or
2. The participant did not provide enough information about the SN for us to pursue the medical records.

These calls include participants from both the original and expansion cohorts. This procedure describes how the calls requesting a medical release form (LTFU or institution-specific HIPAA) and/or additional SN information are to be made and documented.

Tools Needed:

1. CCSS LTFU Participant database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
2. SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
3. CCSS SI Assignments database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
4. **SMN Script - MR follow up or Request for more Info.docx**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\SMN*
5. **Phone Message Guidance_Rev 5-30-2014.docx**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\Calling Tools*
6. **Expired Participant Information Sheet**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\Calling Tools*
7. **LTFU Participant Database Data Entry** SOP, found in the CCSS SOP Library, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx
8. **Script – Email MR to Pt** – located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Procedures\Email LTFU HIPAA to Pt*

9. **CCSS HIPAA Amend 20_0 IRB-Appr 3-25-14**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\SMN and Blood and Tissue\Procedures\Email LTFU HIPAA to Pt*
10. Access to an online search function, such as Google

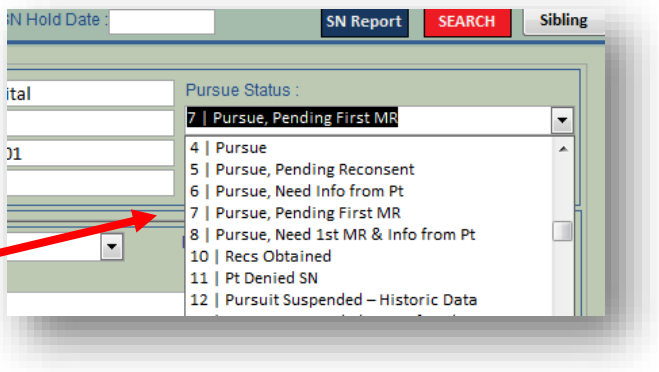
Before The Call:

1. Open the **SI Assignments database** and click the button titled **SNT Case Call Assignments** or **SNT Sibling Call Assignments**, then enter your SI ID number to view the list assigned to you. Starting at the top of the list, select the participant to be called. Consider the need(s) of the call:
    A. Need Info = We need additional information related to their reported condition.
    B. Need HIPAA = We need either an initial signed LTFU HIPAA or an updated LTFU HIPAA.
    C. Need Inst HIPAA = We need a signed Institutional HIPAA as required by that institution.
    D. Needs Reconsent = The participant needs to be reconsented to the CCSS.
    E. You will also need to consider the Pt TZ (Time Zone of the participant), the date of the last call made to them and if they are in Tracing.

2. Build the call profile from the **LTFU Participant database**:
    A. Locate the participant to be called by name or CCSSID number, and open their record.
    B. Check the **Care of:** field – Are you calling for the participant, an LAR, family member or guardian?
    C. Review the Participant tab's **Notes** for any pertinent information.
    D. Check the **Review Contact Log** for the number of times the participant has been called recently, and determine if there is any additional reason why we may be calling this participant.
    E. For participants needing reconsent, review the Age of Majority group on the HIPAA-Participation History tab.

3. Continue building the call profile from the **SNT database**:
    (It is important to remember that the participant may have more than one reported condition and not all reported conditions are pursued. Additionally, there may be multiple facilities where a participant was treated for a single condition.)
    A. Locate the participant to be called and open their record.

B. If we need an **LTFU HIPAA**:



i. Check the **Pursue Status** and the **Purse Status Date** fields (upper far right) for *each condition*. Open/active conditions should indicate a status of 4, 5, 6, 7 or 8.

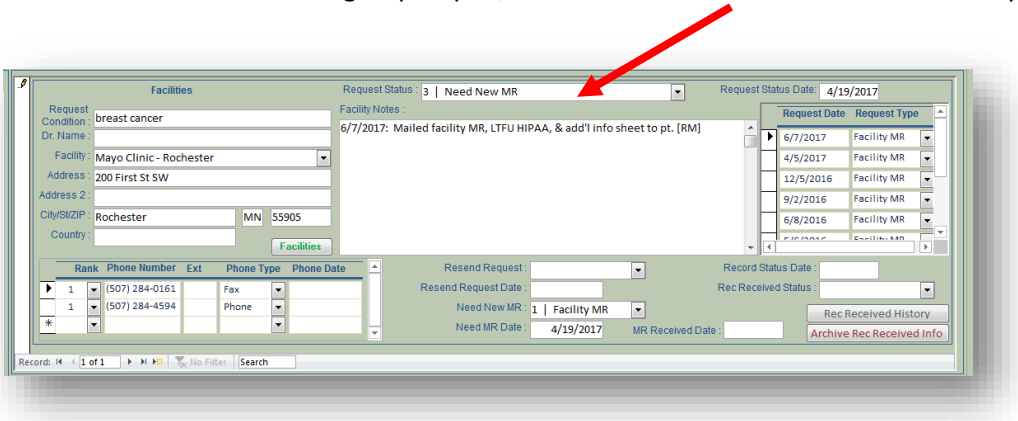
ii. Check the LTFU HIPAA Pursuit group for the date of the last sent HIPAA (lower left of screen). NOTE that this data is participant-specific, so it will have an identical display in every condition record for a given participant.

iii. Review the **Condition Notes**.

C. If we need an **Institutional HIPAA**:

i. Check the **Pursue Status** and **Purse Status Date** fields (upper far right) for *each condition*. Open/active conditions should have a status of "4-Pursue."

ii. Check the Facilities group. Open/active facilities for which we need a facility



medical release (MR) form should have a **Request Status** of "3 – Need New MR"; the **Facility Notes** field should have a dated note that a facility MR was sent to the participant; the **Need New MR** field should display "1 – Facility MR" with a **Need MR Date**; and the **Request Date** and **Request Type** fields should indicate the dates a facility MR was mailed for the current facility.

iii. Do this for each facility in each open condition.

D. If we **Need Info** from the participant:

i. Identify the conditions for which information is needed. The **Pursue Status** should be either "6 – Pursue, Need Info from Pt" or "8 – Pursue, Need 1st MR & Info from Pt" for these conditions. (It is possible we need information on more than one reported condition.)
ii. Check the **Condition Notes** box (far left side of window) for each condition that has a Pursue Status of "6 – Pursue, Need Info from Pt" or "8 – Pursue, Need 1st MR & Info from Pt" to determine exactly what information is needed.
iii. You may also need to check the **Facility Notes** box if a facility has already been pursued and we have encountered some issue (e.g. dates don't match, location of condition doesn't match, facility reports they have no records on this patient).

E. If we need to reconsent the participant, the open conditions should have a **Pursue Status** of "5-Pursue, Pending Reconsent." Review the **Condition Notes** prior to calling the participant.

Make The Call:

1. Call the participant or appropriate representative using all available numbers and following these tools and guidance:
   A. The script document titled **SMN Script - MR follow up or Request for more Info.docx** and
   B. The principles found in the document **Phone Message Guidance_Rev 5-30-2014.docx**
   C. Remember: It is not OK to ask a parent or other family member if, where, when or by whom a person was treated for a specific condition (Protected Health Information) unless we have permission (documented is best!) from the participant to do so. If there is an LAR situation, we may ask this information of the LAR.
2. For **Need MR calls**, when you cannot reach the participant, you can call associates to verify participant contact information and the best time to reach the participant.
3. For **Need Info from Pt calls**,
   A. A participant often has trouble remembering the exact details of where, when or by whom they were treated. In this situation:
      i. Try to get as much information as they can give. (For example, was the doctor a male or female? Did they have their own practice or was it part of a group? etc.)
      ii. Ask if we have permission to ask a spouse, parent, or other family member.
   B. When new provider and/or facility information is obtained, it may be helpful to do a quick online search while the participant is on the phone to ensure the provider/facility can be located and verified.
   C. Note all the information they provide. Thank them for their participation with us.
4. For **Need Reconsent calls**, if the participant reconsents to the study, advise that they will soon receive an LTFU HIPAA in the mail to sign.
5. If the participant **provides information about a new SN** during the call, ask for:
   A. The name of the disease, if known (e.g. glioblastoma)

B. The body site where the disease occurred (e.g. brain)
C. The diagnosis month and year
D. Whether the disease is a new cancer/tumor or a recurrence of a prior cancer/tumor
E. The name of the doctor that diagnosed the new cancer/tumor
F. The name and address of all facilities involved in diagnosing the new cancer/tumor

6. If it is learned that the **participant is now deceased**, complete the **Expired Participant Information Sheet**.

After The Call:

1. **Record the call in the LTFU Participant Database**.
   A. Following the SOP titled **LTFU Participant Database Data Entry**, record all information provided in the participant contact log. Specifically for SN calls:
      i. **Project**: 7 – SMN
      ii. **Contact Reason**: 5 – HIPAA (for LTFU or institutional HIPAA) or 13 – Additional Info
      iii. **Outcome**: 5 – Resend, 9 – Will return by mail/online, 12 – Received (if calling for information and that information was received), or any other outcome that applies. If in doubt, use 10 – Other.
   B. Update participant or associate contact information. Use the SOP titled **LTFU Participant Database Data Entry** for guidance.
   C. Add any helpful, relevant notes in the Participant tab's **Notes** field.

2. **Record the information in the SNT database.**
   IMPORTANT:** *Whenever any of the following fields are populated and need to be updated, ALWAYS include in your notes what the field was changed FROM and what the field was changed TO. See double asterisks below.*
   A. When the call purpose was for an **LTFU HIPAA**:
      i. Participant reports they received the HIPAA and **will return it** - Make a dated note with SI ID in the **Condition Notes** field.
      ii. Participant **refuses** to sign the HIPAA.
         a. **Condition Notes** – Enter a dated note with SI ID documenting the outcome of the call.
         b. **Pursue Status** – Update from 7 or 8 to 3-Condition-Level Project Mgr Action Required. **
         c. **Pursue Status Date** – Update to the current date. **
      iii. Participant requests a **resend of the LTFU HIPAA when no facility request has been issued** (i.e. We need the participant's first signed LTFU HIPAA.):
         a. By mail:

1) **Condition Notes** – Make a dated note documenting the request and noting any changes made to the **Pursue Status** and **Pursue Status Date** fields.
2) **Request Date** in the LTFU HIPAA Pursuit group (lower right of the **Condition Notes** field) – Populate with the current date.
3) **Send Date** in the LTFU HIPAA Pursuit group (lower right of the **Condition Notes** field) – LEAVE BLANK. The Project Manager (PM) will populate this field when the request is fulfilled.
4) **Pursue Status** (top right of the condition record) – Populate with 3-Condition-Level Project Mgr Action Required. **
5) **Pursue Status Date** – Update with current date. **

b. By email – See the section of this document titled *Sending LTFU HIPAA by Email*.

iv. The participant requests a **resend of the LTFU HIPAA when an *updated* HIPAA is sought** (i.e. when we've previously requested medical records from the facility and the facility requires an updated LTFU HIPAA with a more current signature).

a. By mail:
1) **Facility Notes** – Make a dated note documenting the request and noting any changes made to the **Request Status** and **Request Status Date** fields.
2) **Request Date** in the LTFU HIPAA Pursuit group (lower right of the **Condition Notes** field) – Populate with the current date.
3) **Send Date** in the LTFU HIPAA Pursuit group (lower right of the **Condition Notes** field) – LEAVE BLANK. The PM will populate this field when the request is fulfilled.
4) **Request Status** (top center of Facilities group) – Update from 3 to 4- Project Mgr Action Required. **
5) **Request Status Date** – Update with current date. **

b. By email – See the section of this document titled *Sending LTFU HIPAA by Email*.

B. When the call purpose was for an **institutional HIPAA**:

i. Participant reports they **received the HIPAA** and will return it. – Make a dated note in **Facility Notes** with SI ID documenting such.

ii. Participant **refuses** to sign the institutional HIPAA

a. **Facility Notes** – Document the outcome of the call and all changes made to the **Request Status** and **Request Status Date** fields.
b. **Request Status** – Update from 3 to 4-Project Mgr Action Required. **
c. **Request Status Date** – Update to the current Date. **

iii. Participant requests a **resend of the Institutional HIPAA**.

a. **Facility Notes** – Make a dated note with SI ID documenting the request and any changes made to other Facilities group fields.
b. **Resend Request** (under the **Facility Notes** field) **–** Populate with 2-Facility MR. **
c. **Resend Request Date** – Populate with the current date. **
d. **Request Status** – Update to 4-Project Mgr Action Required. **
e. **Request Status Date** – Update with the current date. **

C. When the call purpose was for **additional information** (This can include verification of the reported condition, where treatment was obtained or any other details.) and the needed information was obtained:
   i. **Pursue Status** – Update from 6 or 8 to "3 – Condition-Level Project Mgr Action Required." **
   ii. **Pursue Status Date** – Update with the current date. **
   iii. **Condition Notes** – Make a dated note with SI ID documenting all information obtained and changes to the **Pursue Status** and **Pursue Status Date** fields.
   iv. If the participant provided new provider or facility information.
      a. Perform an online search to verify the facility in question.
      b. Open a new facility record in the appropriate condition.
      c. **Facility** – Use the **Facilities** button to populate this field with the name of the facility reported by the participant. NOTE: If the facility is not found in the database records, see the section of this document titled *Requesting a New Facility to Be Added in the Database*.

D. When the call purpose was for **reconsenting** the participant, if the participant refused or reconsented:
   i. **Condition Notes** – Enter a dated note with SI ID documenting the outcome of the reconsent effort and changes made to the **Pursue Status** and **Pursue Status Date** fields.
   ii. **Pursue Status** – Update from 5 to "3-Condition-Level Project Mgr Action Required." **
   iii. **Pursue Status Date** – Update to the current date. **
   iv. NOTE: Also make the appropriate changes in the LTFU Participant database.

3. If a **new SN was reported during the call**, email the PM with details about the new SN. S/he will determine if a new condition record will be opened.

Sending the LTFU HIPAA by Email

1. Use the email script titled **Script – Email MR to Pt**. The yellow-highlighted text should be updated to the appropriate values.
2. Attach the HIPAA form titled **CCSS HIPAA Amend 20_0 IRB-Appr 3-25-14**.
    A. Update the text "CCSSID" in the bottom left-hand corner with the participant's CCSSID.
    B. IMPORTANT: No other data should be pre-populated on the form.
3. Send the email to the participant's confirmed email address.
4. Document the email in the LTFU Participant database call log. See the SOP titled **LTFU Participant Database Data Entry** for guidance.
5. Document the email in the SNT database.
    A. If the LTFU HIPAA being pursued is the first signed HIPAA for the participant (i.e. we ARE NOT obtaining an updated HIPAA form to meet the requirements of a particular facility):
        i. **Request Date** in LTFU HIPAA Pursuit group – Populate with the date of the email.
        ii. **Send Date** in the LTFU HIPAA Pursuit group – Populate with the date of the email.
        iii. **Condition Notes** for all open conditions (**Pursue Status** is 3 – 8) – Enter a dated note with SI ID documenting that the LTFU HIPAA was emailed.
    B. If the LTFU HIPAA being pursued is an update to a previously-signed HIPAA (i.e. We ARE obtaining an updated HIPAA form to meet the requirements of a particular facility.):
        i. **Request Date** in the LTFU HIPAA Pursuit group – Populate with the date of the email.
        ii. **Send Date** in the LTFU HIPAA Pursuit group – Populate with the date of the email.
        iii. **Facility Notes** in the appropriate facility records (The **Need New MR** field is set to 2-LTFU HIPAA. The **Request Status** is set to 3-Need New MR.) – Enter a dated note with SI ID documenting that the LTFU HIPAA was emailed.

Requesting a New Facility to Be Added in the Database

If a facility needs to be added to the facility record but is not found in the database:

1. Call the facility.
    A. Confirm the fax number and mailing address, including practice name, to be used for requesting medical records (This may be different than the main fax number and address.) as well as the phone number to be used when following up on submitted medical record requests.
    B. If the facility has multiple locations, determine whether the above confirmed information is valid for all locations. If not, determine which locations use the confirmed information.

2. Email the PM to request that s/he add the new facility to the database.
    A. Specify in the email that the contact information was confirmed by telephone to be valid for the medical records department.
    B. Specify the CCSSID and condition number for which the data is being added.
3. In the appropriate facility record:
    A. **Request Status** – Populate with 4-Project Mgr Action Required.
    B. **Request Status Date** – Populate with the current date.
    C. **Facility Notes** – Add a dated note with SI ID documenting (1) the confirmed contact information for medical record requests, (2) that the information was confirmed by phone as accurate for the facility's medical record requests, (3) that the facility is not found in the database, and (4) that an email was sent to the PM to add it.
4. When the PM responds that the facility contact information has been added to the database, review the Facilities group in the appropriate record to ensure the facility has been added as expected. Make any other appropriate documentation according to this or other applicable SOPs.

Revision Record Printed 10/23/2017 1:17 PM

Current Filename:		Subsequent Neoplasm (SN) Participant Calls ver 1_6.docx	
Revision No.	Date	Responsible Author	Change Description
1.1	10/10/11	B. Lewis/D. Rinehart	Initial Development
1.2	7/10/2012	Procedure Team	Formatting, file references updated
1.3	7/11/2012	L. Harrison	Combining steps in MR and SMN info calls
1.4	7/12/12	D. Rinehart	Remove scripts
1.5	10/14/2013	B. Lewis	Content Update: use of SMN form in ET db, use of spreadsheet, updating db
1.6	10/23/17	B. Lewis; C. Briggs; A. Cobble; R. Daniels; D. Rinehart; R. Massey	Clarify title, rework procedures for new SNT database, formatting

Subsequent Neoplasm Pathology Report Reviews

Background

The subsequent neoplasm (SN) project seeks to track SNs with which Long-Term Follow-Up (LTFU) Study participants are diagnosed. When a participant or his/her proxy reports a subsequent cancer, leukemia, tumor, or similar illness during their participation, study staff will pursue a pathology report and/or other medical records from the diagnosing entity to verify the condition.

After a number of medical records are received, the reports are batched and sent to the CCSS pathologist for pathology review. The pathologist's adjudication and notes are returned to the Coordinating Center, documented, and then sent to the CCSS final reviewer for a final decision on whether to accept the condition into the CCSS SN data set. Conditions determined to be true SNs at the final review are documented as such in the SN project tracking database.

This procedure outlines the process for submitting reported conditions and the corresponding medical records for pathology and final reviews. For information about pursuing pathology reports, which precedes this procedure, see the SOP titled **Pursuing Subsequent Neoplasm Pathology Records**.

Procedure

Sending Reports for Pathology Review

After medical records are received and documented, create and send a batch for the CCSS pathologist to review:

1. Open the SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
2. Minimize the Search form and open the Navigation pane.
3. Run the query **qry_RecsReceived_SendtoPathMD_Cases_RM** (for cases) or **qry_RecsReceived_SendtoPathMD_SIBs_RM** (for siblings).
    A. Note the number of conditions for each source. In general, a single batch should include approximately 15 – 25 conditions with about 500 – 800 pages of records (more pages would necessitate fewer conditions, fewer pages would allow for more).
    B. Separate batches should be created for each source (e.g. Expansion Baseline, FU5, FU6, FU7, etc.). Note that conditions for Original Baseline – FU4 can be considered the same source for batching purposes and combined into a single batch. Original and expanded cohorts can be combined in a single source batch, but cases should be in separate batches from siblings.
        i. Source code 84-Other-BL should be combined with source code 41-Expansion Baseline.
        ii. Source codes 75-FU5 Online Partial and 85-Other-FU5 should be combined with source code 5-FU5.
        iii. Source code 86-Other-FU6 should be combined with source code 6-FU6.
        iv. Source code 87-Other-FU6 should be combined with source code 7-FU7.
        v. Source code 80-Other should be updated, where possible, to code 84-Other-BL, 85-Other-FU5, 86-Other-FU6, or 87-Other-FU7 based on the participant's stage of participation when the condition was reported. Seek guidance, as needed.

vi. For source code 42-Death Certificate and 80-Other (when this code cannot be updated to 84, 85 or 86), include the condition in the next Original Baseline – FU4 batch.

C. Query results can be exported to:
   i. FU7 Batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Pathologist Review*, append the date to the file name
   ii. FU6 Batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Pathologist Review*, append the date to the file name
   iii. FU5 Batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\For Pathologist Review*, append the date to the file name
   iv. Original Baseline – FU4 Batches – *Z:\ResearchHome\Departments\Epidemiology CancerControl\common\CCSS\SMN\SN, FU1 - FU4\For Pathologist Review*, append the date to the file name
   v. Expansion Baseline Batches – *Z:\ResearchHome\Departments\EpidemiologyCancer Control\common\CCSS\SMN\SN, Expansion Baseline\For Pathologist Review*, append the date to the file name

4. **Gather the medical record packets** for each CCSSID in the query and **organize them in CCSSID order**.
5. **Create a cover report** for each packet of medical records to be included in the batch:
   A. Restore the Search form of the SNT database and locate the participant in question.
   B. Click the **SN Report** button.
   C. Print the report by right-clicking on the report preview then left-clicking on the Print option.

6. Add the cover report to each packet of medical records.
7. **Add the self-report** to each packet that includes a condition reported on a paper survey or via email.
8. **Create a batch cover page**.
   A. Use the Excel template titled **!Path Review Cover Page, TEMPLATE** (for cases) or **!Path Review Cover Page, Survey-SIB TEMPLATE** (for siblings):
      i. Expansion Baseline batches – Found at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN\SN Expansion, Baseline\For Pathologist Review*
      ii. Original Baseline – FU4 batches – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU1 - FU4\For Pathologist Review*
      iii. FU5 batches – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Pathologist Review*
      iv. FU6 batches – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Pathologist Review*
      v. FU7 batches – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Pathologist Review*
   B. Save the cover page with a new title that includes the batch number.
      i. Expansion Baseline batches – Save as **Path Review Cover Page, Exp Batch ##** (for cases) or **Path Review Cover Page, Exp-SIB Batch ##** (for siblings) at *Z:\Research Home\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, Expansion*

Baseline\For Pathologist Review where the batch number is incremented by one sequentially. For example, if the last expansion batch sent to the pathologist was batch 38, the new batch will be 39.

ii. Original Baseline – FU4 batches – Save as **Path Review Cover Page, OrigBaseline-FU4 Batch ###** (for cases) or **Path Review Cover Page, OrigBaseline-FU4-SIB Batch ###** (for siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN\SN, FU1 - FU4\For Pathologist Review* where the batch number is incremented by one sequentially. For example, if the last OrigBaseline-FU4 batch sent to the pathologist was batch 106, the new batch will be 107.

iii. FU5 batches – Save as **Path Review Cover Page, FU5 Batch ##** (for cases) or **Path Review Cover Page, FU5-SIB Batch ##** (for siblings) at *Z:\ResearchHome \Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\For Pathologist Review* where the batch number is incremented by one sequentially. For example, if the last FU5 batch sent to the pathologist was batch 85, the new batch will be 86.

iv. FU6 batches – Save as **Path Review Cover Page, FU6 Batch ##** (for cases) or **Path Review Cover Page, FU6-SIB Batch ##** (for siblings) at *Z:\ResearchHome \Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Pathologist Review* where the batch number is incremented by one sequentially. For example, if the last FU6 batch sent to the pathologist was batch 56, the new batch will be 57.

v. FU7 batches – Save as **Path Review Cover Page, FU7 Batch ##** (for cases) or **Path Review Cover Page, FU7-SIB Batch ##** (for siblings) at *Z:\ResearchHome \Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Pathologist Review* where the batch number is incremented by one sequentially. For example, if the last FU7 batch sent to the pathologist was batch 15, the new batch will be 16.

C. Using the query results, above, copy and paste each CCSSID in the batch along with the reported condition to be reviewed by the pathologist, the reported body site, the participant's original diagnosis (cases only), and the participant's original diagnosis date (cases only) into the cover page.

D. Update the cover page to include the batch date, batch type and number (e.g. Baseline Batch 45), and number of conditions in the header.

E. Sort the rows by CCSSID if not already sorted.

F. Correct the date formats, if necessary.

G. Set the print area.

H. Save the revisions to the cover page.

I. Print the cover page.

9. Create an Excel **spreadsheet where the reviewing pathologist will place his/her findings**.

A. Use the template titled **!SN Pathologist Review TEMPLATE**, located at:

i. Expansion Baseline batches – *Z:\ResearchHome\Departments\EpidemiologyCancer Control\common\CCSS\SMN \SN, Expansion Baseline\For Pathologist Review*

ii. Original Baseline-FU4 batches – *Z:\ResearchHome\Departments\Epidemiology CancerControl\common\CCSS\SMN \SN, FU1 - FU4\For Pathologist Review*

iii. FU5 batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN \SN, FU5\For Pathologist Review*

iv. FU6 batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN \SN, FU6\For Pathologist Review*

v. FU7 batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Pathologist Review*

B. Save the spreadsheet with a new name.
   i. Expansion Baseline batches – Save as **SN Pathologist Review, Exp Batch ##** (cases) or **SN Pathologist Review, Exp-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common \CCSS\SMN\SN, Expansion Baseline\For Pathologist Review*.
   ii. Original Baseline-FU4 batches – Save as **SN Pathologist Review, OrigBaseline-FU4 Batch ###** (cases) or **SN Pathologist Review, OrigBaseline-FU4-SIB Batch ###** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common \CCSS\SMN\SN, FU1 - FU4\For Pathologist Review*
   iii. FU5 batches – Save as **SN Pathologist Review, FU5 Batch ##** (cases) or **SN Pathologist Review, FU5-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\For Pathologist Review*.
   iv. FU6 batches – Save as **SN Pathologist Review, FU6 Batch ##** (cases) or **SN Pathologist Review, FU6-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Pathologist Review*.
   v. FU7 batches – Save as **SN Pathologist Review, FU7 Batch ##** (cases) or **SN Pathologist Review, FU7-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Pathologist Review*.

C. For sibling batches, remove the Original CCSS Dx and Original CCSS Dx Date columns.
D. Enter (COPYING ONLY from the original query results and NOT the batch cover page, since the cover page has already been resorted):
   i. Each CCSSID along with the self-reported condition(s), self-reported sites, self-reported grid location(s), and self-reported diagnosis date(s).
   ii. For case batches, each original diagnosis and diagnosis date.
E. Sort the sheet by CCSSID if not already sorted.
F. Save the revisions to the spreadsheet.

10. **Scan all pages into a single PDF file** (batch cover page followed by body grid for FU6 and higher surveys followed by each CCSSID's cover report and medical records in CCSSID order).
    A. For expansion baseline batches, save as **Path Reports, Exp Batch ##** (cases) or **Path Reports, Exp-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, Expansion Baseline\For Pathologist Review*.
    B. For Original Baseline-FU4 batches, save as **Path Reports, OrigBase-FU4 Batch ###** (cases) or **Path Reports, OrigBase-FU4 Batch ###** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU1 - FU4\For Pathologist Review*.
    C. For FU5 batches, save as **Path Reports, FU5 Batch ##** (cases) or **Path Reports, FU5-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\For Pathologist Review*.
    D. For FU6 batches, save as **Path Reports, FU6 Batch ##** (cases) or **Path Reports, FU6-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Pathologist Review*.
    E. For FU7 batches, save as **Path Reports, FU7 Batch ##** (cases) or **Path Reports, FU7-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Pathologist Review*.

11. **Send the PDF and Excel files to the pathologist**.
    A. Drag the medical records PDF from the above scanning step (e.g. **Path Reports, FU5-SIB Batch 66**) to the Box folder titled SN Project Pathologist Reviews.
    B. Email the spreadsheet for the pathologist's findings to the CCSS pathologist team.
        i. Use encrypted email technology.
        ii. Copy the Principal Investigator, Project Director, Research Scientist, and any other applicable parties.
        iii. Subject: [Encrypt] Medical Records to Review, [Survey] Batch ## (e.g. Medical Records to Review, FU5-SIB Batch 66)
        iv. Attach the Excel spreadsheet (e.g. **SN Pathologist Review, FU5-SIB Batch 66**) where the reviewing pathologist will place his/her findings.
        v. Key in the emailed message.
        vi. Send.
12. Add the batch to the **SN Batch Tracking** Excel file located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN*.

Batches for Pathologist Review					
Batch #	Source	Number of Conditions	Date Sent	Download Date	Date Received from Pathologist
65	FU5	14	7/27/2017		
66	FU5-SIB	16	7/27/2017		

13. **Document** that the pathology report has been sent to the pathologist by populating the **Date Sent Path Review** field with the current date, updating the **Pursue Status** field from 10 to 40, and updating the **Pursue Status Date** field to be the current date.
    A. Run the applicable "send to path MD" query to confirm the results to be updated. Seek assistance, if necessary.
    B. Open the query in Design View.
    C. On the Access Ribbon's Design tab, click the Update icon to change the query from a Select query to an Update query. A new row labeled "Update To:" will replace the "Sort:" and "Show:" rows in the lower pane of the design view interface.
    D. Update the appropriate fields:
        i. DateSentPathReview from <null> to current date
        ii. PursueOutcome from 10 to 40
        iii. PursueOutcomeDate to the current date
        iv. In the Notes field, append a note for all Notes that are not null that the Pursue Status field was updated from 10 to 40 and Pursue Status Date field was updated to the current date.
    E. Click the Run icon on the Design tab of the Access Ribbon to update the database.
    F. To confirm the update was successful, click the Select icon on the Access Ribbon's Design tab to change the query back to a Select query, then click the Run icon to run the Select query. The participants in the batch should no longer appear in the query results. If *all* outstanding pathology reports were sent, the query should now return empty results.

Documenting Pathology Review Complete

When the pathology review has been completed and returned by the pathologist(s):

1. **Update the batch** in the **SN Batch Tracking** Excel file located at *Z:\SJShare\SJCOMMON\ECC\CCSS\SMN*, to indicate as such.

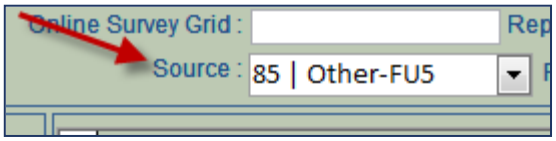
Batches for Pathologist Review

Batch #	Source	Number of Conditions	Date Sent	Download Date	Date Received from Pathologist
54	FU5	27	1/30/2017	4/12/17	4/30/17

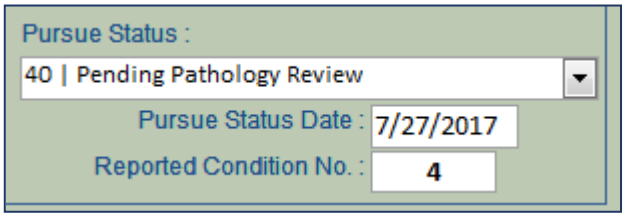
2. Move the batch cover page, comment spreadsheet, and PDF to the Sent folder.
   A. Expansion Baseline batches – *Z:\ResearchHome\Departments\Epidemiology CancerControl\common\CCSS\SMN\SN, Expansion Baseline\For Pathologist Review*
   B. Original Baseline-FU4 batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU1 - FU4\For Pathologist Review*
   C. FU5 batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\For Pathologist Review*
   D. FU6 batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Pathologist Review*
   E. FU7 batches – *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Pathologist Review*
3. **Save the pathologist's returned results** as an Excel file. Include the date the pathologist returned the results in the file name.
   A. Expansion Baseline batches – Save as **Completed SN Pathologist Review, Exp Batch ##, mmddyy** (cases) or **Completed SN Pathologist Review, Exp-SIB Batch ## mmddyy** (siblings) where mmddyy is the date the pathologist returned the results. Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, Expansion Baseline\Reviewed by Pathologist*.
   B. Original Baseline-FU4 batches – Save as **Completed SN Pathologist Review, OrigBase-FU4 Batch ###, mmddyy** (cases) or **Completed SN Pathologist Review, OrigBase-FU4-SIB Batch ###, mmddyy** (siblings) where mmddyy is the date the pathologist returned the results. Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU1 - FU4\Reviewed by Pathologist*.
   C. FU5 batches – Save as **Completed SN Pathologist Review, FU5 Batch ##, mmddyy** (cases) or **Completed SN Pathologist Review, FU5-SIB Batch ##, mmddyy** (siblings) where mmddyy is the date the pathologist returned the results. Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\Reviewed by Pathologist*.
   D. FU6 batches – Save as **Completed SN Pathologist Review, FU6 Batch ##, mmddyy** (cases) or **Completed SN Pathologist Review, FU6-SIB Batch ##, mmddyy** (siblings) where mmddyy is the date the pathologist returned the results. Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\Reviewed by Pathologist*.
   E. FU7 batches – Save as **Completed SN Pathologist Review, FU7 Batch ##, mmddyy** (cases) or **Completed SN Pathologist Review, FU7-SIB Batch ##, mmddyy** (siblings) where mmddyy is the date the pathologist returned the results. Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\Reviewed by Pathologist*.
4. Create a new worksheet titled Revised in the Excel workbook, and copy the pathologist's entire review worksheet to the new worksheet. In the new worksheet:

A. **Unprotect the comment sheet**, if applicable.
B. **Unhide** any hidden columns.
C. **Add a column titled Source** to the Excel worksheet, just after the CCSSID column.

5. For each condition in the pathologist's Excel review sheet:
   A. Locate the participant and condition record in the SNT database.
   B. Review the **Source** field in the database then add the DatStat source code to the "Revised" worksheet using the current DatStat data dictionary. This data will be used when uploading to DatStat for the final reviewer, below.



   C. **Date Returned Path Review** – Enter the date the pathologist returned the review into this database field.
   D. **Pursue Status** – Update this database field to be 41-Pending Final Review so the status will print correctly on the final reviewer's cover rpt.
   E. **Pursue Status Date** – Update this database field with the current date.



   F. **Condition Notes** – Enter a dated note in this database field describing the changes to the **Pursue Status** and **Pursue Status Date** fields. In the note, also document the pathologist's returned diagnosis date, diagnosis, and body location and any pathologist notes.
   G. If a **new condition is returned by the pathologist that was not reported by the participant**, add the condition to the SNT database.
      i. Click the New (blank) record button in the participant's record.
      ii. **Reported Condition No.** – Determine the highest existing condition number for this participant and enter the next sequential number in this field.
      iii. **Reported Condition** – Enter the disease name as recorded by the pathologist.
      iv. **Reported Body Site** – Enter the site as recorded by the pathologist
      v. **Reported Month/Year of Occurrence** – Enter the month and year of the diagnosis date provided by the pathologist.
      vi. **Source** – Enter the appropriate "other" code (e.g. 87-Other-FU7), depending on the participant's stage of participation. Seek guidance, if needed.
      vii. **Pursue Status** – Populate with 41-Pending Final Review.
      viii. **Pursue Status Date** – Populate with the current date.
      ix. **Condition Notes** – Enter a dated note, with initials, documenting that the condition was added by the pathologist. Document any pathologist notes for this condition. *Example: 10/9/2019: Condition added by pathologist during review of condition 2. He also noted, "Re-excision 8/26/19 with no residual tumor." [RM]*
      x. **Date 1st Review** – Populate with filler-date 11/11/1811.
      xi. **Date Sent Path Review** – Populate with filler-date 11/11/1811.
      xii. **Date Returned Path Review** – Enter date the condition was returned by the pathologist.

6. Save the changes to the Excel workbook containing the pathologist's reviews.

Sending Pathology Reports for Final Review

After the pathologist returns his/her findings and notes on the pathology reports and after the pathologist's adjudications are recorded, the conditions are sent for a final review.

1. **Update/create the appropriate documents** to be sent for final review of the conditions.
   A. In the Excel spreadsheet containing the pathologist's review notes:
      i. **Resave the workbook in a new location** and with a new name.
         a. Expansion Baseline batches
            1) Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN\SN, Expansion Baseline\For Final Review*.
            2) Save as **SN Final Review, Exp Batch ##** (cases) or **SN Final Review, Exp-SIB Batch ##** (siblings) where ## is the corresponding batch number.
         b. Original Baseline-FU4 batches
            1) Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN\SN, FU1 - FU4\For Final Review*.
            2) Save as **SN Final Review, OrigBase-FU4 Batch ###** (cases) or **SN Final Review OrigBase-FU4-SIB Batch ###** (siblings) where ### is the corresponding batch number.
         c. FU5 batches
            1) Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN\SN, FU5\For Final Review*.
            2) Save as **SN Final Review, FU5 Batch ##** (cases) or **SN Final Review, FU5-SIB Batch ##** (siblings) where ## is the corresponding batch number.
         d. FU6 batches
            1) Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN\SN, FU6\For Final Review*.
            2) Save as **SN Final Review, FU6 Batch ##** (cases) or **SN Final Review, FU6-SIB Batch ##** (siblings) where ## is the corresponding batch number.
         e. FU7 batches
            1) Save at *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN\SN, FU7\For Final Review*.
            2) Save as **SN Final Review, FU7 Batch ##** (cases) or **SN Final Review, FU7-SIB Batch ##** (siblings) where ## is the corresponding batch number.
      ii. In the newly saved workbook, **delete the worksheet without the Source column**.
      iii. **Ensure the worksheet is unprotected**. If it is currently protected, click the Unprotect Worksheet icon in the Changes group of the Review tab.
      iv. Ensure there are no hidden columns.
      v. **Add a column labeled "Batch" in the next blank column**. Populate this column with the batch type and final review batch number (e.g. BL-45 or FU7-12).
      vi. If any conditions are being added or removed:
         a. Make the necessary changes.
         b. Resort the rows, if needed.
      vii. Save the revision.
   B. **Create a new batch cover page**.
      i. Use the Excel template titled **!Final Review Cover Page, TEMPLATE** or **!Final Review Cover Page SIB TEMPLATE**, as appropriate.

a. Expansion Baseline batches – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, Expansion Baseline\For Final Review*.
b. Original Baseline-FU4 batches – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU1 - FU4\For Final Review*.
c. FU5 – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\For Final Review*.
d. FU6 – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Final Review*.
e. FU7 – Found at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Final Review*.

ii. Save the cover page with a new name:
a. Expansion Baseline batches – Save as **Final Review Cover Page, Exp Batch ##** (cases) or **Final Review Cover Page, Exp-SIB Batch ##** (siblings) at *Z:\Research Home\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, Expansion Baseline\For Final Review*.
b. Original Baseline-FU4 batches – Save as **Final Review Cover Page, OrigBase-FU4 Batch ###** (cases) or **Final Review Cover Page, OrigBase-FU4-SIB Batch ###** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU1 - FU4\For Final Review*.
c. FU5 batches – Save as **Final Review Cover Page, FU5 Batch ##** (cases) or **Final Review Cover Page, FU5-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\For Final Review*.
d. FU6 batches – Save as **Final Review Cover Page, FU6 Batch ##** (cases) or **Final Review Cover Page, FU6-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Final Review*.
e. FU7 batches – Save as **Final Review Cover Page, FU7 Batch ##** (cases) or **Final Review Cover Page, FU7-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Final Review*.

iii. Update the new batch cover sheet to show the final review batch date, final review batch type and number (e.g. Baseline Batch 40), and the new number of conditions in the new cover page header.
iv. Populate the cover page with the CCSSIDs, conditions, body sites, original diagnosis (cases only), and original diagnosis dates (cases only) for the batch.
v. Set the print area.
vi. Resave the updated cover page.
vii. Print the new cover page.

C. **Print new cover reports** for each medical record packet in the batch, but delay replacing the existing reports. See the section of this document titled *Sending Reports for Pathology Review* for instructions for printing cover reports.

D. Before attaching the new cover reports to each record packet (see below), **print the batch indicator** "Final Review – SURVEY – XX" in the footer. In the indicator, SURVEY = the batch type (e.g. Exp Baseline, FU7, etc.) and XX = the final review batch #. (e.g. Final Review – FU7 – 12)

E. **Replace the cover reports** on each record packet. Transfer any handwritten notes to the new reports. The reports that were sent for pathology review can be shredded.
F. **Remove packets** for any row removed from the batch during pathology review, if applicable. Likewise, **add packets** for any conditions being added to the final review batch.
G. **Scan** the new cover page, body grid for FU6 survey and higher, and files with new cover reports into a final review PDF in CCSSID order. **Save the PDF file** that will be sent to the final reviewer:
   i. For expansion baseline batches, save as **Path Reports Final Review, Exp Batch ##** (cases) or **Path Reports Final Review, Exp-SIB Batch ##** (siblings) at *Z:\Research Home\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, Expansion Baseline\For Final Review*.
   ii. For Original Baseline-FU4 batches, save as **Path Reports Final Review, OrigBase-FU4 Batch ###** (cases) or **Path Reports Final Review, OrigBase-FU4-SIB Batch ###** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU1 - FU4\For Final Review*.
   iii. For FU5 batches, save as **Path Reports Final Review, FU5 Batch ##** (cases) or **Path Reports Final Review, FU5-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU5\For Final Review*.
   iv. For FU6 batches, save as **Path Reports Final Review, FU6 Batch ##** (cases) or **Path Reports Final Review, FU6-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU6\For Final Review*.
   v. For FU7 batches, save as **Path Reports Final Review, FU7 Batch ##** (cases) or **Path Reports Final Review, FU7-SIB Batch ##** (siblings) at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN, FU7\For Final Review*.

2. Notify the appropriate members of the ECC Databases and Systems team via email to preload DatStat with the final review data.
   A. Provide him/her with a copy of the Excel data file (e.g. **SN Final Review, FU5 Batch 78**).
   B. Update the **SN Batch Tracking** workbook's Date DatStat Upload Requested field for the appropriate batch. The workbook is located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN*.

Batches for Final Review							
Path Batch #	Final Batch #	Source	# of Condi-tions	Date DatStat Upload Requested	Date DatStat Upload Complete	Date Sent For Final Review	Download Date
FU5 Batches							
68	78	FU5	33	6/20/18	7/3/18	7/3/18	7/11/2018 Neglia

3. When notice is received that the file is uploaded to DatStat, update the **SN Batch Tracking** workbook's Date DatStat Upload Complete field for the appropriate batch with the date of the notice.
4. **Send the PDF and revised Excel files to the final reviewers**.
   A. Drag a copy of the pdf file with the medical records (e.g. **Path Reports Final Review, FU5 Batch 78**) to the Box folder titled SN Project Final Reviews.

B. Drag a copy of the Excel worksheet with the pathologist's reviews (e.g. **SN Final Review, FU5 Batch 78**) to the Box folder titled SN Project Final Reviews.
C. Email the final reviewer team to indicate there is a new batch to be reviewed.
   i. Copy the Principal Investigator, Project Director, Research Scientist, and any other applicable parties.
   ii. Subject: Medical Records for Final Review, [Survey] Batches ## and ## (e.g. Medical Records for Final Review, FU5 Batch 78)
   iii. Key in the message. Include the link to the DatStat final review "survey."
   iv. Send.
   v. Update the **SN Batch Tracking** workbook's Date Sent for Final Review field for the appropriate batch with the date of the email.

Batches				
Pathologist Batch #	Final Batch #	Source	Number of Conditions	Date Sent For Final Review
54	63	FU5	75	5/15/17

5. **Update** the **Date Sent 2nd Review** field in the database after the file and spreadsheet are uploaded to Box and the email is sent. It may be possible to create a Select query of all conditions returned by the pathologist on a given date to confirm the results are accurate, then change the Select query to an Update query to update the **Date Sent 2nd Review** field. Seek assistance, if necessary.
6. Attach the physical record packets to the front of the SN folder for each CCSSID. If no folder is found:
   A. Ensure the folder is not checked out, per the Excel file **Checked Out SN Files**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN*.
   B. Confirm neither the B&T project team nor the coding team have the folder.
   C. Confirm the folder is not out of file for a special project.
   D. Ensure the SN Report does not indicate a folder should exist.
   E. Create a new SN folder for the CCSSID in question.
7. Use the batch cover page to compare the number of physical files to the number of unique CCSSIDs in the final review batch to ensure no packets were erroneously missed.
8. Have the new record bundles added to the scanned copy of the SN folder. The folder can then be refiled.
9. If appropriate, add the conditions to the master list for the next onsite final review session.
10. When the final reviewer reports the final reviews for a batch are complete, update the Date Final Review Received cell in the **SN Batch Tracking** Excel file, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl \common\CCSS\SMN*, to indicate the date of receipt.

For information on how to retrieve and enter the final review results, see the SOP titled **Retrieving and Documenting Subsequent Neoplasm Final Reviews**.

Revision Record Printed 8/26/2019 3:10 PM

[302]Current Filename:		Subsequent Neoplasm Pathology Report Reviews v1_3.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	7/1/15	L. Harrison	Initial ; overhaul of SMN Confirmation Process
1.1	2/16/16	R. Massey, L. Barnes, A. McDonald, J. Ford	Updated title, expanded background and directives
1.2	8/10/17	R. Massey	Update procedures based on new SNT database, expand to include siblings and new survey sources
1.3	8/26/19	R. Massey	Update network paths, fix typos, indicate use of Box instead of FTA, add directives to add new bundles to scanned folder, add FU7 directives

Suicidal Ideation Follow-Up from Baseline and FU5 Surveys

Background

When adult participants (cases or siblings) complete the baseline or Follow-Up 5 (FU5) survey online or with a Survey Interviewer (SI), the participant is asked if s/he has experienced "thoughts of ending your life" within the past seven days.

Queries have been designed to flag responses that need follow-up with a mental health professional. The current procedure flags surveys with an answer of "moderately," "quite a bit," or "extremely" to this question. The results of these queries should be checked by the LSI or designee preferably every day and absolutely no more than every three days. Any new results should be passed on to the designated mental health professional.

When paper baseline or FU5 surveys are processed for cases and siblings, they are manually reviewed to check this item. If warranted, a staff member will bring the proper documentation to the LSI or designee to be passed on to the designated mental health professional.

Procedures

For Surveys Completed Online:

Complete the process in its entirety for case baseline surveys, repeat the process for sibling baseline surveys, and repeat again for FU5 surveys.

NOTE: This procedure should be done *after* contact information has been updated from the completed surveys so that the mental health professional will have current information. See the SOPs titled **Daily Expansion Tracking Data Entry – Case**, **Daily Expansion Tracking Data Entry – Siblings**, and **Daily LTFU Participant and Ancillary Database Updates** for detailed instructions.

1. Open the Expansion Tracking (for case and sibling baseline surveys) or the LTFU Participant (for FU5 surveys) database.

2. Open the Navigation Pane in the appropriate database, and select "Queries" from the menu.

3. Using the **Search** bar:
   A. In the Expansion Tracking database, find the query named:
      i. qryBlaireEoLGT18 – for Expansion case baseline surveys
      ii. qryBlaireEoLGT18_SIB – for Expansion sibling baseline surveys
   B. In the LTFU Participant database, find the query named qry_FU5_EoLGT18, which is for FU5 case *and* sibling surveys.

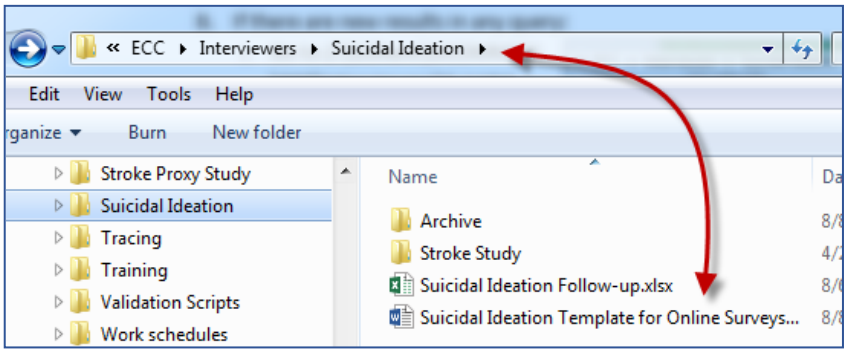
4. Run the appropriate query. NOTE: Each query should be run independently. Evaluate the results of *each* query to identify any new data that have populated since the last date the query was checked.

A. If there are no new results in the query, the process is completed for the survey type in question. Begin the process for the next survey type, if any.

B. If there are new results in the query:

i. Go to *Z:\SJShare \SJCOMMON\ECC\Interviewers\Suicidal Ideation*

ii. Open the document titled **Suicidal Ideation Template for Online Surveys**.



iii. Copy the appropriate cells from the first new row of the query results and paste the data into the corresponding fields of the template, replacing the red writing with the data.

qryBlaireEoLGT18 OR qryBlaireEOLGT18_SIB OR qry_FU5_EoLGT18				
CCSSID or SIBID	ENDLIFETHOUGHTS	Survey Returned Date	Int ID	PERSONCOMPLETINGSPEC
Pt ID	ANSWER	DATE	ID	PERSON CODE

Populate row with data from query results

Filed with staff psychologist: DATE FILED ← Type date filed.

ENDLIFETHOUGHTS	PERSONCOMPLETINGSPEC
1=not at all	1=participant completed the survey
2=a little bit	2=someone other than the participant completed the survey
3=moderately	
4=quite a bit	
5=extremely	

iv. Type the "Filed with staff psychologist" date as the current date, replacing the red writing with the date.

v. Print the document, then close the document without saving your changes.

vi. Repeat the steps to print the **Suicidal Ideation Template for Online Surveys** document for each new participant in the query results. Only one participant should be on each printed template.

vii. For each new CCSSID or SIBID that was included in the new results of any query, make the appropriate screenshot. *NOTE: If the relevant data entry for completed surveys has not been done, the updated address and phone numbers should be entered prior to taking the screen shots.*

a. For baseline cases, make a screen shot of the Quest tab in the blue case record in the Expansion Tracking database.

b. For baseline siblings, make a screen shot of the Sib Info tab in the green sibling record in the Expansion Tracking database.
c. For FU5 cases, make a screen shot of the Participant Info tab in the blue case record in the LTFU Participant database.
d. For FU5 siblings, make a screen shot of the Participant Info tab in the green sibling record in the LTFU Participant database.

viii. For each screen shot:
a. Paste each screen shot into its own MS Word document
b. Print the MS Word document with the screenshot.
c. For former St. Jude patients (CCSSID begins with "15"), highlight or circle the MRN.
d. Do not save this document.

ix. Update the spreadsheet titled **Suicidal Ideation Follow-Up**, located at *Z:\SJShare\SJCOMMON\ECC \Interviewers\Suicidal Ideation*, for each new CCSSID or SIBID that was included in the results of any query. Follow the column headings and the format of previous entries.

1			1=online 2=paper		1=self 2=other		
2	CCSSID or SIBID	Date Survey Completed	Survey Completion mode	Survey Response	Person completing survey	Date given to Psychologist	NOTES
178	[redacted]	[redacted]	1	3	1	7/30/2014	Processed on 7/30/2014 [140] FU5
179	[redacted]	[redacted]	1	3	1	8/1/2014	Processed on 8/1/2014 [158] FU5
180	[redacted]	[redacted]	1	3	1	8/4/2014	Processed on 8/4/2014 [137] FU5
181	[redacted]	[redacted]	1	3	1	8/4/2014	Processed on 8/4/2014 [137] FU5
182	[redacted]	[redacted]	1	3	1	8/5/2014	Processed on 8/5/2014 [158]
183	[redacted]	[redacted]	1	4	1	8/6/2014	Processed on 8/6/2014 [137]
184	[redacted]	[redacted]	1	3	1	8/12/2014	Processed on 8/12/2014 [137]

x. Staple each screen shot of the Quest/Sib Info/Participant Info tab to the printed template for that participant, then place the packet in the staff psychologist's 6th floor mailbox. Mailboxes are located behind the administrative front desk, across from the staff break room.

xi. Send an email to the designated mental health professional.
a. Alert him/her to the new suicidal information in his/her mailbox.
b. For former St. Jude patients, note the former St. Jude status and MRN in both the subject bar and in the body of the email.

For Paper Surveys:

1. The 5th-floor staff member will provide copies of four pages from the paper survey to the LSI or designee:
   A. The front page of the survey
   B. The page that indicates the suicidal ideation response
   C. The back page of the survey with updated contact information
   D. The signed HIPAA page

2. Go to *Z:\SJShare\SJCOMMON\ECC\Interviewers\Suicidal Ideation*.

3. Update the spreadsheet titled **Suicidal Ideation Follow-Up** by following the column headings and the format of previous entries.

1			1=online 2=paper		1=self 2=other		
2	CCSSID or SIBID	Date Survey Completed	Survey Completion mode	Survey Response	Person completing survey	Date given to Psychologist	NOTES
178	[redacted]	[redacted]	1	3	1	7/30/2014	Processed on 7/30/2014 [140] FU5
179	[redacted]	[redacted]	1	3	1	8/1/2014	Processed on 8/1/2014 {158} FU5
180	[redacted]	[redacted]	1	3	1	8/4/2014	Processed on 8/4/2014 [137] FU5
181	[redacted]	[redacted]	1	3	1	8/4/2014	Processed on 8/4/2014 [137] FU5
182	[redacted]	[redacted]	1	3	1	8/5/2014	Processed on 8/5/2014 [158]
183	[redacted]	[redacted]	1	4	1	8/6/2014	Processed on 8/6/2014 [137]
184	[redacted]	[redacted]	1	3	1	8/12/2014	Processed on 8/12/2014 [137]

4. For each CCSSID or SIBID that was included in the paper copies:
   A. For baseline cases, make a screen shot of the Quest tab in the blue case record in the Expansion Tracking database.
   B. For baseline siblings, make a screen shot of the Sib Info tab in the green sibling record in the Expansion Tracking database.
   C. For FU5 cases, make a screen shot of the Participant Info tab in the blue case record in the LTFU Participant database.
   D. For FU5 siblings, make a screen shot of the Participant Info tab in the green sibling record in the LTFU Participant database.

5. For each screen shot:
   A. Paste each screen shot into its own MS Word document
   B. Print the MS Word document with the screenshot.
   C. For former St. Jude patients (CCSSID begins with “15”), highlight or circle the MRN.
   D. Do not save this document.

6. Staple all 5 pages for each CCSSID or SIBID together, and put them in the designated mental health professional’s 6th floor mailbox. Mailboxes are located behind the administrative front desk, across from the staff break room.

7. Send an email to the designated mental health professional.
   A. Alert him/her to the new suicidal information in his/her mailbox.
   B. For former St. Jude patients, note the former St. Jude status and MRN in both the subject bar and in the body of the email.

Revision Record Printed 9/3/2015 2:12 PM

[191] Current Filename:		Suicidal Ideation Follow Up from Baseline and FU5 Surveys ver1_6.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/20/2012	M. Jackson	Initial Development
1.1	7/3/12	Procedure Team	Content and format refinement
1.2	6/19/13	D. Rinehart	Content revision
1.3	11/4/2013	R. Massey	Updated title to include siblings, updated screen shots, format refinement, updated template
1.4	8/14/2014	R. Massey	Content revision to include FU5
1.5	11/24/2014	D. Rinehart, R. Massey	Content Revision: Directives for former SJ patients
1.6	8/8/2015	R. Massey	Content Revision: Clarified FU5 query for cases and sibs, replaced specific psychologist with generic identifier

Survey Interviewer Call Quality Assurance Audit Procedures

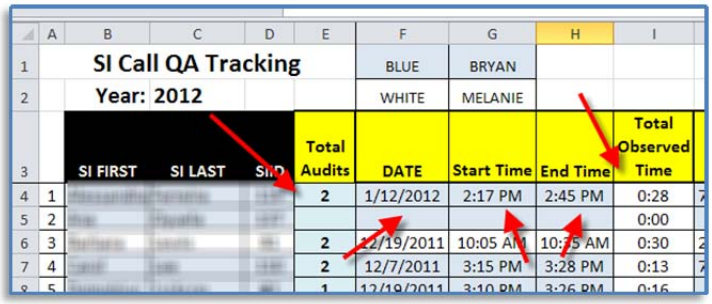
Background

To ensure call quality, both scheduled and unscheduled phone call QA audits will be conducted by the Lead Survey Interviewers. The observations will be documented and reviewed in private with the applicable Survey Interviewer following the audit. The follow-up review will allow the LSI to praise areas of performance, as well as address opportunities for improvement. QA Audit should be conducted every 4 to 6 weeks per interviewer, or more frequently as needed (i.e., after new research projects have been added or new SI's have come out of training).

Procedures

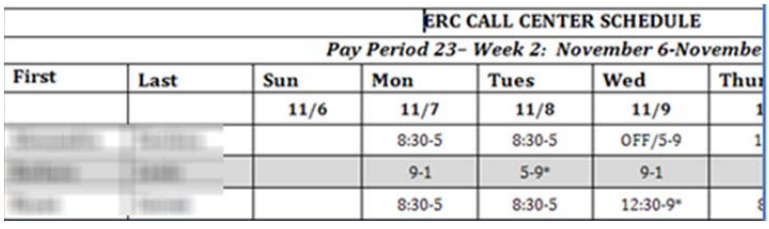
Scheduled Audits

1. Scheduled audits will be performed on a rotating basis, by one or more LSI, using the Excel spreadsheet, *SI Call QA Audit Tracking mm-dd-yyyy.xlsx*, located at:
   Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI.
   a. This tracking system ensures fairness by keeping a record of which SI was audited at what date, time and the duration of the audit.
   b. It also tracks how many audits have been completed with each SI.
   c. The LSI reviews this information when scheduling an audit with a SI.
   d. (Note: The total audit observational time does not include the follow-up meeting.)



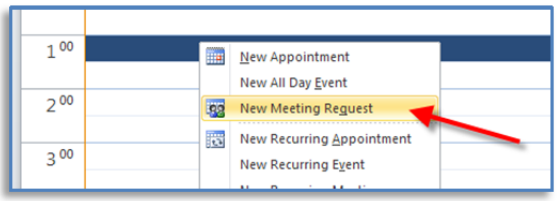
	A	B	C	D	E	F	G	H	I
1		SI Call QA Tracking				BLUE	BRYAN		
2		Year: 2012				WHITE	MELANIE		
3		SI FIRST	SI LAST	SID	Total Audits	DATE	Start Time	End Time	Total Observed Time
4	1				2	1/12/2012	2:17 PM	2:45 PM	0:28
5	2								0:00
6	3				2	12/19/2011	10:05 AM	10:35 AM	0:30
7	4				2	12/7/2011	3:15 PM	3:28 PM	0:13
8	5				1	12/19/2011	3:10 PM	3:26 PM	0:16

2. Open the applicable SI schedule, located at:
   Z:\SJShare\SJCOMMON\ ECC\Interviewers\Work schedules

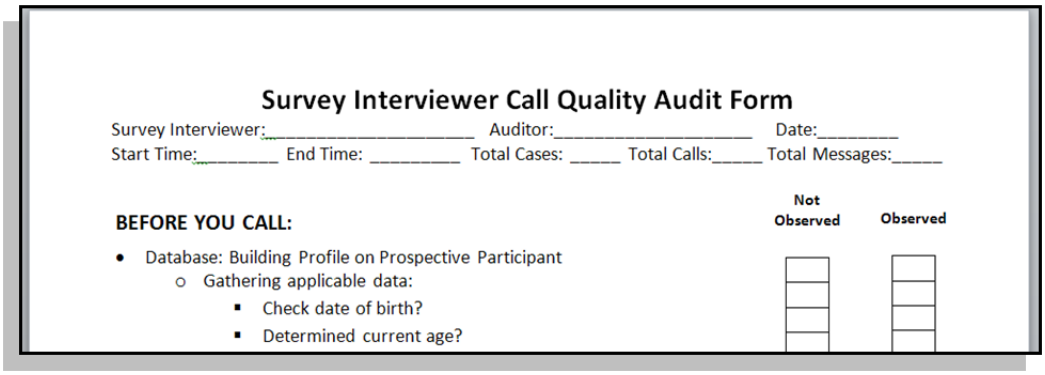


ERC CALL CENTER SCHEDULE						
Pay Period 23– Week 2: November 6-Novembe						
First	Last	Sun	Mon	Tues	Wed	Thu
		11/6	11/7	11/8	11/9	1
			8:30-5	8:30-5	OFF/5-9	1
			9-1	5-9*	9-1	
			8:30-5	8:30-5	12:30-9*	

3. Use the MS Outlook Calendar to schedule the audit, using the "Request a Meeting" function, to send a meeting request to the applicable SI.



4. Open and print the observation form, *SI Call Quality Audit Form 10-20-2011 dr.doc* . Use this form to capture pre, during and post-call procedure observations, analysis, performance ratings and any other notes relative to the quality of the call.



Survey Interviewer Call Quality Audit Form

Survey Interviewer:_____ Auditor:_____ Date:_____
Start Time:_____ End Time: _____ Total Cases: _____ Total Calls:_____ Total Messages:_____

BEFORE YOU CALL: | Not Observed | Observed

- Database: Building Profile on Prospective Participant
  - Gathering applicable data:
    - Check date of birth?
    - Determined current age?

5. 15 minutes is the target observation period to conduct the audit. Adjustments to the period will be made, if needed. Review times may also be extended on a case-by-case basis.

   a. If ***NO*** *contact has been made* between the SI and the participant during the 15 minute audit, then the LSI will reschedule the audit within a few days to conduct the audit again. The LSI will still document pre- and post-call activities on the review form.

   b. If *contact **IS** made* and participant identification has been confirmed, the SI will inform the participant that the call may be monitored by their supervisor for quality and training purposes.

      i. *If the participant approves* their call being monitored, the LSI will use the muted phone handset extension to monitor the conversation.

      ii. *If the participant is **NOT** willing* to have the call monitored, then the LSI will unplug the phone extension and simply observe the SI's call activities and data entry.

6. The LSI fills out the QA audit form completely, and documents using clear, concise and complete notes in the comments section at the bottom of the form.

Post Audit Review

1. Following the completion of the audit, the LSI will meet privately in the conference room with the SI to:
   a. Give a copy of the form to the observed SI
   b. Review all observations, ratings and notes
   c. Highlight positive aspects of call quality and performance
   d. Review policies and/or procedures relevant to opportunities for improvement and ask if the SI understands and agrees with the assessment
   e. Collaborate with the SI on strategies for improvement, and give support by scheduling a follow-up audit
   f. Answer any questions

2. The LSI will then:
   a. File the QA audit form in a securely locked location
   b. Forward a summary audit report to the Coordinator
   c. Deliver the completed QA audit forms to the coordinator on the first Monday following the audit, and discuss any issues that may need to be addressed

Unscheduled Audits

1. Unscheduled audits will involve all steps above, except the LSI will:
   a. Begin with step 4 (print the observation form)
   b. Randomly select a SI to audit

2. Conduct the audit

3. Follow the post-audit review process and subsequent steps

Revision Record Printed 7/31/2012 11:59 AM

Current Filename:		SI Call Quality Assurance Audit ver1_4.docx	
Revision No.	Date	Responsible Author	Change Description
1.1	12/6/11	D. Rinehart	Initial Development
1.2	1/5/12	A. McDonald	Copy revision
1.3	7/17/12	D. Rinehart	Formatting, Background, procedure clarification, updated screen shots
1.4	7/27/12	Procedure Team	Content revisions

Survey Interviewer Guidelines for Creating and Updating SOPs

Background

To ensure Survey Interviewer (SI) standard operating procedures (SOPs) contain the most accurate and up-to-date information, an SI from each project team will be assigned to create and/or update the associated project SOP(s). This document is to be used in conjunction with the SOP titled **Creating and Updating Procedure Documents for the SOP Manual**, which is located in the SOP Library.

Please note that SOPs published in the SOP Library may or may not strictly follow these guidelines. Those documents are "grandfathered" and do not need to be updated for the sake of formatting or convention deviations from this guidance document. Please consult with an LSI or the Coordinator, if needed.

SOP Conventions

The table below illustrates the formatting conventions used to underscore or emphasize important ideas. Please follow the conventions below to clarify instructions when revising or creating a new SOP.

Item	Font	Font Style	Font Color	Examples (from the SOP titled **Follow Up 5 Survey – Incoming Calls**)
Field and **Button** Names	Calibri	**Bold**	**Black**	Review the **IPad Due Date** field to determine the window of eligibility for the incentive.
Document Name	Calibri	**Bold**	**Red**	See the SOP titled **Reconsenting During Follow-Up 5 Survey Calls** for full details.
Main Ideas	Calibri	**Bold**	**Blue**	If the participant **refuses** to complete the FU5 survey…
Network Paths or *Examples*	*Calibri*	*Italic*	Black	Paper copies of the Follow-Up 5 surveys (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\FU5\Surveys*)
Emphasis, USED SPARINGLY to avoid diminishing impact	*Calibri* or CALIBRI	*Underlined Italic* or ALL CAPS	Black	NEVER use the back/forward buttons in the internet browser.

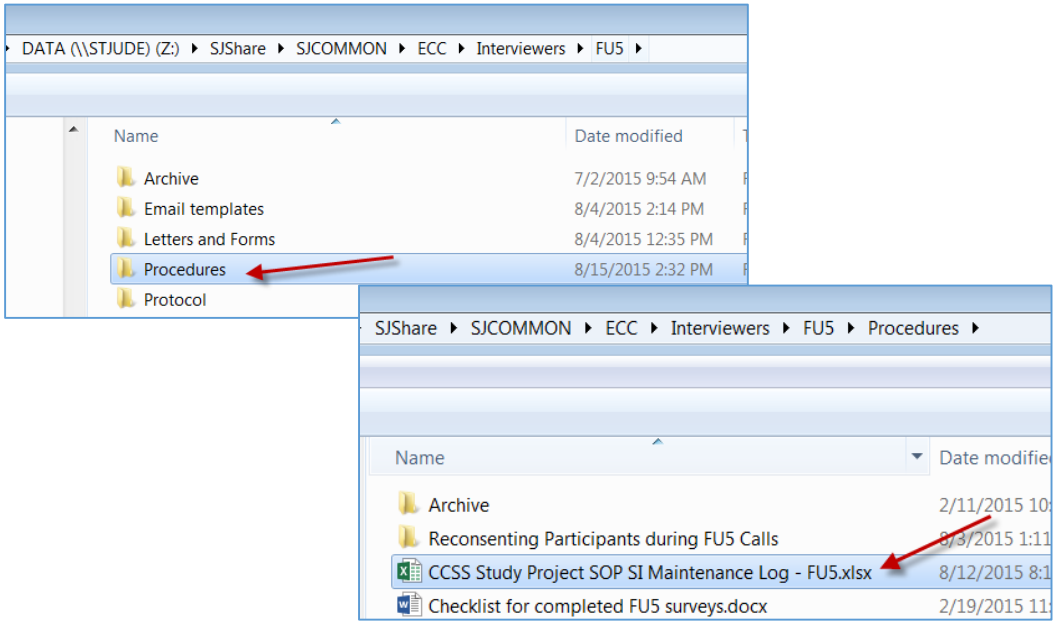
Procedures

To Update an Existing Procedure Document

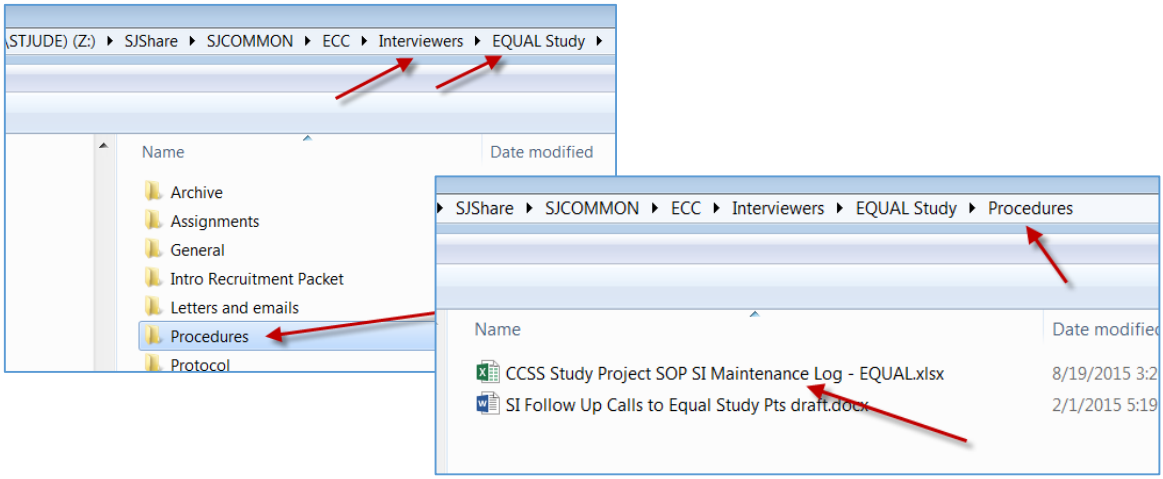
Quarterly Review – Each SOP should be reviewed every three months for needed updates.

1. Open the Excel file **CCSS Study Project SOP SI Maintenance Log – *[project name]***, located in the Procedures folder of the *specific CCSS project folder*.

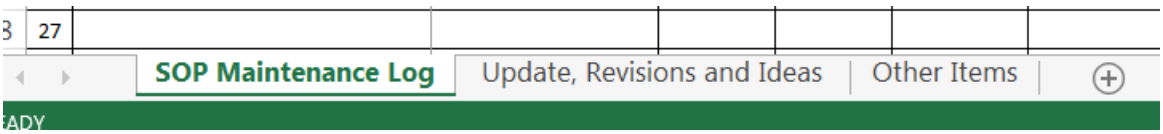
For example, the maintenance log for the FU5 project is located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\FU5\Procedures*



The maintenance log for the EQUAL project is located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\EQUAL\Procedures*



2. The **CCSS Study Project SOP SI Maintenance Log – *[project name]*** has three worksheets:

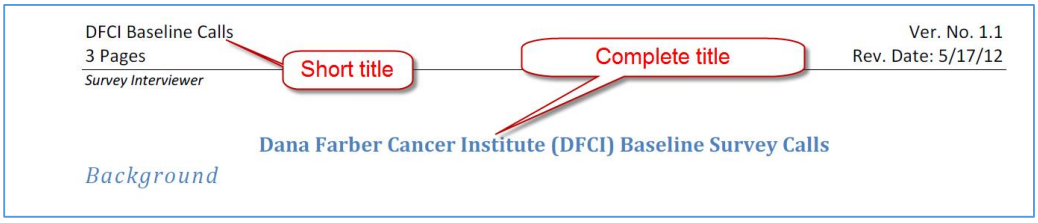


A. SOP Maintenance Log – Log all maintenance activities on this worksheet for review, revision, or creating a new document.
B. Update, Revisions and Ideas
   i. Store all updates, revisions, and ideas on this worksheet as they occur to you.
   ii. Use the data entered to revise the SOP at a later date.
C. Other Items – Save screen shot copies or other information to update the SOP.

3. **Review Only, No SOP Revision Needed** – If a review of the document is all that is needed, enter the document name, the event "Review Only," the **Event Start Date** as the date you began, and the **Review Only Date** as the date you finished the review.

A	B	C	D	E	F	G	H	I	J	K
No.	Document Name	Event	Event Start Date	Review Only Date	Date Requested	Date Received	Date Submitted to Project Team	Date Submitted to LSI / Coord.	Date Submitted for Publishing	Comments
1	Emailing Follow-Up 5 Survey Links	Review Only	8/19/15	8/19/15						

4. **Document Revision** – When an SOP document needs to be revised:
   A. Enter the document name, event "Revision," and the **Event Start Date** in the **CCSS Study Project SOP SI Maintenance Log – *[project name]***.
   B. Email the Lead Survey Interviewer (LSI) team.
      i. Request the most recent version of the procedure to be revised, specifying the procedure's complete title. (See the example SOP **Dana Farber Cancer Institute (DFCI) Baseline Survey Calls**. Note the "short title" for this document is "DFCI Baseline Calls.")



      ii. An LSI will request the most recent version of the procedure from the SOP Librarian and forward the document to the requesting SI for updates.
   C. After sending the email request to the LSI team, enter the date of the request in the **Date Requested** field of the **CCSS Study Project SOP SI Maintenance Log – *[project name]***. See the examples above.
   D. Once the document has been received by the updating SI, s/he should enter the date in the **Date Received** field of the **CCSS Study Project SOP SI Maintenance Log – *[project name]***.
   E. Complete the necessary updates to the current version.
      i. For general instructions, see the section, "*To Update An Existing Procedure Document*" in the SOP titled **Creating and Updating Procedure Documents for the SOP Manual**.
      ii. Open a new email before beginning the updates, and keep a bulleted list of changes as the SOP is updated. This can be used later to notify stakeholders of what was changed.
      iii. Document all field names, button names, etc., in the SOP exactly as they are displayed. (e.g. Refer to the Associates tab instead of the Assoc tab.)

iv. When referencing documents, use the ***exact*** name of the document. If a date is included as part of the file name, use a general format (e.g. mm-dd-yyyy).
v. When acronyms are used, the first instance of the entity in the document should be spelled out with the acronym following in parentheses [e.g. Long-Term Follow-Up (LTFU) Study]. All subsequent instances can use the acronym alone (e.g. LTFU Study).
vi. Keep all directives as brief as possible while maintaining clarity and completeness.
vii. Keep the action at the front of each directive whenever possible. (e.g. *"Paste the note into the **Comments** field, where applicable"* is usually better than "*Where applicable, paste the note into the **Comments** field*.")
viii. Use list formats, when possible, to make the SOP user-friendly.
ix. Few, if any, assumptions should be made about what the reader already knows. All steps should be included in the order in which they will occur.
x. Procedures should cover all standard/expected variations, but cannot anticipate all unusual occurrences.
xi. Avoid referring to specific step numbers (e.g. "See step 3."), because these are likely to change over time. Instead, refer to the section of the document (e.g. "See the section of this document titled 'During the Call: Completing the Online Survey'.").
xii. No procedure should be repeated in an SOP if that procedure is already described in a different SOP document. Doing so necessitates multiple updates when that procedure changes. Instead, refer to the original procedure. (e.g. See the SOP titled **LTFU Participant Database Data Entry** for instructions.)
xiii. SOP file names should match the SOP title to assist the Librarian in locating files.
xiv. The SOP title should accurately reflect the procedure it includes. Procedures change over time, sometimes warranting a title change. When this occurs, the file name should be updated as well.

F. Submit the revision for review. – Wait at least one day after completion of an SOP update to ***proofread*** it, and submit the revision for review ***only after it has been proofed***. When a draft is submitted for review, always include a concise summary of the changes made.

Example:
Please review the attached revised SOP draft, Suicidal Ideation Follow-Up from Baseline and FU5 Surveys*. The main changes are:*

- *Updated reference to SOP titled* Database Updates from Online Follow-Up 5 Surveys *to refer instead to that SOP's current title:* Daily LTFU Participant and Ancillary Database Updates
- *Clarified that case and sibling suicidal ideation reported on FU5 surveys are returned in a single query rather than separate queries*
- *Removed references to "Dr. Kimberg" and replaced with the more generic "staff psychologist" or "the designated mental health professional"*
- *Updated formatting*

i. Send the revised SOP to the other SIs assigned to the same CCSS project team, if applicable. Skip this step if there are no other SIs assigned to the project.
1. Update the **Date Submitted to Project Team** field in the **CCSS Study Project SOP SI Maintenance Log – *[project name]*.**

2. Make any appropriate updates based on the team's feedback.

ii. Forward the revision to the LSI team and update the **Date Submitted to LSI/Coord.** field in the **CCSS Study Project SOP SI Maintenance Log – *[project name]*** after the project team has reviewed the revised document and applicable updates have been made.

1. If it is determined minor revisions need to be made (e.g. typo corrections, formatting, etc.), the LSIs may make the updates before forwarding the SOP for publication to the SOP Library.
2. If it is determined other revisions need to be made, the LSIs will return the SOP to the assigned SI for updates.

G. Once it is determined no revisions need to be made, the LSIs will forward the SOP for publication to the SOP Library. The LSI will update the **Date Submitted for Publishing** field.

A	B	C	D	E	F	G	H	I	J	K
No.	Document Name	Event	Event Start Date	Review Only Date	Date Requested	Date Received	Date Submitted to Project Team	Date Submitted to LSI / Coord.	Date Submitted for Publishing	Comments
1	Emailing Follow-Up 5 Survey Links	Revision	8/19/15		8/19/15	8/27/15	8/30/15	9/1/15	9/5/15	1. Corrected location of email templates 2. Specified that the full body of email shou NOT be copied into contact log Notes field

H. Upon publication, an LSI will notify the assigned SI that the SOP has been published.

I. The assigned SI will email the Survey Interviewer team, copying the LSIs and Coordinator, that the SOP has been updated and will include a summary of the revisions.

<u>To Create a New Procedure Document</u>

1. Refer to the SOP titled **Creating and Updating Procedure Documents for the SOP Manual** for instructions.
2. Use the same conventions and guidelines described above in the section of this document titled *To Update an Existing Procedure Document*.
3. Update the following fields in the **CCSS Study Project SOP SI Maintenance Log – *[project name]*.**

J. **Document Name** – Enter the draft name.

K. **Event** – Enter the "New Document Development" event.

L. **Event Start Date**

M. Send the draft to the other SIs on the project team, if applicable, and update the **Date Submitted to Project Team** field.

N. After the team has reviewed the document, send it to the LSI team (copy the Coordinator) for review, and update the **Date Submitted to LSI/Coord.** field.

H	I	J	K
Date Submitted to Project Team	Date Submitted to LSI / Coord.	Date Submitted for Publishing	Comments
8/30/15	9/1/15	9/5/15	1. Corrected location of ema 2. Specified that the full body NOT be copied into contact l

O. If no changes are required, the LSI team will forward the document to the SOP librarian for publication and update the **Date Submitted for Publishing** field.
P. Once published, the LSI team will notify the assigned SI to send an email to the SI team announcing the new document and to include a summary of the key points in the body of the email.

A	B	C	D	E	F	G	H	I	J	K
No.	Document Name	Event	Event Start Date	Review Only Date	Date Requested	Date Received	Date Submitted to Project Team	Date Submitted to LSI / Coord.	Date Submitted for Publishing	Comments
1	Pre-Post Checklist for Sending FU5 Emails	New Document Development	8/19/15				8/30/15	9/1/15	9/5/15	

To Archive a Procedure Document

When an SOP is no longer relevant, it must be **archived**. To archive an SOP:

1. Send an email request to the LSI team, and include:
    a. The full-name of the SOP
    b. A short summary/explanation justifying the archived status
    c. The preferred effective date
2. The LSIs will review the request and, when determined appropriate, submit it the SOP Librarian.

Please consult with a member of the LSI team, if questions arise or assistance is needed.

Revision Record Printed 9/3/2015 2:44 PM

Current Filename:		SI Guidelines for Creating and Updating SOPs ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	8/20/15	D. Rinehart, A. DiScenza, R. Massey, A. Stock	Initial Development

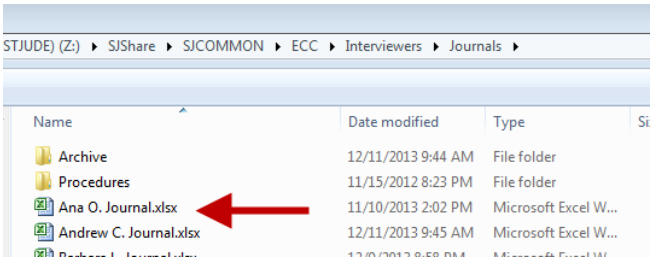
Survey Interviewer Journal Data Entry

Background

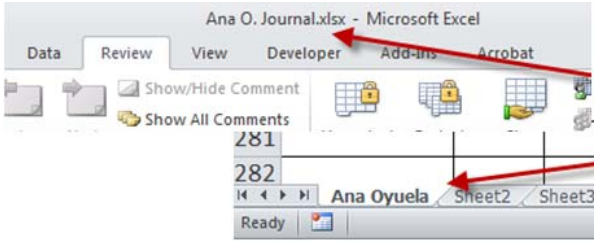
Fair assessment of productivity requires dividing a given task by available amount of time to complete that task. Because of the many layers of additional random tasks performed by the Survey Interviewer (SI) in support of the CCSS Call Center on a daily basis, the time-burden of these additional tasks must be captured and deducted from the SI's available time to gain a more realistic analysis of call assignment productivity. To capture this time-burden, the SI **Journal** was created. This procedure outlines the steps for data entry in the SI **Journal**.

Procedures

1. The Survey Interviewer (SI) opens their individual SI **Journal** located at: *Z:\SJShare\SJCOMMON\ECC\Interviewers\Journals*.



2. Once the Journal is open, the SI checks to ensure that they have the correct **Journal** open by checking the file name at the top of the screen and at the bottom tab.



3. After confirming the correct **Journal** is open, the SI uses the keyboard shortcut, "Ctrl – ;" (hold down the Ctrl key, and hit the semicolon key) to add a date in the cell of the first empty row under the **Date** column header.

	Date	Event Code	
13			
14	7/17/2012		

4. Next, the SI selects an Event Code from the Event Code legend at the top of the **Journal** and enters this number in the cell on the same row to the right of the date.
   a. If no event matches the task that was completed, the SI chooses code 20-Other and types the task in the cell to the right of the code, under the **"Other" Description** column.
   b. NOTE: See additional notes, below, regarding activities recorded/not recorded in the **Journal**.

Code	Event	Code	Event
1	CCSS Meeting	11	Completed Learn Center Module
2	Call Center Meeting	12	Read Other Training Materials
3	Study Specific Training Meeting	13	Processed Incoming Call
4	St. Jude Training	14	Assisted Another SI with a Complex Case
5	Meeting with Coordinator	15	Call Center Housekeeping
6	Meeting with LSI	16	Administrative Assignment
7	Completed Training with LSI	17	FFQ Coverage for SJL
8	Facilitated Training with SI	18	Assisted Another Department
9	Received Training from Another SI	19	Assisted the Coordinator
10	Partially Completed Learn Center Module	20	Other

	Date	Event Code	"Other" Description	Total Hours	Total Minutes
13					
14	7/17/2012	20	picked up call center appointment calendar from BMC		20

5. The SI will save and close his or her **Journal**.

NOTE: It is important that the SI only enters tasks in the Journal that are *outside of participant call assignments* or any of their related support procedures.

Some tasks that DO NOT get recorded in the Journal:

- Survey calls/procedures completed in 1 hour or less. (If the survey call and procedures take more than one hour, record *only* the time exceeding the first hour.)
- Verbal HIPAA calls/procedures completed in 30 minutes or less. (If the verbal HIPAA call and procedures take more than 30 minutes, record *only* the time exceeding the first 30 minutes.)
- Ancillary study calls for which they are allocated to work.

Some exceptions to this rule:

- The SI partially completes a survey with a participant. All time spent on an incomplete survey and related procedures should be recorded in the **Journal**.
- The SI completes any other task for a participant who is in a study which they have not been assigned allocation hours to work. (e.g., a SI who is trained as a back-up for an ancillary study, but is not allocated hours to work that study)
- The SI makes calls to "possible" numbers found by the Tracing team for a participant on their assignment list when those calls are not otherwise captured by the database call log or call assignment spreadsheet. List the total number of calls made in the **"Other" Description** column.
- There may be other rare exceptions, which the SI should discuss with the LSI team or Call Center Coordinator.

Revision Record Printed 12/13/2013 8:43 AM

Current Filename:		Survey Interviewer Journal Data Entry ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	4/28/11	D. Rinehart	Initial Development
1.1	7/17/12	D. Rinehart	Updated process and screen shots
1.2	10/22/13	R. Massey	Add directive to include number of tracing calls.
1.3	12/11/2013	D. Rinehart	Content revision

SURVEY INTERVIEWER PHONE CONTACT CHECK OFF LIST

Survey Interviewer:_____ Auditor:_____ Date:_____
Start Time:_____ End Time: _____ Total Cases: _____ Total Calls:_____ Total Messages:_____

BEFORE YOU CALL:

	Not Observed	Observed
• Database: Building Profile on Prospective Participant		
o Gathering applicable data:		
▪ Check date of birth?		
▪ Determined current age?		
▪ Checked alive status?		
▪ Reviewed diagnosis and date?		
▪ Checked date of last phone call?		
▪ Reviewed address date and source?		
o Phone number(s): Checked Rank and date?		
o Call Logs viewed?		
o Comments section reviewed?		
o Outcome fields and dates reviewed?		
o Checked date packets sent or returned?		
o Alternate contact information reviewed?		

DURING THE CALL:

	Needs Improvement	Good	Excellent	Outstanding
• SI tone friendly, courteous, and professional?				
• Script adherence quality?				
• Tactful, assertive and helpful?				
• Conflict management skills (if applicable)?				
• Answered questions or concerns satisfactorily?				
• Gained commitment?				

AFTER THE CALL:

	Not Observed	Observed
• All data entry fields updated?		
o Comments clearly, concisely and accurately reflect call outcome?		
o Date and Interviewer ID included?		
o Applicable follow-up email communication delivered?		
o Call Logs updated appropriately?		
o Address, phone, email fields updated?		

Overall observation comments:

_____

_____

_____

Survey Interviewer Self-Scheduling

Background

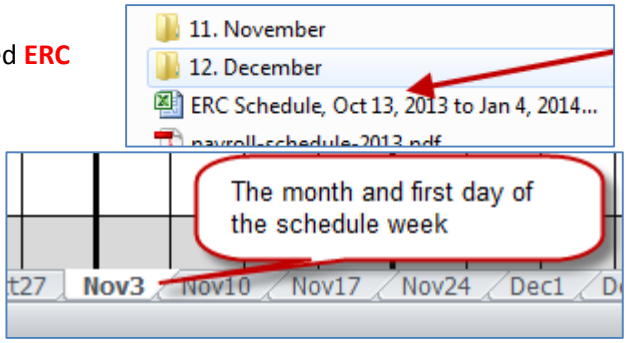
Each Survey Interviewer (SI) is responsible for entering her/his individual schedule into the appropriate MS Excel workbook titled **ERC Schedule [date range]** before the scheduling deadline for each scheduling period. Scheduling deadlines are generally two weeks in advance of the schedule's publishing date. While SIs may enter schedules farther in advance, they must have the indicated schedule entered by midnight on the scheduling deadline. Schedule workbooks are posted quarterly at *Z:\…\Interviewers\Work schedules\[yyyy] Pay Periods*.

For information regarding the scheduling policy, please refer to the SOP titled **CCSS Call Center Scheduling Policy**. For questions, please see a member of the LSI team and/or the Call Center Coordinator.

Procedures

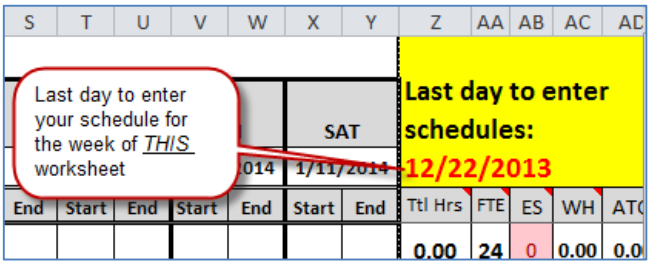
1. Prepare to enter the schedule.
   A. Open the appropriate **[yyyy] Pay Periods** folder at Z:…\ECC\Interviewers\Work schedules.

   B. Open the appropriate MS Excel workbook titled **ERC Schedule [date range]**.

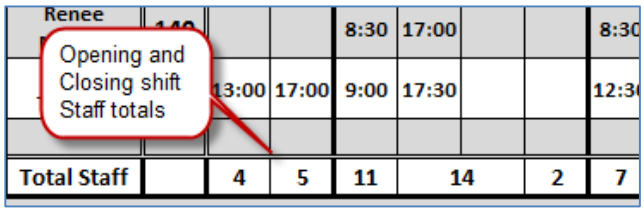


   C. Select the worksheet that contains the desired calendar week. Each tab displays the month and date for the Sunday of the week in question.

   D. At the top right-hand corner of each schedule worksheet, there is a courtesy reminder of the week's scheduling deadline. There is also a chart located at the end of this document.



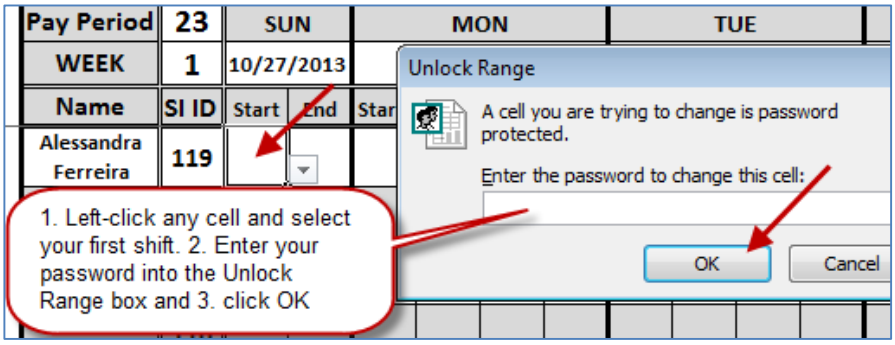
   E. If the week's schedule is already populated by other interviewers, review the shift coverage totals at the bottom of the worksheet. Where possible, plan to enter shifts that will provide the best (i.e. adequate and even) coverage throughout the week.



2. Enter the schedule.

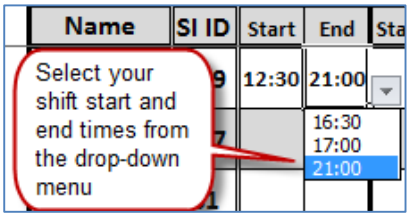
A. Click the **Start** cell for the shift to be entered and make a start time selection.

B. In the **Enter the password to change this cell** field, enter your password. Click the **OK** button.

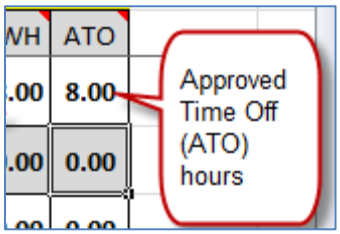


C. Using the drop-down menus, select the start and end times for each shift based on shift options defined in the SOP titled **CCSS Call Center Scheduling Policy**.

NOTE: For exceptions to the defined shift options (e.g. due to vacation hours), consult with the Call Center Coordinator and LSI team.



D. In the cell under the column header **ATO** (Approved Time Off), enter the total holiday hours plus the total approved time off hours (approved by the Call Center Coordinator through the TimeOff system) for the week.

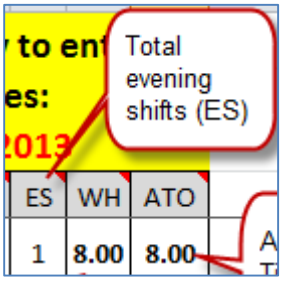


i. If an SI (1) has submitted a request through the TimeOff system before the scheduling deadline but (2) has not received a determination by her/his last shift before the deadline, s/he should enter the time off in the **ATO** column to meet the appropriate total weekly hours. If the request is not approved, the Coordinator will collaborate with the SI to adjust her/his schedule without penalty before the schedule is published.

ii. NOTE: If the ATO column is populated but no corresponding request has been submitted through the TimeOff system, the Coordinator will assume it was populated in error, clear the cell, and adjust the SI's schedule to meet the needs of the Call Center.

E. Check the **ES** (Evening Shifts) column to ensure at least one evening shift is scheduled for the week.

NOTE: Exceptions to the minimum number of weekly evening hours must be approved by the Coordinator in advance.



F. Check to see if the **Ttl Hrs** column (shift hours plus **ATO** hours) matches the number in the **FTE** column field.

i. If **Ttl Hrs** is less than **FTE**, the SI has not entered enough hours and should adjust as necessary.
ii. If **Ttl Hrs** exceeds the number in the **FTE** column, the SI has entered too many hours and should adjust as necessary.

G. Review entries for errors:
i. Is the week range in row 3 correct?
ii. Are the shift start/end times for each day correct?
iii. Are the days of the week scheduled correct?
iv. Is there at least one 4-hour evening shift from Monday to Thursday scheduled?
v. If the schedule was already populated, is there adequate coverage for the opening and closing shifts?

3. Save and close the document.

Courtesy reminder for last day to enter each week's schedule:

Third Quarter

Pay Period	Week	Last Day to Enter Schedules	1st Day of the Week, Sunday	7th Day of the Week, Saturday
15	1	6/21/2015	7/5/2015	7/11/2015
15	2	6/28/2015	7/12/2015	7/18/2015
16	1	7/5/2015	7/19/2015	7/25/2015
16	2	7/12/2015	7/26/2015	8/1/2015
17	1	7/19/2015	8/2/2015	8/8/2015
17	2	7/26/2015	8/9/2015	8/15/2015
18	1	8/2/2015	8/16/2015	8/22/2015
18	2	8/9/2015	8/23/2015	8/29/2015
19	1	8/16/2015	8/30/2015	9/5/2015
19	2	8/23/2015	9/6/2015	9/12/2015
20	1	8/30/2015	9/13/2015	9/19/2015
20	2	9/6/2015	9/20/2015	9/26/2015
21	1	9/13/2015	9/27/2015	10/3/2015

Fourth Quarter

Pay Period	Week	Last Day to Enter Schedules	1st Day of the Week, Sunday	7th Day of the Week, Saturday
21	2	9/20/2015	10/4/2015	10/10/2015
22	1	9/27/2015	10/11/2015	10/17/2015
22	2	10/4/2015	10/18/2015	10/24/2015
23	1	10/11/2015	10/25/2015	10/31/2015
23	2	10/18/2015	11/1/2015	11/7/2015
24	1	10/25/2015	11/8/2015	11/14/2015
24	2	11/1/2015	11/15/2015	11/21/2015
25	1	11/8/2015	11/22/2015	11/28/2015
25	2	11/15/2015	11/29/2015	12/5/2015
26	1	11/22/2015	12/6/2015	12/12/2015
26	2	11/29/2015	12/13/2015	12/19/2015
1	1	12/6/2015	12/20/2015	12/26/2015
1	2	12/13/2015	12/27/2015	1/2/2016

First Quarter

Pay Period	Week	Last Day to Enter Schedules	1st Day of the Week, Sunday	7th Day of the Week, Saturday
2	1	12/20/2015	1/3/2016	1/9/2016
2	2	12/27/2015	1/10/2016	1/16/2016
3	1	1/3/2016	1/17/2016	1/23/2016
3	2	1/10/2016	1/24/2016	1/30/2016
4	1	1/17/2016	1/31/2016	2/6/2016
4	2	1/24/2016	2/7/2016	2/13/2016
5	1	1/31/2016	2/14/2016	2/20/2016
5	2	2/7/2016	2/21/2016	2/27/2016
6	1	2/14/2016	2/28/2016	3/5/2016
6	2	2/21/2016	3/6/2016	3/12/2016
7	1	2/28/2016	3/13/2016	3/19/2016
7	2	3/6/2016	3/20/2016	3/26/2016
8	1	3/13/2016	3/27/2016	4/2/2016

Second Quarter

Pay Period	Week	Last Day to Enter Schedules	1st Day of the Week, Sunday	7th Day of the Week, Saturday
8	2	3/20/2016	4/3/2016	4/9/2016
9	1	3/27/2016	4/10/2016	4/16/2016
9	2	4/3/2016	4/17/2016	4/23/2016
10	1	4/10/2016	4/24/2016	4/30/2016
10	2	4/17/2016	5/1/2016	5/7/2016
11	1	4/24/2016	5/8/2016	5/14/2016
11	2	5/1/2016	5/15/2016	5/21/2016
12	1	5/8/2016	5/22/2016	5/28/2016
12	2	5/15/2016	5/29/2016	6/4/2016
13	1	5/22/2016	6/5/2016	6/11/2016
13	2	5/29/2016	6/12/2016	6/18/2016
14	1	6/5/2016	6/19/2016	6/25/2016
14	2	6/12/2016	6/26/2016	7/2/2016

Revision Record

Printed 9/2/2015 3:31 PM

[ ] Current Filename:		Survey Interviewer Self Scheduling ver1_2.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	10/9/2013	D. Rinehart	Initial Development
1.1	9/9/2014	R. Massey, D. Rinehart	Content Revision: Added directive for time off not approved/rejected by deadline, added note regarding ATO values with no TimeOff request
1.2	8/8/2015	R. Massey	Content Revision: Updated courtesy reminder chart, removed shortcut instructions

Survey Interviewer Tech Support Procedures

Background

Hardware and software technical issues of various degrees affect workflow and productivity in the Call Center. To minimize the burden on technical service providers who also support the organization, it is critical that the Survey Interviewer (SI) seek the correct technical support personnel based upon the following procedure.

Procedure

If an SI is experiencing issues with his or her computer, he or she will save and close all programs, completely shut down, and then restart his or her computer ***before contacting anyone***. If the issues persist after the restart, then the SI should log on and attempt to access the program(s) on one or more alternate computers within the Call Center. If problems continue, then the SI should request assistance from an LSI or the Coordinator *via email*, and include the following information:

1. The SI's PC *asset number* (located on the outside case of the computer tower)
2. The *timeframe* in which the issue(s) occurred
3. *The name of the program(s)* that were causing the issue(s)
4. *Any other programs* that were running, both *before* and *after* the restart, and their performance status
5. *All alternate PC asset number*(s) the SI used to test the program(s)

If a LSI or Coordinator is *not available*, then forward the email to the appropriate point(s) of contact, and copy the LSIs and Coordinator, based on the point of contact's area of support:

- Helpdesk (ext 2000):
  - *Computer hardware problems (e.g.,printer, scanner, monitor, mouse, keyboard)*
  - *MS Office (Outlook, Word, Excel, PowerPoint, Access), Acrobat, Reference Manager, OneNote, other programs not listed below*
  - *Telephone or all other issues not indicated below*
- ECC-Databases and Systems (ECC-DatebasesandSystems@stjude.org):
  - *Database problems*
  - SPSS, SAS, STATA, MPlus, TeleForm, Alchemy, DatStat, Adobe Acrobat Pro
- Chris Vukadinovich (ext. 4686, chris.vukadinovich@stjude.org) or Christie Cooper (ext. 6352, Christie.cooper@stjude.org):
  - *Network security, folder/ file access or permissions*
- Christie Cooper (ext. 6352, Christie.cooper@stjude.org):
  - *All paper and online survey issues*
- Chris Vukadinovich (ext. 4686, chris.vukadinovich@stjude.org):
  - *Hardware/software recommendations/purchases*
- Aimee Montgomery (ext. 6078, aimee.montgomery@stjude.org):
  - Laptop computer reservation or check in

Revision Record Printed 9/26/2016 2:00 PM

[211] Current Filename:		Survey Interviewer Tech Support Procedures ver1_2.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	6/27/12	C. Vukadinovich, D. Rinehart	Initial Development
1.1	7/9/13	C. Vukadinovich, R. Massey	Update Points of Contact
1.2	2/18/16	D. Rinehart, A. DiScenza, A. Cobble	Content revision
2.0	9/21/16	A. Cobble, D. Rinehart, R. Daniels	Content revision

Survey Quality Assurance Review

Background

After Long-Term Follow-Up (LTFU) Study paper surveys have been in-processed, coded, scanned, and verified, 10%-25% of the surveys are selected for a full quality assurance (QA) review that compares the entire scanned and verified data set to the actual questionnaire responses. The remaining 75%-90% undergo an abbreviated review for QA.

The key task of the QA review is to ensure the data set matches the respondent's answers and to make corrections to the dataset where necessary. All surveys are reviewed for QA by a team member other than the employee that scanned and verified the survey.

Procedure

1. Surveys assigned to a CRA for QA review may be delivered either to the CRA's work-in-progress (WIP) folder or directly to the CRA from the team member that scanned and verified the survey.

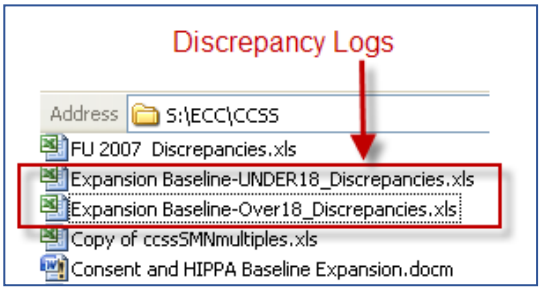
2. For each survey type to be reviewed for QA, the CRA should **select 10%-25% of the surveys for a full QA review**.

3. **Gather documents** specific to the survey type in question that are useful for the QA process:
   A. Data dictionaries – This document lists the possible response codes for each item on the survey.
      i. Expansion baseline adult case – **QA Baseline Expansion 2007 Adult ANSWER KEY-with text box types-v3 4-12-2011** and **rptExpansionAdultTeleformKey**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\BASELINE ANSWER KEY*S
      ii. Expansion baseline minor case – **QA Baseline Expansion 2007 Minor ANSWER KEY-with text box types-v4 4-12-2011** and **rptExpansionMinorTeleformKey**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\BASELINE ANSWER KEYS*
      iii. Expansion baseline adult sibling – **Sibling-Baseline Expansion 2007 Adult Key-Expanded**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\BASELINE ANSWER KEYS-SIBLING*
      iv. Expansion baseline minor sibling – **Sibling-Baseline Expansion 2007 _Minor Key**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\BASELINE ANSWER KEYS-SIBLING*
      v. Follow-Up 5 (FU5) adult case – **FU5 Adult Key**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5\Data Dictionary*
      vi. FU5 minor case – **FU5 Minor Key**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5 Minor\Data Dictionary*

vii. FU5 adult sibling – **FU5 Sibling Key**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5 Sibling*

B. Survey-specific guidance from the SOP library (e.g. **Expansion Baseline Questionnaire: Verifying and Quality Assurance Guide**)

C. Discrepancy log



i. Expansion baseline adult case – **Expansion Baseline-Over18_Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

ii. Expansion baseline minor case – **Expansion Baseline-UNDER18_Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

iii. Expansion baseline adult sibling – **Expansion Baseline-Over18_SIBLING_Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

iv. Expansion baseline minor sibling – **Expansion Baseline-UNDER18_SIBLING_Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

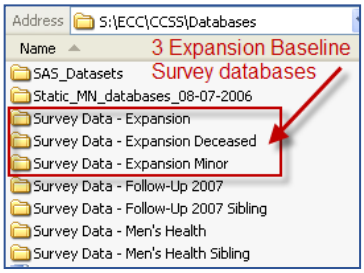
v. FU5 (one discrepancy log for all participant/survey types) – **FU5 Survey Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

4. **Open the database** containing the scanned data.

A. Expansion baseline adult case – Expansion survey data, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - Expansion*

B. Expansion baseline minor case – Expansion Minor survey data, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - Expansion Minor*

C. Expansion baseline adult sibling – SIBLING Expansion survey data, located at *Z:\SJShare\SJCOMMON\ECC\CCSS \Databases\Survey Data - SIBLING Expansion*



D. Expansion baseline minor sibling – SIBLING Expansion Minor survey data, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - SIBLING Expansion Minor*

E. FU5 adult case – FU5 survey data, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5*

F. FU5 minor case – FU5 Minor survey data, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5 Minor*

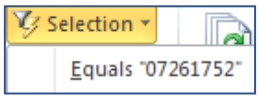
G. FU5 adult sibling – FU5 Sibling survey data, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5 Sibling*

5. **Open the table for the first section** of the questionnaire by double-clicking the table name in the Navigation Pane. NOTE: When working in the data tables, exercise extreme caution. Do

not delete records. Do not sort the records. Do not rearrange the columns in the tables. Do not change or delete values unless warranted.

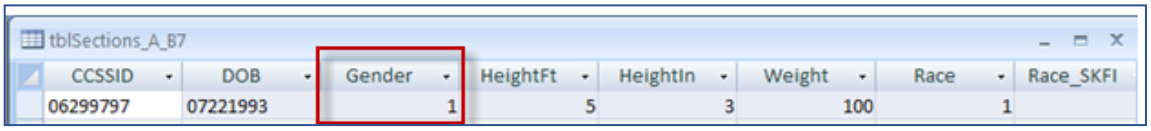
6. **Search for the CCSSID or SIBID** in question using the Find feature in Access.

7. In the Sort & Filter group of the Home tab, **use the Selection filter** to show only records with "Equals CCSSID/SIBID". This should clear the screen of all records except the single record to be reviewed.

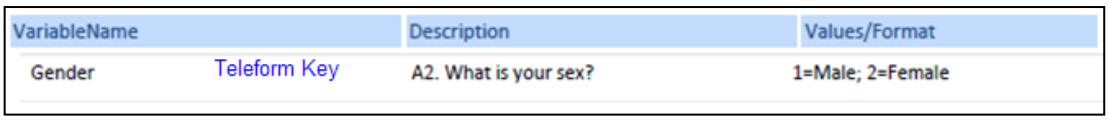


NOTE: If more than one record is displayed for a single CCSSID or SIBID, notify the Senior Coordinator-Clinical Research Operations or CRA2 before proceeding.

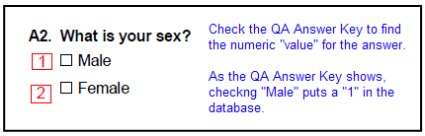
8. **Conduct the QA review for the table in question**.



A. For the 10%-25% of each survey type that will be checked item-for-item, read across the row, comparing the data in each field of the table with the corresponding response recorded on the paper survey to ensure they match. Match the column headers to the data dictionary to determine which question the data is for. If necessary, make corrections.



i. Multiple choice entries and checkboxes



a. Match the participant's response to the corresponding numeric value in the data dictionary, then ensure the value recorded in the table matches the numeric value from the data dictionary.

b. More than one answer marked or answer changed – The SOP titled **Verifying Scanned Paper Questionnaires** defines how the verifier handles questions where the respondent marked more than one answer or changed an answer. During QA, the reviewer should evaluate what s/he would have entered during verification and compare this to the data set.

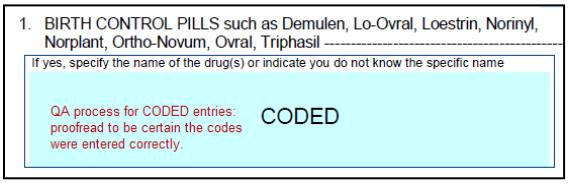
1) If the QA reviewer agrees with the entry, s/he should ensure the data exception and resolution were accurately entered into the discrepancy log.

2) If the QA reviewer does NOT agree with the entry, s/he should confer with the party who verified the survey to discuss the entry. If after conferring:

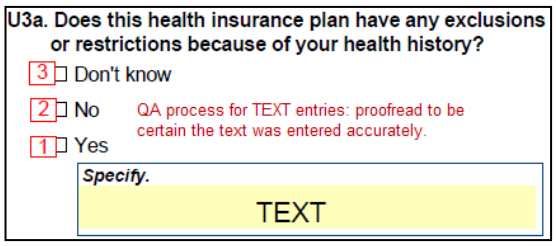
A) Both parties agree, the QA reviewer should ensure the value in the table matches the joint decision and check the discrepancy log to verify the discrepancy between the data in the table and the response on the survey has been appropriately recorded.

B) Both parties do not agree, they should consult with a third person (e.g. CRA2 or another CRA) for a tie-breaking interpretation. If necessary, correct the table and check the discrepancy log to verify the discrepancy has been appropriately recorded.

ii. Coded entries – Ensure each code recorded in the table matches each code recorded on the paper survey by the coding analyst.



iii. Text entries – Ensure the transcribed text exactly matches the participant's written text, including misspellings, etc.



iv. SKFI fields – Table fields containing "SKFI" represent skip patterns in the survey and should always be blank.

v. Discrepancy log – During QA, ensure all discrepancies and modifications to the survey response are documented in the appropriate log.

	A	B	C	
1	CCSS ID #	PROBLEM	PAGE NUMBER & QUESTION NUMBER	
44	01004042	Problem - Answer (age) wasn't clear	p. 15 Question K3- migraine?	Resolution - Question was left blank at verification
45	01004682	Problem- Participant checked 2 answers, c. and oth	p. 11 Question F15 c. "My menstrual periods are irregular	RESOLUTION-Question / answer for C was left blank ar
46	01004682	Problem- 2 people completed this survey	Front page (Your Relationship) was checked by participa	RESOLUTION-Your Relationship was left blank at verific
47	01004682	Problem - Participant had 2 people completing surv	p. 1, Person completing this questionnaire - "self" & "pare	Resolution - Entered "self"
48	01004813	Problem- Participant checked 2 answers	p. 10 Question F2, "No" & Yes and condition still present"	Resolution-"YES" was marked at verification because P
49	01004813	Problem- Participant checked 2 answers	p. 14 Question J37, (any other surgery?) "Yes and NO" ma	Resolution-"YES" was marked at verification because P
50	01004813	Problem - Participant checked 2 answers	p. 10, Question F2 - underactive thyroid gland - "No" & "Ye	Resolution - Question was left blank at verification, adde
51	01004813	Problem - Participant checked 2 answers	p. 14, Question J37 - Any other surgery - "No" and "Yes" m	Resolution - Entered "Yes" and entered listed surgeries
52	01004813	Problem - Participant provided information regardin	p. 23, Question Q3 - Births - Participant listed adoption	Resolution - Question was left blank at verification
53	01004813	Problem - Participant child - unknown parents due t	p. 23, Question Q4 - Name of biological parents	Resolution - Question was left blank at verification

a. In the appropriate discrepancy log, search (Ctrl-F) for the CCSSID or SIBID associated with the survey being reviewed.

b. Locate the discrepancy for the specific item by the page and question numbers. NOTE: The log may include multiple issues for a single participant ID.

c. If the discrepancy IS noted in the log, verify that the documented resolution matches what is in the data table.
   1) If it does match, no further action is needed.
   2) If it does not match, confer with the individual who verified the survey for an explanation. As needed, correct the discrepancy log.

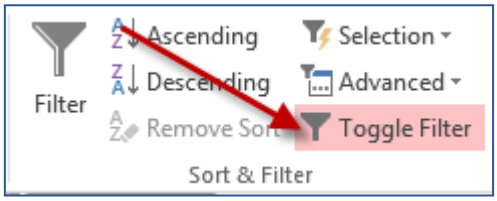
d. If the item IS NOT in the discrepancy log:
   1) And the database DOES need to be corrected, document the issue and resolution in the first blank row of the discrepancy log, then change the entry in the database.
   2) And the database DOES NOT need to be corrected, document the issue and resolution in the first blank row of the discrepancy log.

B. For the 75%-90% of each survey type that will undergo the abbreviated QA review:

i. At a minimum, verify that the CCSSID/SIBID is found in the data table. If it is not in the first table, check the other tables, and then give the survey to the Senior Coordinator-Clinical Research Operations or CRA2, reporting the situation as you

found it. (The survey will likely need to be scanned and verified again after corrections are made to any tables in which the CCSSID/SIBID did appear.)

ii. When time allows, also review the survey page by page and complete the "full QA" procedures only on:
   a. Coded entries (in red)
   b. Text entries
   c. Questions where more than one answer was recorded or an answer was changed



9. **Toggle the filter off** so that the entire table is displayed again.

10. **Close the table** in question. If a prompt displays to save changes to the design of the table, click the **No** button.

11. **Repeat the QA procedures on each table** starting with the second table and moving sequentially through the entire survey. – The database contains a table for each section of the survey. Note that some tables may contain multiple survey sections. Start at the BEGINNING of the completed questionnaire, and work sequentially through each section. Example from Expansion Baseline:

1. tblCoverPage_HIPAA
2. tblSections_A-B7
3. tblSection_B8
4. tblSection_C
5. tblSections_D_E
6. tblSections_F_G
7. tblSections_H_I
8. tblSection_J
9. tblSection_K
10. tblSection_L
11. tblSections_M_N
12. tblSection_O
13. tblSections_P_Q
14. tblSections_RSTUV (in the MINOR database, this is called tblSection_R_S_T_U_V)
15. tblContact_Info

12. For ALL surveys: If the QA finds more than a few differences between the data in the tables and the responses on the survey, flag the survey booklet pages and then refer the survey to the CRA2 after making the corrections in the data tables. The CRA2 monitors to find out if there is a systematic problem with scanning/verifying

13. After the entire survey is checked, **document the QA** just above the horizontal line at the bottom right of the survey as follows:
   A. For the 10%-25%: "full QA –initials date".
   B. For the 75%-90%: "QA –initials date".

14. **Update the appropriate assignment spreadsheet**:
   A. Expansion baseline cases and siblings – **!TrackingBaselineScanning-QA**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\!ASSIGNMENTS*

B. FU5 cases and siblings – **!FU5TrackingScanning**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5*

15. **File the survey** numerically by participant ID in the appropriate locked cabinet.

Revision Record Printed 10/30/2015 4:07 PM

Current filename:		QA Review for Expansion-Baseline-post scanning ver 3_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	2/12/09	S. Wahpehah/N. Huffman	Initial Development
2.0	12/7/09	J. Bates	
2.1	7/3/12	J. Bates	Filter records in db tables; add ref to scanning/verify guide
3.0	8/3/12	J. Bates	Define random selection and QA rules
3.1	10/30/15	R. Massey, J. Ford	Title change, reorganization of content, added location of tools, updated abbreviated QA procedures, removed section-specific tips for baseline

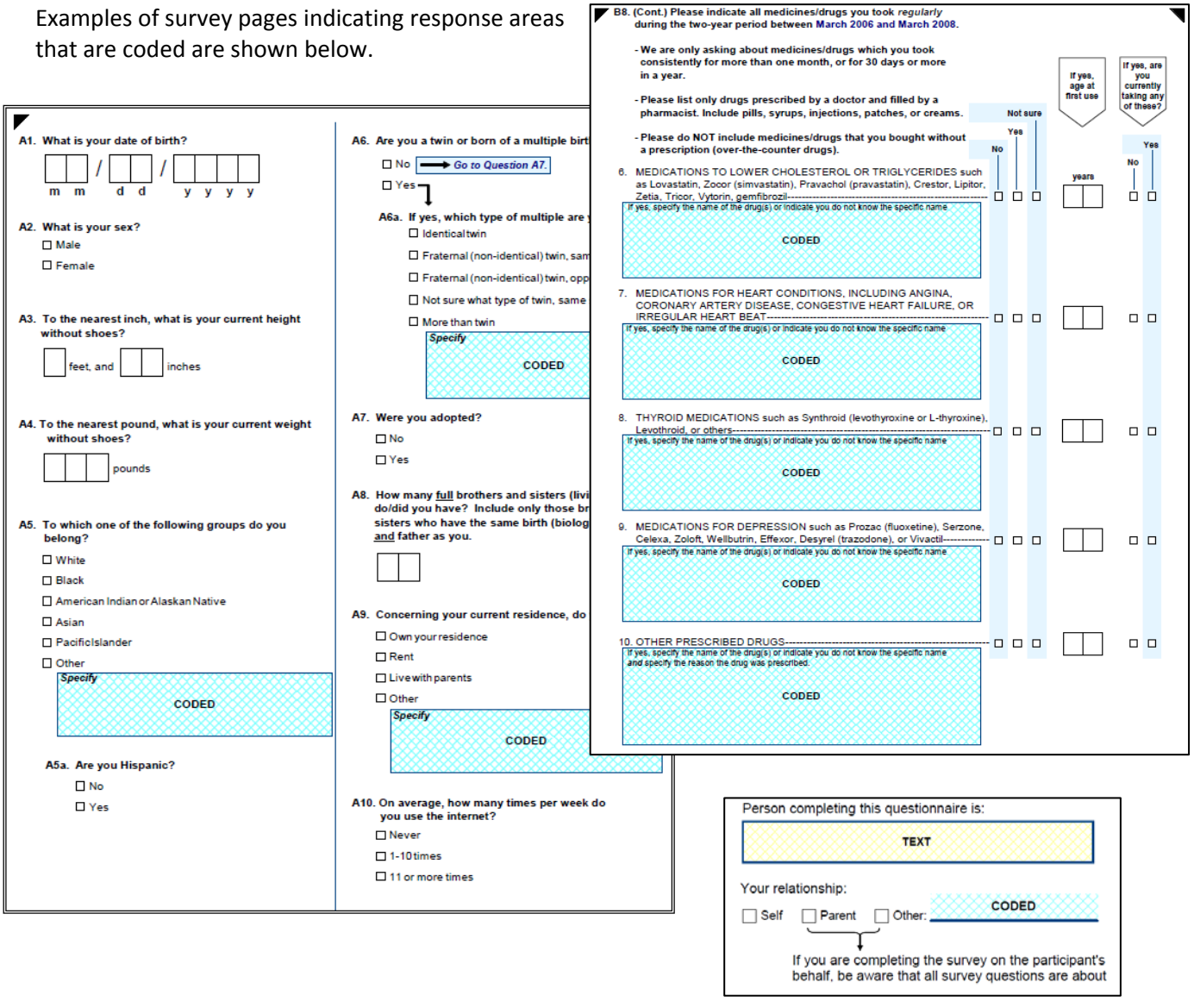
Survey Response Coding

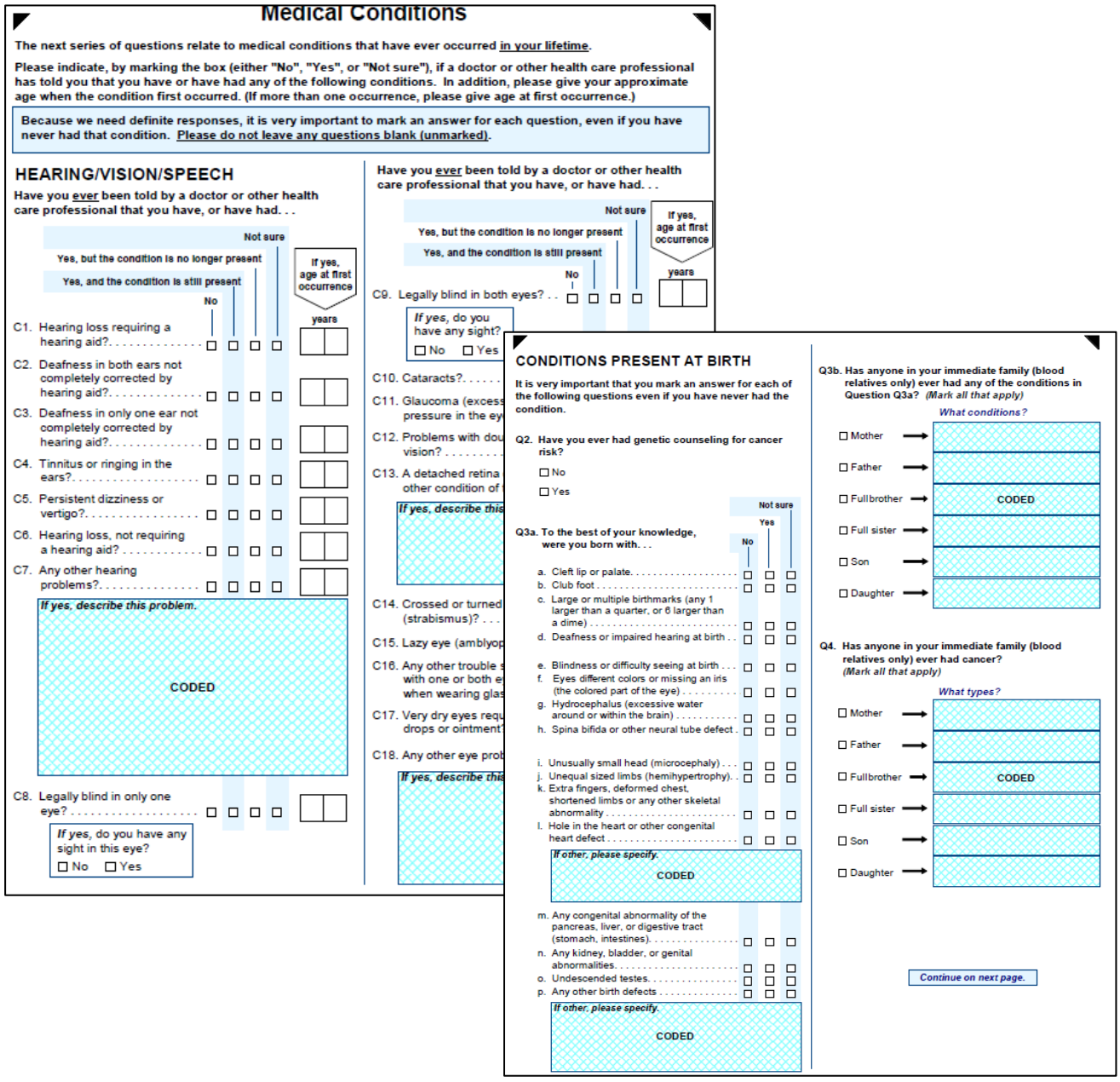
Background

Some responses to survey questions need to be translated to coded values. These items include responses that describe conditions, diagnoses, treatments, medications, as well as certain other values. The coding is done after the survey is in-processed, but before the document in scanned. During the scanning verification process, the coded values are manually keyed into the verification system using the coded value that the nosologist hand-wrote on the paper questionnaire. Questionnaires submitted online are coded using a separate database that inputs the numeric code into the survey data set. The appropriate code book is used for each coding category.

Code book	Used for
ICD-9 CM	Diagnoses/diseases
MedSupnu	Drugs
Department-created lists	Demographics

Examples of survey pages indicating response areas that are coded are shown below.





Medical Conditions

The next series of questions relate to medical conditions that have ever occurred in your lifetime.

Please indicate, by marking the box (either "No", "Yes", or "Not sure"), if a doctor or other health care professional has told you that you have or have had any of the following conditions. In addition, please give your approximate age when the condition first occurred. (If more than one occurrence, please give age at first occurrence.)

Because we need definite responses, it is very important to mark an answer for each question, even if you have never had that condition. Please do not leave any questions blank (unmarked).

HEARING/VISION/SPEECH

Have you ever been told by a doctor or other health care professional that you have, or have had. . .

	No	Yes, and the condition is still present	Yes, but the condition is no longer present	Not sure	If yes, age at first occurrence (years)
C1. Hearing loss requiring a hearing aid?	☐	☐	☐	☐	
C2. Deafness in both ears not completely corrected by hearing aid?	☐	☐	☐	☐	
C3. Deafness in only one ear not completely corrected by hearing aid?	☐	☐	☐	☐	
C4. Tinnitus or ringing in the ears?	☐	☐	☐	☐	
C5. Persistent dizziness or vertigo?	☐	☐	☐	☐	
C6. Hearing loss, not requiring a hearing aid?	☐	☐	☐	☐	
C7. Any other hearing problems?	☐	☐	☐	☐	

If yes, describe this problem.

CODED

C8. Legally blind in only one eye?	☐	☐	☐	☐	

If yes, do you have any sight in this eye? ☐ No ☐ Yes

Have you ever been told by a doctor or other health care professional that you have, or have had. . .

	No	Yes, and the condition is still present	Yes, but the condition is no longer present	Not sure	If yes, age at first occurrence (years)
C9. Legally blind in both eyes?	☐	☐	☐	☐	

If yes, do you have any sight? ☐ No ☐ Yes

C10. Cataracts?

C11. Glaucoma (excess pressure in the ey

C12. Problems with dou vision?

C13. A detached retina other condition of

If yes, describe this

C14. Crossed or turned (strabismus)?

C15. Lazy eye (amblyop

C16. Any other trouble with one or both e when wearing glas

C17. Very dry eyes requ drops or ointment

C18. Any other eye prob

If yes, describe this

CONDITIONS PRESENT AT BIRTH

It is very important that you mark an answer for each of the following questions even if you have never had the condition.

Q2. Have you ever had genetic counseling for cancer risk?

☐ No
☐ Yes

Q3a. To the best of your knowledge, were you born with. . .

	No	Yes	Not sure
a. Cleft lip or palate	☐	☐	☐
b. Club foot	☐	☐	☐
c. Large or multiple birthmarks (any 1 larger than a quarter, or 6 larger than a dime)	☐	☐	☐
d. Deafness or impaired hearing at birth	☐	☐	☐
e. Blindness or difficulty seeing at birth	☐	☐	☐
f. Eyes different colors or missing an iris (the colored part of the eye)	☐	☐	☐
g. Hydrocephalus (excessive water around or within the brain)	☐	☐	☐
h. Spina bifida or other neural tube defect	☐	☐	☐
i. Unusually small head (microcephaly)	☐	☐	☐
j. Unequal sized limbs (hemihypertrophy)	☐	☐	☐
k. Extra fingers, deformed chest, shortened limbs or any other skeletal abnormality	☐	☐	☐
l. Hole in the heart or other congenital heart defect	☐	☐	☐

If other, please specify.

CODED

m. Any congenital abnormality of the pancreas, liver, or digestive tract (stomach, intestines)	☐	☐	☐
n. Any kidney, bladder, or genital abnormalities	☐	☐	☐
o. Undescended testes	☐	☐	☐
p. Any other birth defects	☐	☐	☐

If other, please specify.

CODED

Q3b. Has anyone in your immediate family (blood relatives only) ever had any of the conditions in Question Q3a? *(Mark all that apply)*

	What conditions?
☐ Mother →	
☐ Father →	
☐ Full brother →	CODED
☐ Full sister →	
☐ Son →	
☐ Daughter →	

Q4. Has anyone in your immediate family (blood relatives only) ever had cancer? *(Mark all that apply)*

	What types?
☐ Mother →	
☐ Father →	
☐ Full brother →	CODED
☐ Full sister →	
☐ Son →	
☐ Daughter →	

Continue on next page.

Revision Record

Printed 7/9/2012 1:05 PM

Current Filename:		Survey Coding ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	11/16/10	J.Bates	Initial Development

Survey Scanning, Verifying, and Quality Assurance Tracking

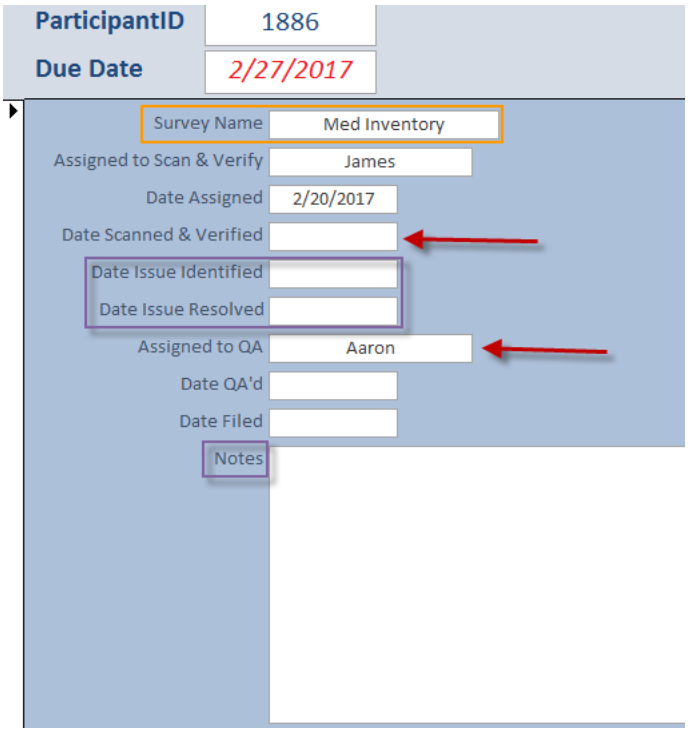
Background

After surveys are received and in-processed, they are assigned to a coder (if applicable) and to at least two staff members to scan, verify, and quality assurance check (SVQA). In order to keep track of the flow of the SVQA process, all SVQA activities are logged in the Survey SVQA Tracking database, with the exception of a few projects (e.g., St. Jude LIFE). If during the SVAQ process a survey discrepancy is found (e.g., the participant marked multiple answers), then these are also entered in the database.

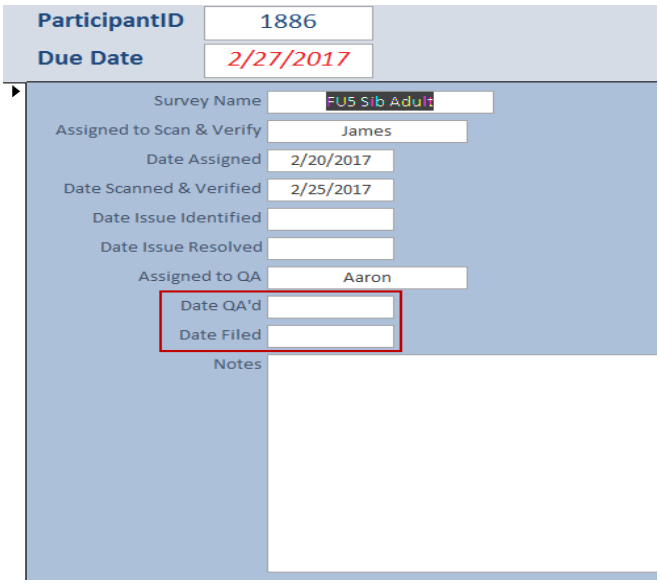
Procedures

Assignment Tracking

1. Click the *Assignment Tracking* button to see all surveys that need to be scanned and verified, QA'd, and/or filed.
2. Search by *ParticipantID* to find the survey record of interest
   a. A *Due Date* is assigned to each survey (typically 7 days for CCSS survey; more for non-CCSS)
3. Verify that the *Survey Name* matches the survey type
4. If you are assigned to scan and verify a survey:
   a. Enter the date you scanned and verified in the *Date Scanned & Verified* field
      i. If there was an issue with scanning and verifying:
         1. Enter the date in *Date Issue Identified*
         2. Add a note in the *Notes* field (e.g., gave survey to Christie to add space)
      ii. After Christie returns the survey to you, enter the date in *Date Issue Resolved*
   b. Place the survey in the hanging folder of the person *Assigned to QA*



5. If you are <u>assigned to QA</u> a survey:
   a. Enter the date you QA'd in the *Date QA'd* field
      i. If there was an issue with QAing:
         1. Enter the date in *Date Issue Identified*
         2. Add a note in the *Notes* field (e.g., gave survey to Christie to add space)
      ii. After Christie returns the survey to you, enter the date in *Date Issue Resolved*
      iii. File survey in the appropriate cabinet and enter *Date Filed*



<u>To View Assignments</u>

1. To see a snap-shot of the surveys <u>assigned to you to scan and verify</u>
   a. Click *Scanning & Verifying Assignments,* enter your name, and click *OK*
   b. This report shows all surveys assigned to you that do not have a *Date Scanned & Verified*

Scanning & Verifying Assignments

Due Date	Survey Name	ParticipantID	Assigned to S&V	Date S&V	Assigned to QA	Date Issue Identified	Date Issue Resolved
2/27/2017	FU5 Adult	1886	Jane		John		
2/27/2017	FU5 Minor	1886	Jane		John		
2/27/2017	FU5 Sib Adult	1886	Jane		John		

2. To view the surveys <u>assigned to you to QA</u>
   a. Click *QAing Assignments*, enter your name, and click OK
   b. This report shows all surveys assigned to you that do not have a *Date QA'd* and/or *Date Filed*

QAing Assignments

Due Date	Survey Name	ParticipantID	Assigned to S&V	Date S&V	Assigned to QA	Date QAd	Date Issue Identified	Date Issue Resolved	DateFiled
2/27/2017	FU5 Adult	1886	Jane	2/21/2017	John				
2/27/2017	FU5 Minor	1886	Jane	2/21/2017	John				
2/27/2017	FU5 Sib Adult	1886	Jane	2/21/2017	John				

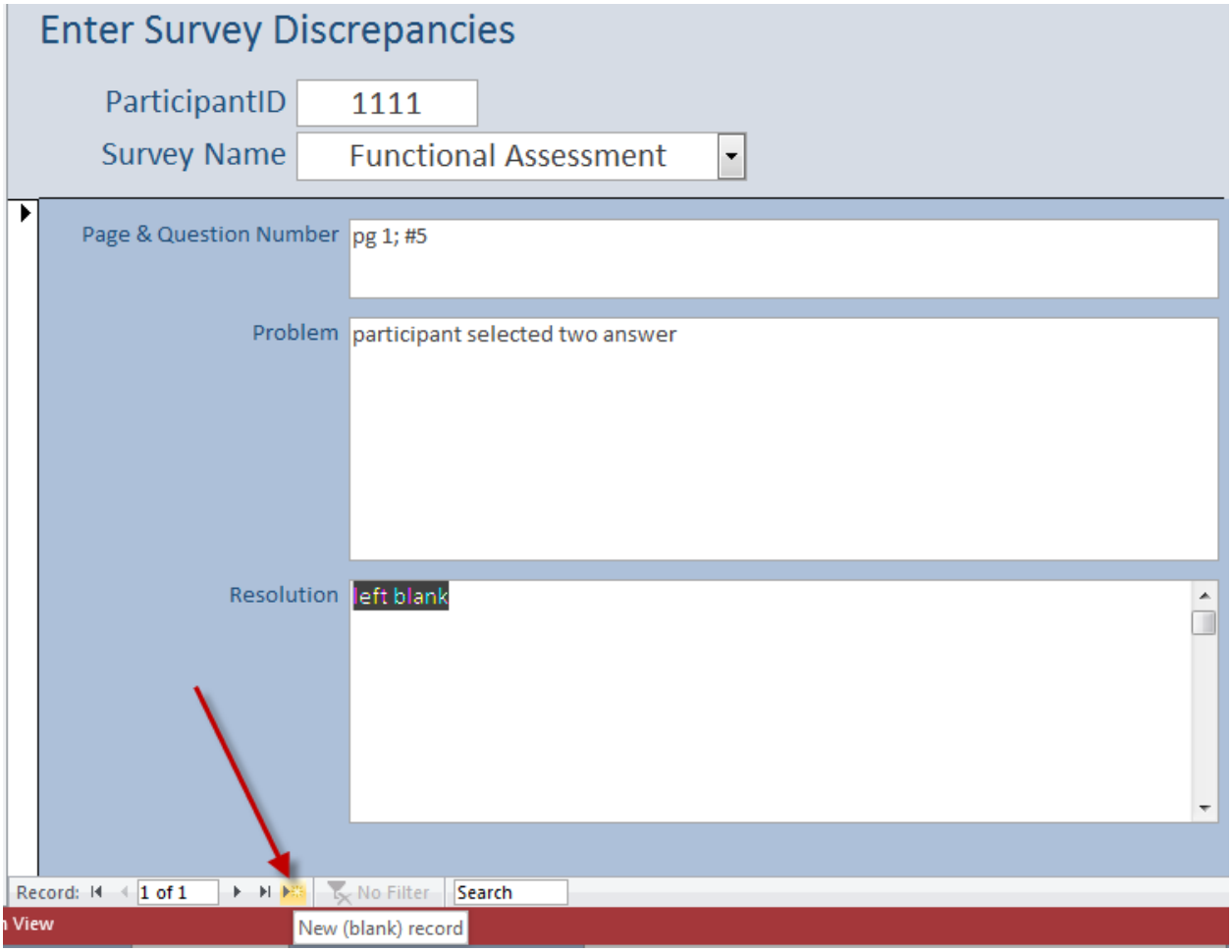
3. To view the surveys assigned to you that <u>have a scanning, verifying or QA issue</u>
   a. Click *Surveys with SVQA Issues*, enter your name, and click OK
   b. This report shows all surveys assigned to you with a *Date Issue Identified* but *Date Issue Resolved* is blank

Surveys with Scanning, Verifying, or QAing Issues

Due Date	Survey Name	ParticipantID	Assigned to S&V	Date S&V	Assigned to QA	Date QAd	Date Issue Identified	Date Issue Resolved	DateFiled	Notes
2/27/2017	FU5 Adult	1886	John	2/21/2017	Jane		2/22/2017			need more space for question E10
2/27/2017	FU5 Minor	1886	John	2/21/2017	Jane		2/22/2017			unable to commit survey after scanning three time; gave to Christie
2/27/2017	FU5 Sib Adult	1886	John	2/21/2017	Jane		2/22/2017			need more space for question A4

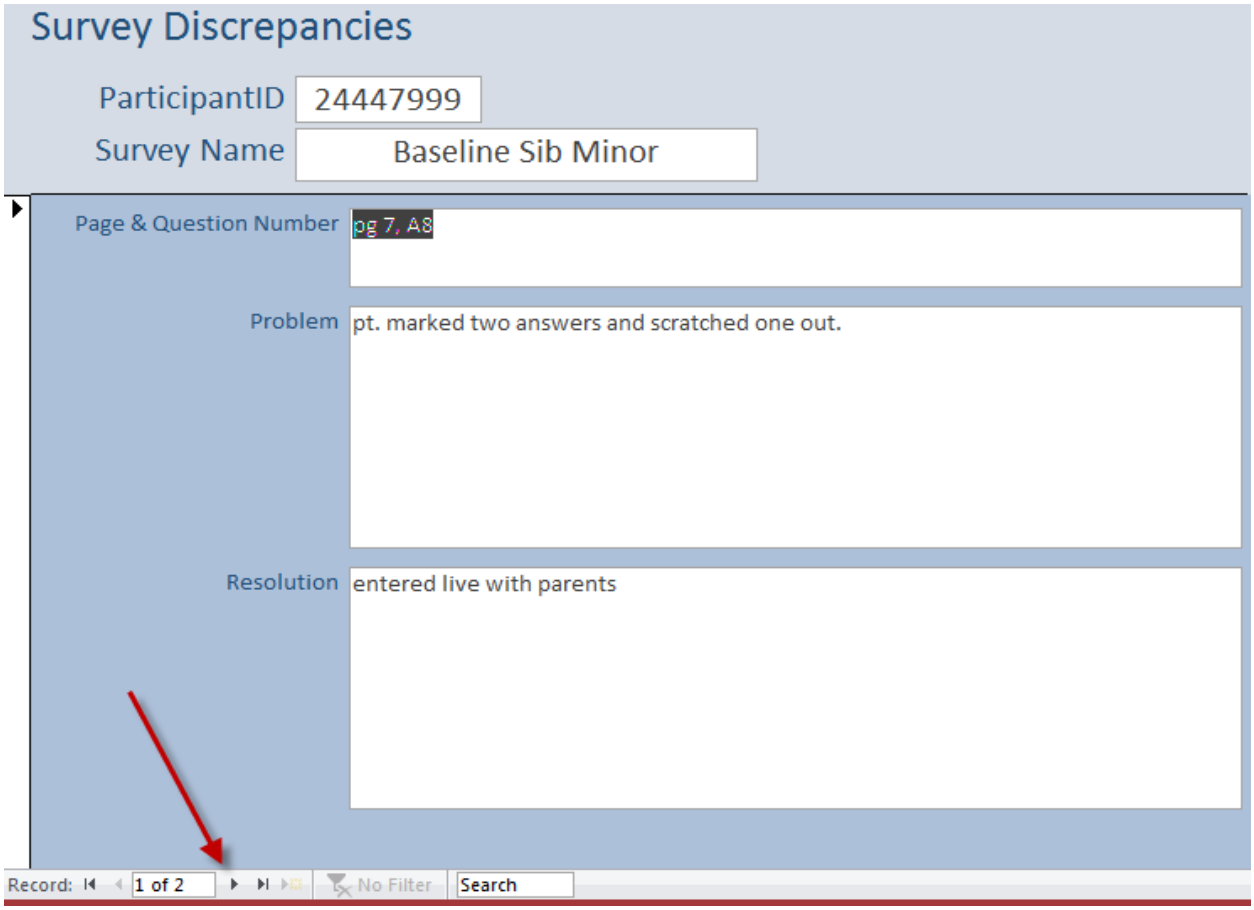
Entering Survey Discrepancies

1. When you identify a discrepancy on a survey, click the *Enter Discrepancies* to open a blank record
2. Enter *ParticipantID*
3. Select the appropriate *Survey Name* from the dropdown menu
4. Add *Page & Question Number, Problem,* and *Resolution* (NOTE: Be sure to move your cursor out of the last field in which you entered data in order to save your work)
5. If you need to enter multiple discrepancies:
   a. Click the *New (blank) record* button to create a new, blank record



Viewing Survey Discrepancies

1. To view survey discrepancies, click *View Discrepancies,* enter *ParticipantID*, and click *OK*
   a. This form shows all survey discrepancies logged for the *ParticipantID*
2. Verify that the *Survey Name* matches the survey type
   a. You may need to scroll through several records before you find the discrepancies of interest
3. If necessary, you can edit the *Page & Question Number, Problem,* and *Resolution* fields
4. To view the discrepancies for a different participant, either press F5 on your keyboard or close the form and reopen it from the main menu



Revision Record
Printed 4/3/2017 12:43 PM

Current Filename:		Survey SVQA Tracking ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	4/4/17	J. Ford	Initial Development

Telegenetics Pilot Project Calls

Background

The University of Pennsylvania may be able to work remotely with the Long-Term Follow-Up (LTFU) Study participants (pts) who have questions about their personal or family history of cancer, to provide counseling from a licensed genetic counselor to help them to better understand their risk.
This is NOT part of the LTFU Study, however, given the importance of the topic of family cancer risk, we are initiating a Telegenetics Pilot Project (TPP), to make selected pts aware of this opportunity to receive high quality genetic assessment.

The CCSS Coordinating Center will mail letters with informational flyers (Telegenetics Pilot Mailing) to 20 CCSS pts. Approximately 14 days later, follow-up calls begin to all TPP non-responders. The role of the SI is to provide the program contact information only. If the pt has questions, we will acknowledge their question *("That's a great question…"*), then give them the program contact information. Calls end when we reach a "Terminal Call Outcome" or have called all numbers for the pt 5 times.

Tools Needed:

1. **TPP Call Assignments.xlsx**
2. **Telegentics flyer followup script_dr_r2.docx**
3. **Telegenetics SI Email Template rev.docx**
4. **The SOP**, **LTFU Participant Database Data Entry** (*Located in Sharepoint…SOP Library*)
5. **CCSS LTFU Participant Database**

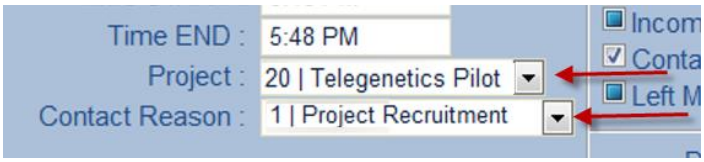
Procedure

Before the Call

1. Open the assignments Excel file, **TPP Call Assignments.xlsx**, (from this location, *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\Interviewers\Telegenetics Pilot*)
2. Open the **CCSS LTFU Participant Database** (*Located in Sharepoint…*)
3. Locate the pt and perform a pre-call profile analysis
    a. What time zone does the pt reside?
    b. Any CCSS Study outcomes or CCSS Holds?
    c. Are the Tracing fields populated?
    d. When was the last time the pt was called and why?
    e. Is there any critical information in any of the Notes fields? (Contact/Trace Logs, Participant/Associate/Project tabs)
    f. Is the pt currently in more than one active study project?
    g. Is there any reason we should NOT contact the pt?
    h. When were the contact fields last updated for the pt?
    i. What is the history of the HIPAA, CCSS and Ancillary project history?

During the call:

1. Use the **Telegentics flyer followup script_dr_r2.docx** (from this location, *Z...Interviewers\Telegenetics Pilot*)
2. Verify/confirm all **contact information** for the pt and his/her associates, according to the instructions in the SOP, **LTFU Participant Database Data Entry** (*Located in Sharepoint…SOP Library*).
3. Create a new **Contact Log,** in the **LTFU Participant Database**
    a. Follow the general guidelines and procedures outlined in the SOP, **LTFU Participant Database Data Entry**
    b. Populate the **Project** field, **20 Telegenetics Pilot**
    c. Populate the **Contact Reason** field, **2 Project Recruitment**



    d. **Standard Call Outcomes**
        i. **2 No Answer**
        ii. **3 No answer/left message**
        iii. **4 Appt made**
        iv. **5 Resend** (*When pt requests a resend of the Telegenetics Pilot Mailing and/or an email with this information, but does not indicate commitment to call the Telegenetics Program Manager at the University of Pennsylvania*). Use the email template, **Telegenetics SI Email Template rev.docx** (from this location, *Z...Interviewers\Telegenetics Pilot*), when sending emails to the pt.
        v. **6 Disconnect**
        vi. **10 Other**
        vii. **11 Wrong #**
    e. **Incoming Call Outcomes**
        i. **Other**
            1. If transferring the call to the assigned pilot project SI
            2. If caller provides non-project terminal information (see section, **Project Terminal Call Outcomes**)
        ii. Unsure? If call outcome is not a project terminal outcome
            1. Consult with an LSI, Coordinator, Project Manager or Research Scientist

4. **Project Terminal Call Outcomes**
    a. For ***ALL TERMINAL OUTCOMES*** (outcomes that end project follow-up calls), follow the call Outcome chart below

No.	Call Scenarios	Contact/Trace Log Outcome Field	Notes Field	Other Actions Required
1	Pt is not interested	**7 Refused**	Specifying pilot-only refusal	Email PM. No other actions.

No.	Call Scenarios	Contact/Trace Log Outcome Field	Notes Field	Other Actions Required
2	Pt refuses project only	**7 Refused**	Specifying pilot-only refusal	Email PM. No other actions.
3	Pt refuses project and CCSS	**7 Refused**	Specifying pilot and CCSS refusal	Email PM. Complete all processes outlined in the appropriate SOPs
4	Pt has expired	**8 Deceased**	As necessary	Email PM. Complete all processes outlined in the appropriate SOPs
5	Pt is interested and says that they will enroll	**13 Will Enroll**	As necessary	Email PM. No other actions.
6	Pt says they already enrolled	**13 Will Enroll**	As necessary	Email PM. No other actions.
7	Pt is interested and requests information via email	**13 Will Enroll**	Add a note indicating the request	Email PM. Send an email using the project email template. No other actions.
8	Pt is interested, requests a resend of the Telegenetics Pilot Mailing, and says they plan to enroll	**13 Will Enroll**	Add a note indicating the request	Email PM. Send an email using the project email template. No other actions.

b. Send an email to the Project Manager (James Ford), and copy the Research Scientist (Aaron McDonald), Coordinator (Dayton Rinehart) and LSI Team (Andrew Cobble and Robbin Daniels).

Revision Record Printed 5/16/2018 12:05 PM

Current Filename:		Telegenetics Pilot Project Calls ver1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	4/27/18	D. Rinehart	Initial Development
2	5/15/18	P. Davis, D. Rinehart	Content revision

Tracing Database Data Entry

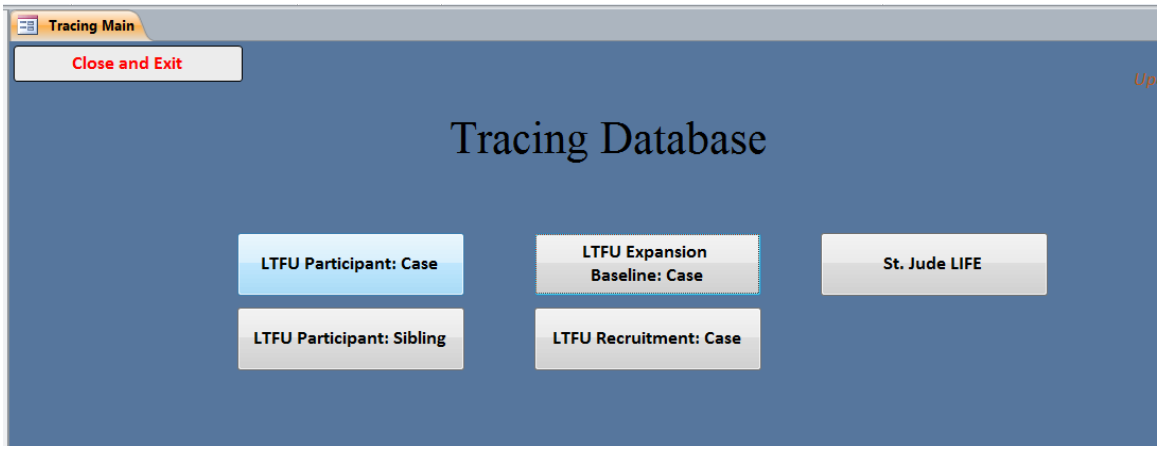
Background

In order to preserve grant funds, Tracing resources were streamlined in 2015 by changing from individual LexisNexis (LN) searches to batch data from LN. Three times annually, the Coordinating Center submits all active Long-Term Follow-Up (LTFU) Study and St. Jude Life (SJLIFE) Study parties to LN, and LN either returns deceased information for the party or returns the 3 best mailing addresses, 3 best telephone numbers, 6 best relatives with address and phone number, and 6 best associates with address and telephone number. Active study parties include potential participants being recruited to the LTFU Study, participants who have initiated enrollment by signing the institutional HIPAA but who still need to complete the LTFU Study baseline survey, alive participants who have completed the LTFU Study baseline survey and who have not refused all else, and SJLIFE participants.

The returned LN batch data will be stored in the CCSS Tracing Database and will be accessed by the Tracing team as well as the Survey Interviewer (SI) team. Tracers will actively update this database with tracing notes and other tracing information, and SIs will generally use the database as a read-only resource.

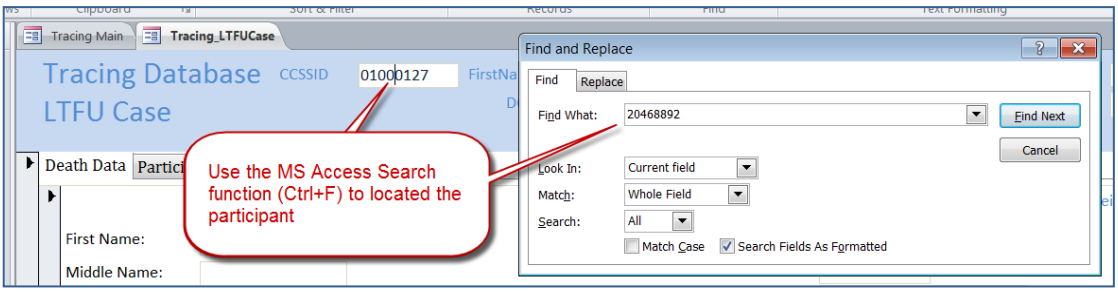
Procedures

1. Open the CCSS Tracing Database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx. The main switchboard will display.



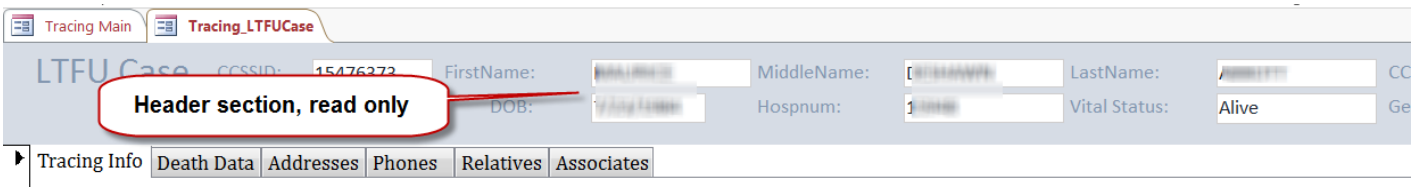
2. Click the button for the database and participant status of the party in question.
   NOTE: Each participant is found in the Tracing Database only once. For example, an expanded cohort case that has rolled over from the CCSS Recruitment database to the CCSS Expansion Tracking database to the CCSS LTFU Participant database will have a historical record in all three of these databases but will *only* be found in the Tracing Database under the **LTFU Participant: Case** button.

3. Use the MS Access Find feature to locate the record in question.
   A. Click into the field on which the search should be based. *For example, click in the CCSSID field of the header to search based on CCSSID*.



   B. Either click the Find (binoculars) button in the Find group on the Home tab of the Access Ribbon or use the <Ctrl><f> shortcut to open the Find and Replace window.
   C. In the **Find What** field, enter the search criteria. *For example, if searching by CCSSID, enter the CCSSID of the participant in question*.
   D. Select the appropriate value in the **Match** field.
   E. Uncheck the **Search Fields As Formatted** checkbox.
   F. Click the **Find Next** button one or more times until the correct record displays.

4. Review the information provided in the participant's LN batch data.
   A. Header – The header group displays read-only information from the parent database.



   B. Death Data tab – The Death Data tab displays at the front of the participant record. If LN believes the party to be deceased, the death data will be returned and all other data collection in the batch for this party stops. The Participant, Relative, and Associates tabs will not contain new information from LN for these parties.

i. Data Sent to LN – The first column displays the participant information sent to LN by the Coordinating Center. This is the information LN used to locate their best matched data.

ii. Lexis Nexis Data – The second column displays the deceased party LN matched to the submitted data, if any. This column also displays codes to indicate specifically which data was matched. *For example, a code of NS indicates that the deceased party's name and full SSN matched the submitted data but does not indicate a match based on address, city/state, or ZIP code*.

a. **Review Status** – Deceased information returned by LN will need to be reviewed by a Tracer for confirmation. The outcome of such review (i.e. confirmed deceased, confirmed alive, or unable to determine) will be indicated in this field.

b. **Review Status Date** – If a Tracer has reviewed the deceased information and entered a determination outcome, the date of the outcome will be documented here.

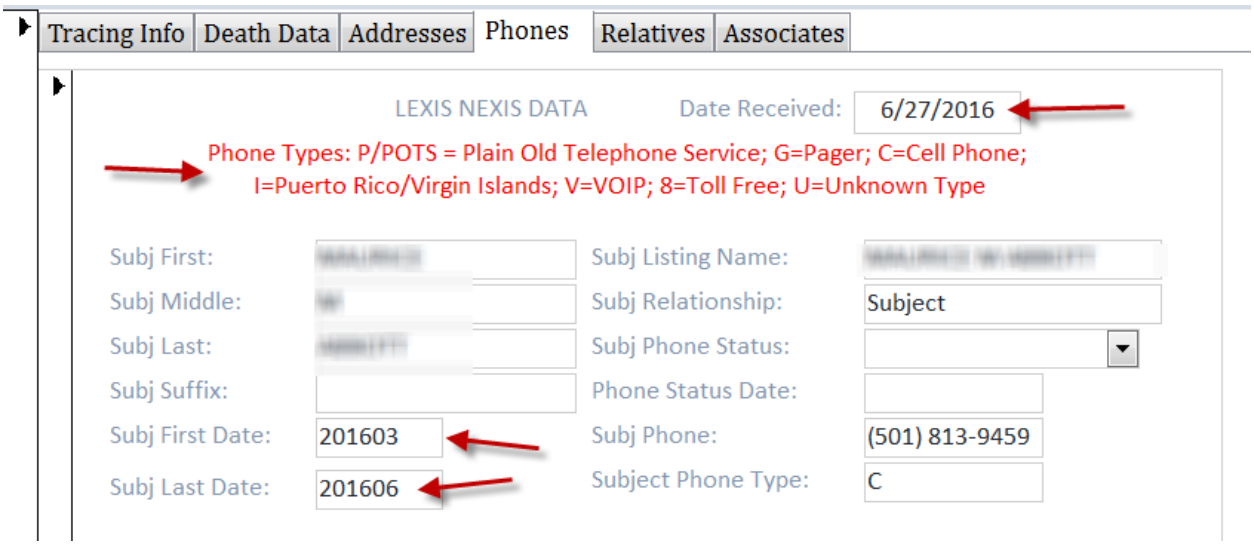
C. Phone tab – The Phone tab provides the best 3 phone numbers for the participant.

i. Date Received – the date Lexis Nexis sent us the data

ii. Phone Types – the legend for the value in the field, "Subject Phone Type"

iii. Subj First Date – the earliest date the number is associated with the participant

iv. Subj Last Date – the last date the number is associated with the participant

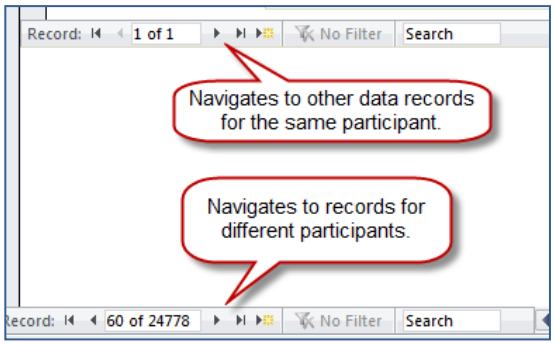


D. Relatives tab – The Relatives tab displays the 6 best matches for potential relatives based on the information the Coordinating Center sent to LN. Each potential relative will display a name and LN's best address and telephone number for the potential relative.

E. Associates tab – The Associates tab displays the 6 best matches for potential associates based on the information the Coordinating Center sent to LN. Each potential associate will display a name and LN's best address and telephone number for the potential associate.

F. Tracing Info tab – The Tracing Info tab will display prior tracing notes along with the date and Tracer ID for each past trace. *Individual tracing calls and call outcomes are recorded in the Trace Log of the parent database.*

G. Note that each tab has the potential to store records from multiple LN data batches. For any party that has data from multiple batches, use the forward and backward buttons to navigate to data from previous or subsequent LN batches.



5. Update the Tracing Info tab – Tracers should enter non-call-related tracing notes into the Tracing tab for each trace. Note that once the user has left a newly created record, the record cannot be edited.
   A. **Trace Date** – Enter the date the trace occurred.
   B. **Tracer ID** – Enter the SI ID of the Tracer creating the trace record.
   C. **DB Change** – If an LSI-level change needs to be made to the participant's or potential participant's record in the parent database (e.g. DOB change, gender change, participant is suspected to be ineligible, legal name change, survival status change, etc.), flag the change request using the drop-down menu in this field. *IMPORTANT: Clear notes regarding the change request must be documented in the **Tracer Comments** field of the same trace record.*
   D. **Address Found** checkbox – If the party's mailing address is located in online resources, mark this checkbox.
   E. **Address Confirmed** checkbox – If the party's address is confirmed with a live person, mark this checkbox.
   F. **Phone Found** checkbox – If the party's telephone number is located in online resources, mark this checkbox.
   G. **Phone Confirmed** – If the party's telephone number is confirmed with a live person, mark this checkbox.
   H. **Tracer Comments** – Enter clear, concise, and thorough notes of all non-call-related information relevant to this trace. If an LSI-level change was requested in the **DB Change** field of this trace record, ensure clear notes regarding the requested change are also documented in this field.

Revision Record — Printed 7/5/2016 10:08 AM

[295]Current Filename:		Tracing Database Data Entry ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	5/28/2015	A. McDonald, D. Rinehart, R. Massey	Initial Development
1.1	6/28/2016	A. Cobble, R. Daniels, D. Rinehart	Content revision

Tracing Lost Participants

Background

Potential and existing study participants whom we have been unable to contact by mail or phone are referred for tracing. The Call Center Coordinator assigns these "lost participants" to members of the Tracing team. The tracing effort is a search for new information from both electronic and human sources to verify the contact information for the participant or his/her legal representative, preferably by making direct contact with the person sought.

Successful tracing depends first on a thorough review of our documented information, including past tracing history, to avoid unnecessary duplication of effort. The Survey Interviewer (SI) Tracer ultimately seeks to identify a web of interconnections which may pinpoint the person in question. Procedurally, the Tracer thoroughly documents the resources used, potential connections identified, and the outcomes of contacting the connections so there will be a historical record to inform future tracing for the case or sibling. Tracing succeeds when we obtain a phone number and/or physical address confirmed as belonging to the individual sought. When a case or sibling is successfully traced, the appropriate contact/tracking database is updated and the tracing code is cleared.

Note: The following information is subject to change. Please contact a Lead Survey Interviewer (LSI) or the Coordinator if you have any questions.

Procedures

Background Review

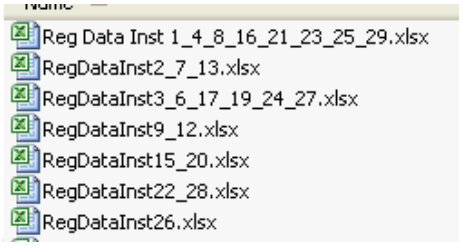
1. Familiarize yourself with what we already know about the participant:
    A. Name, age, date of birth
    B. Vital status (living or deceased) and date of death, if deceased
    C. Address and phone numbers currently on file
    D. Name, address, and phone numbers of parents, spouse, additional contacts, and other associates
    E. Archived addresses (for case/sibling as well as relatives)
    F. Contact history and last evidence of contact
    G. Any notes indicating why the participant was sent to tracing (e.g., when recent mail was returned to sender, when existing phone numbers were last called, when phone numbers were coded as disconnected, etc.)
    H. Note any phone numbers coded with "37" which means DO NOT CALL this number.
    I. Notes from previous tracing efforts, including potential connections identified and calls to individuals who were found to NOT have information. This may include potential phone numbers that were called without actual contact being made.

2. For Expansion Cohort *RECRUITMENT* Cases:
    A. The Recruitment database houses records for expanded cohort cases we are currently attempting to recruit or have previously recruited to the LTFU Study.
        i. The Recruitment database screens useful to Tracers are:
            a. The main form header, which displays the case's name, **Birth Date**, gender (1 = male, 2 = female), diagnosis, **Diagnosis Date**, **Death Date**, **Spanish Status**, and **Alive** (1= alive, 2=deceased) fields. A red message box indicates the case has already been recruited and has rolled over to the Expansion Tracking database.
            b. The QUEST tab, which displays the case's most recent address, phone number(s), email address(es), and the **Comments** field. The Quest tab also has buttons that let you access a call log for each phone number displayed.
            c. The TRACKING tab, which displays eligibility, **Tracing Code** (indicating that we need a good mailing address, phone number, or both) with **Tracing Date**, mailing activity, and **Outcome Code** with **Outcome Date**. The **Recruit Notes** provide information about mailings that were returned to sender. This tab also includes an inset for recording **Tracing Notes** and a button to view a full-screen version of all the Tracing notes for the case.
            d. The ARCHIVE ADDRESSES tab, which lists contact information that was archived and the date on which the archive occurred. Archiving is done by the SIs when one or more parts of an address (case, parent, or additional contact) is/are replaced with newer information.
            e. The PARENTS tab shows the father's and mother's name, address, and phone information as well as phone call logs for each number listed. This screen also displays a short **Notes** field for each parent.
            f. The SPOUSE tab shows the spouse's name, address, and phone number as well as phone call logs for each number. This screen also displays a short **Notes** field for the spouse.
            g. The ADDITIONAL CONTACT INFO tab shows the name, relationship, address, phone number, and email address of individuals that the case or his/her representative authorized us to contact when having difficulty contacting the participant. The screen has buttons to view a phone log for each telephone number listed, and a **Notes** field is also displayed. NOTE: There can be multiple "additional contact" records for an individual case.
            h. The FED EX TRACKING tab is available for records that were mailed a FedEx package during a pilot effort during the first quarter of 2012. For those cases, the tab displays the address on the FedEx package as well as final delivery disposition.

ii. When a case is successfully recruited, the case's record and contact information "rolls over" into the Expansion Tracking database for completion of the baseline survey.

B. *Eligibility*: Ensure the case you are tracing is eligible for the study. Tracing someone who is not eligible wastes resources.
   i. Review the Tracking tab's **Ineligible** checkbox and **Ineligible Reason** field.
   ii. If you learn that the individual is deceased, calculate whether the person survived at least 5 years from the date of diagnosis. If the person did not survive 5 years, the person is not eligible and should NOT be traced further.
      a. See the section of this document titled *New Vital Status – Deceased*.
      b. On the Quest tab, add a dated note with your SI ID that the participant is ineligible because he/she survived less than 5 years after diagnosis.

C. Check the information submitted by the originating institution when they registered the case for the study (**RegData**). These spreadsheets are organized by institution code and are located in *Z:\SJShare\SJCOMMON\ECC\Interviewers\Tracing \01. Expansion Recruitment Tracing\Recruitment Reg Files.*



3. Expansion Cohort *BASELINE* cases and siblings - The Expansion Tracking database houses records for expanded cohort cases and siblings from whom we need a completed baseline survey or from whom we have previously completed a baseline survey. See the SOP titled **Decoding CCSSID** for details on how to identify an expanded cohort case or sibling participant.
   A. The Expansion Tracking database screens useful for tracing *cases* (blue records) are:
      i. The header, which displays the case's name, DOB, **Survival Status** (blank = alive, 2=deceased), **Death Date** (if applicable/known), **Gender** (1 = male, 2 = female), SSN, diagnosis, **Diagnosis Date**, **Spanish Status**, **Call Log/History**, and **Tracing Log/History** – Previous call and tracing history can be found using the buttons in the header.
      ii. The Quest tab, which displays the most recently documented address, phone number(s), email address(es) and **Comments** - The case's tracing and hold codes are also displayed on this tab.
      iii. The Baseline tab, which displays mailing and emailing activity, eligibility status, and **Baseline Outcomes** (e.g. refusal to complete baseline survey)
      iv. The Additional Contact Info tab, which displays the name, relationship, address, phone number, and email address of individuals that the case or his/her representative authorized us to contact when having difficulty contacting the participant - There can be multiple "additional contact" records for an individual case.

v. The USC tab, which may display information about who completed the HIPAA, the date of the HIPAA, contact information at the time of the HIPAA, and any notes from the time of recruitment
vi. The Reg tab, which displays the name, address, and phone number of the mother, father, and spouse - This tab also displays study outcome codes in the **Outcome** and **Outcome Date** fields.
vii. The Archived Address Info tab, which displays prior addresses and phone numbers of the case that were replaced with the more recent information displayed on the Quest tab
viii. The Age of Majority tab, which shows the case's **Age Now** field

B. MS Word **Phone Contact Log** – For those cases who have a MS Word **Phone Contact Log**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Participant call logs*, reviewing this record of previous contact attempts can be useful to the Tracer.

C. The Expansion Tracking database screens useful for tracing *siblings* (green records) are:
i. The header, which displays the sibling participant's name, DOB, **Survival Status** (blank = alive, 2=deceased), death date (if applicable/known), **Gender** (if known; 1 = male, 2 = female), and **Spanish Status**.
ii. The Permission tab, which displays who provided permission to contact the sibling, the format in which permission was received, and how long ago permission was received. There may also be contact information of interest in the Permission tab, documented during the Permission effort.
iii. The Sib Info tab, which displays the most recently documented address, phone number(s), email address(es) and **Comments**. The sibling participant's tracing and hold codes are also displayed on this tab.
iv. The Sib Baseline tab, which displays mailing and emailing activity, eligibility status, and **Baseline Outcomes** (e.g. refusal to complete baseline survey).
v. The Additional Contact Info tab, which displays the name, relationship, address, phone number, and email address of individuals that the sibling participant or his/her representative authorized us to contact when having difficulty contacting the participant. A **Comments** field is also located in this screen. There can be multiple "additional contact" records for an individual sibling participant.
vi. The Sib Reg tab, which displays the name, address, and phone number of the mother and father along with a **Comments** field and information about whether or not the parent is an authorized additional contact. This tab also displays study outcome codes in the **Sibling Outcome** and **Sibling Outcome Date** fields.
vii. The Archived Address Info tab, which displays prior addresses and phone numbers of the sibling participant that were replaced with the more recent information displayed on the Sib Info tab.
viii. The Age of Majority tab, which shows the sibling participant's **Age Now** field.

ix. The Case tab, which displays contact information for the case as well as a button to access the associated case's live record.
x. Reports accessed via the **Call Log/History** and **Tracing Log/History** buttons at the bottom of the screen, which display previous call and tracing history

D. For more information about tracing sibling cases, see the SOP titled **Tracing Sibling Permission and Survey Calls**.
E. When a case or sibling participant has completed the baseline survey, the information about the individual "rolls over" to the LTFU Participant database. This "roll over" process occurs approximately once quarterly.

4. All *POST-BASELINE* Cases and Siblings - The LTFU Participant database houses records for original and expanded cohort cases and siblings who have completed at least a baseline survey. See the SOP titled **Decoding CCSSID** for details on how to identify an original vs. expanded cohort participant and how to identify a case vs. a sibling participant.
   A. The LTFU Participant database screens useful for tracing *cases* (blue records) and *siblings* (green records) are:
      i. The header, which displays the participant's name, **Spanish Status**, DOB, gender, survival status (1 = alive, 2=deceased), **Death Date** (if applicable/known), SSN, diagnosis, diagnosis date, study outcome, hold status, email log, call log/history, and tracing log/history – Previous call, email, and tracing history can be found using the buttons in the header.
      ii. The Participant tab, which displays the most recently documented address, phone number(s), and email address(es) for the participant along with the **Notes** button, the **History Names** button, and the participant's tracing codes
      iii. The FU5 Tracking tab, which displays mailing activity, **FU5 Baseline Outcomes** (e.g. refusal to complete the FU5 survey), and age of majority information
      iv. The Associates tab, which displays the name, relationship, address, phone number, and email address of individuals associated with the participant, including those that the participant or his/her representative authorized us to contact when having difficulty contacting the participant - There can be multiple associate records for an individual participant.
      v. The Archived Address Info tab, which displays prior addresses of the participant and his/her associates that were replaced with the more recent information displayed on the Participant and Associates tabs
   B. Other database information sources for post-baseline participants:
      i. The REG database houses historical records for cases and siblings in the original cohort from before the fully-enrolled participants were "rolled over" to the LTFU Participant database. See the SOP titled **Decoding CCSSID** for details on how to identify an original participant and how to identify a case vs. a sibling participant.
         a. The REG database screens possibly useful in Tracing *cases* are:

1. The header, which display the case's name, **Alive** status (1=alive, 2=deceased), DOB, and diagnosis date
2. The Page 1 tab, which displays the most recently documented address, phone number(s), and email address(es) prior to rolling over to the LTFU Participant database – This screen also has a **Tracing History** field, which may contain information of interest, and it displays the **Edit Reg** button, which opens additional forms that may have information of interest to the Tracer.
3. The Contact Info tab, which displays the name, relationship, address, and phone number of individuals that the case or his/her representative authorized us to contact when having difficulty contacting the participant - There can be multiple "additional contact" records for an individual case.

b. The REG database screens possibly useful in tracing *siblings* are:

1. The header, which display the *case*'s name, **Alive** status (1=alive, 2=deceased), DOB, and address
2. The Sib Permission tab, which displays the sibling's name, DOB, most recently documented address, phone number(s), and email address(es) prior to rolling over to the LTFU Participant database – This screen also has a **Notes** field, which may contain information of interest to the Tracer.
3. The Sib Contact tab, which displays the name, relationship, address, and phone number of individuals that the sibling or his/her representative authorized us to contact when having difficulty contacting the participant - There can be multiple "additional contact" records for an individual sibling participant.
4. The Sib email address tab, which displays the email addresses recorded for the sibling prior to rolling over to the LTFU Participant database.

ii. Ancillary Study Databases - In addition to the LTFU Participant and REG databases, you may also need to refer to tracking activity in any one of the ancillary study management databases. Each participant in an ancillary study is ALWAYS also in the LTFU study and can therefore be found in one or more of the "parent" databases described above. However, the ancillary tracking database may also have additional telephone call records or notes about an individual participant. For more information about tracing for ancillary studies, see the specific study's project tracing SOP in the SOP library.

C. MS Word **Phone Contact Log** – For those cases who have a MS Word **Phone Contact Log**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Original Cohort Call Logs - Reg db*, reviewing this record of previous contact attempts can be useful to the Tracer.

Level 1 Tracing - *Gathering Information*

Tracing Codes

Code 18 – indicates an invalid address but does not make any indications about the recorded phone numbers

Code 19 – indicates disconnected or invalid phone numbers

Code 13 – indicates an invalid address AND disconnected or invalid phone numbers

Check current phone numbers: Check viability of EXISTING phone numbers on file for the participant.

1. For every phone number NOT coded '37' (Do Not Call), call the number to see if you make contact with the participant or an associate.
   *Note: Open all databases and call logs that pertain to the individual study being traced.
   a. If disconnected, code the phone number status with '9' (out of service).
   b. If the call is answered by an answering machine, leave an appropriate message.
      i. *Example: "Hello, this is <interviewer name>. I am calling for <participant name> regarding some information we recently mailed. Please call me at <number>. Thank you very much."*
      ii. *Example: "Hello, this is <interviewer name> calling from the Long Term Follow-Up Center. I am calling for <participant name> regarding some information we recently mailed. Please call me at <number>. Thank you very much."*
      iii. NOTE: For more examples of approved guidance, see the document titled **Phone Message Guidance** located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools*.
   c. If the call is answered by the participant or an associate, obtain updated contact information (address, phone).
      i. If updated contact information is obtained, update the appropriate database record by archiving the existing information, posting new information, selecting the appropriate button to update the print tables (depending on what new information was entered), and then removing or updating the tracing codes. Add a dated note with your SI ID in the appropriate field indicating that the **Tracing Code** (13, 18, 19) and **Tracing Date** (date in database) were cleared or updated and why.
      ii. For calls answered by the participant, attempt to obtain an additional contact and document the contact's information in the database. If the participant does not want to provide an additional contact, add a dated note in the appropriate comments field indicating, "Participant declined to provide an ADDITIONAL CONTACT."
      iii. If updated contact information is not obtained, determine whether parents, spouse, and/or additional contacts may have information available, and then pursue.
2. Record the call in the appropriate call log with outcome codes and call effort counters.

3. Review all the phone numbers in the tracing history that we have not yet been able to reach. (Messages may have been left, but no response obtained.)
    a. Keep the number of calls to and messages left at these numbers within the pre-defined limits for a given time period.
    b. Document each call made in the appropriate Tracing notes field/log. Indicate the number called, name of person, relationship or possible relationship to participant, outcome of call, and any new information obtained.

Levels 2 and 3 Tracing - *Utilizing Tracing Resources*

In general, start with existing information already on file for the case. This includes contacts and relatives as well as possible connections uncovered but unconfirmed during previous tracing efforts.

- Consider the date we have on file for the current information to get a sense of how long ago it was obtained (and was supposedly correct).
- Consider the records of recent tracing history: What resources were searched? How long ago were those resources used? Could the resources now have updated information?
- Although the individual may no longer reside at an archived address, researching the old address using web resources may uncover the names of other persons who lived there who may also be related.

1. **LEVEL 2 TRACING**: When information currently on file does NOT produce a confirmed contact, begin LEVEL 2 tracing, which uses *no-fee* websites.
    a. Using the no-fee websites (See the **Tracing Resources** document located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Tracing\Tracing Resources*.), begin searching for the case then move to all known connections that we already have (parents, additional contacts, spouse) as well as any new connections identified through talking with a known contact.
    b. It is ordinarily expected that level 2 tracing will be undertaken *before using the level 3 tracing resources*. This order may be reversed only if the Coordinator approves the reversal based on issues of resource allocation.

2. **LEVEL 3 TRACING** (Using LexisNexis): When it is clear that no further leads can be uncovered through the no-fee websites, you may escalate the tracing to LEVEL 3, which uses fee-based websites. Please see the **Tracing Resources** document, located at located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Tracing\Tracing Resources*, for instructions on how to access LexisNexis.
    a. Please see the fee schedule provided by LexisNexis, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Tracing\Admin\Accurint, Lexis Nexis*. On the current fee structure for LexisNexis, the larger fee is associated with initiating a Person Investigations search. Once results from a Person Investigations search are displayed, using the "Relatives, Associates, and Neighbors" panel to display known relatives and associates is billed at a lower rate.

b. Entering an address on file for the parent or an archived address will usually provide results for all the immediate family that once lived at that address for the fee of one Person Investigations search.
    i. Next, rather than initiating a NEW search for each person thought to be connected to a case, wisely choose which person to use at the CORE of the search, and then use the "Relatives, Associates, and Neighbors" feature to fan out to connections for that core person.
    ii. You may also need to do a Person Investigations search using the most current address of the individual you are using for the CORE of the search for the most current phone information.
c. As you trace, print or record on paper the information you will need to continue your search. This prevents loss of the information as the time out feature of LexisNexis sometimes prevents users from re-accessing the information when the **Back** button is selected in the internet browser.

Confirmation

What is "Confirmation"? Confirming means you have made phone contact with a live person (the participant, a relative, or someone who answers the phone) who verbally confirms the party's current contact information.

NOTE: If the answering machine has a personalized announcement that confirms you have reached the correct party (e.g., you are tracing John Davis, and the machine message says "This is John Davis, please leave a message…"), this may sometimes be considered "confirmation." *CAUTION*: Because there could be more than one "John Davis", these should be brought to the LSI team/Coordinators for a case-by-case determination on whether or not to consider a personalized voicemail announcement as "confirmation".

1. When the Tracer has CONFIRMED the party has been successfully traced:
    a. Fully document the tracing outcome in the Tracing Log.
    b. Archive the information currently on file.
    c. Update the applicable address/phone fields in the appropriate database:
        i. Enter the new information, the date you obtained the information, and the information source.
        ii. Clear the tracing code and tracing date.
        iii. Enter a note about the changes to the Tracing fields.
        iv. If a resend request is warranted (i.e. the tracing code was a result of returned materials other than returned newsletters), enter the resend code and the current date or notify the project manager a resend can be processed.
        v. Update applicable print tables.

2. Once a tracing case has been confirmed, send an email to the SI assigned to work the case for follow up.

3. If the Tracer has NOT CONFIRMED the new information is correct (e.g. He/she was only able to leave a message on a machine, no one answered the phone, or a valid phone number was not found for the participant/relative/neighbor), the case stays in tracing until speaking to someone who can confirm the information. This can be a challenge, because a large percentage of people are using cell phones only with no land lines. Search engines do not usually provide cell phone information at this time.

4. Dry Tracing - On rare occasions, the Coordinator will assign cases requiring a "dry trace." A dry trace includes all the tracing steps up to but NOT including a phone confirmation with a live person. When, according to the experienced Tracer's professional judgment, we have obtained a good address for the party but do not have an explicit phone confirmation, the obtained address can be entered into the database and the tracing code cleared. It is critical that the notes indicate the address has *not* been confirmed by voice contact.

Documentation

Each tracing event needs to be fully documented in the applicable database Trace log and, for those calls where a party associated with the participant is reached, the appropriate database call log. Include the resources used, unconfirmed numbers/addresses located, associates identified (and their respective information, including their relationship to the participant), as well as the date and status of the tracing event at the close of the day's work.

New Vital Status: Deceased

When tracing determines that a participant believed to be living is actually deceased:

1. Complete **Expired Participant Information Sheet** and submit the form via the appropriate hanging file for LSI processing
2. Log the updated vital status in the **Call Outcomes Log**.
3. If the participant is in the Recruitment phase, determine whether the participant is still eligible.
    a. Cases must survive 5 years from date of diagnosis. Sibling participants must survive 5 years from date of birth. If the person did not survive 5 years, the person is not eligible and should NOT be traced further.
    b. If not eligible, document the suspected ineligibility in the Tracing notes and all appropriate database comments fields.
4. Send email notification of the vital status change to the SI assigned to the participant.
5. Document in the Tracing Log for the participant.
6. If the participant is deceased, you will be tracing to contact the family of the deceased. Exact tracing directives for deceased participants may depend on which study initiated the tracing request. (Some studies involve proxies for deceased participants, in which case you are tracing a potential proxy.)

Gender Change

When tracing a participant reveals the gender we have on file is incorrect:

1. Log the gender change in the **Call Outcomes Log**.

2. Send email notification of the gender change to the SI assigned to the participant.
3. Document in the Tracing Log for the participant.

Cognitively Disabled Participants - Legal Guardianship (LARs)

If while speaking to a participant the SI suspects the participant has a disability, the following questions can be asked to determine how to proceed:

1. Did you receive the packet of information we mailed to you?
2. Do you have any questions about it?
3. Do you understand the contents of the package?
4. Are you interested in participating?
5. Is there someone who helps you with this type of information?
6. Would you prefer that we speak directly with that person regarding the study?

NOTE: Avoid directly asking the participant if he/she has a legal guardian. This will prevent offending a participant who has mild cognitive impairments or disabilities but is capable of handling his/her own business matters.

Databases and Tracing Tools for Specific Studies

For procedures and information regarding specific research projects and databases, refer to the applicable SOP manual in the SOP Library. Consult with a Lead Survey Interviewer (LSI) or the Coordinator if you have any questions.

When to STOP Tracing a Participant and Apply a HOLD Code

Certain situations warrant a tracer's suspending the tracing effort and putting the case on hold or passing the case to another tracer. For each of the following situations, the tracer will use discretion to apply the appropriate hold code. How long to place the case on hold will depend on information found in tracing and/or conversations with the case or family. If doubt exists, bring the details of the participant's situation to the Tracing Board meeting for discussion and a directive from the Coordinator or Research Scientist.

Situation	*ACTION: Tracer uses discretion to apply appropriate hold code, based on…*	*Outcome (hold) code*
1. Active outstanding **criminal warrants** are found for participant.	…based on information found via tracing.	3, 6, or 12 month hold
2. Participant is **incarcerated**.		3, 6, or 12 month hold
3. Participant is a **minor**, and there is **no address or parental information** in database.		6 month hold
4. Participant is discovered to be	…based on response, reaction or	3, 6, or 12 Month Hold

Situation	*ACTION: Tracer uses discretion to apply appropriate hold code, based on…*	*Outcome (hold) code*
deceased via contact with family.	request of the family. Note that some want to participate immediately, while others want to be contacted in 6 months.	
5. Participant is **agitated** by the number of calls and/or implies that we are bothering him/her.	…based on conversation with the participant. (After voicing their discontent, some will choose to participate, others request a hold.	
6. Participant is **ill or hospitalized** with a serious condition.	…based on conversation with the participant or family.	
7. Participant is a **minor** currently found to be living in **foster care**.	…based on information found via tracing or contact with family.	3, 6, or 12 Month Hold
8. Participant is **traveling outside the country** and cannot be reached.		
9. Adult Participant **living at home. Parents request "Do not cal**l."		6 or 12 Month Hold
10. All listed relatives (potential proxies) are found to be deceased.	…based on information found via tracing.	Apply the "No Proxy Available" Outcome code
11. ***Other unusual circumstances***.	…based on discussion and review at Tracing Board meeting.	3, 6, or 12 Month Hold
12. Participant contact information is invalid in the database. All tracing efforts result in no new information for the lost participant.	Confer with Coordinator about reassigning the case.	Case may be reassigned to the next Tracer with full details of tracing efforts to date until all Tracers have exhausted efforts with no new contact information.

Revision Record

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Current Filename:		Tracing Lost Participants ver1_1 revdr.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	9/14/12	A. McDonald	Initial Development
1.1	7/17/14	D. Davis, M. Wilson, K. Rothammer, D. Rinehart, R. Massey	Content and format revision

Tracing Pass Procedure

Background

When a Tracer has exhausted all resources in their quest to gain new contact information for a case that is determined to be *not* ineligible or placed on hold, the Tracer will "Pass" the case to another Tracer who will then continue the tracing process. A Tracer can pass a case via verbal agreement, email communication, or at a Tracing Board meeting.

Procedures

Passing the Case- The Standard Procedure

1. The Tracer who decides to pass a case discusses the case with an alternate Tracer.
2. If the alternate Tracer agrees to accept the case, the Tracer will provide the alternate with the case ID number.

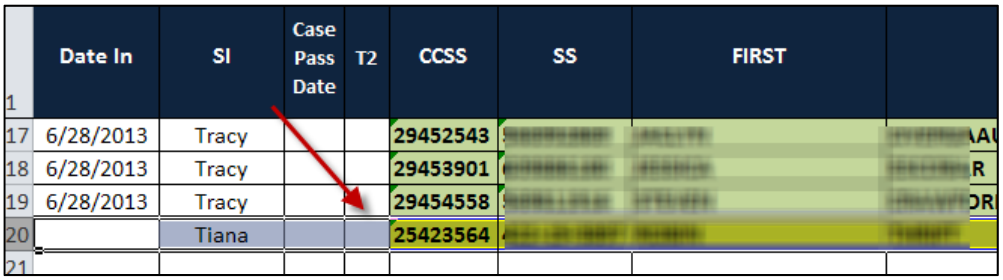
Passing the Case- When The Case Goes Before the Board

1. The Tracer will present the case to the Clinical Research Scientist, Coordinator, LSI team, and fellow Tracers at the next available Tracing Board meeting.
2. Under the guidance of the Clinical Research Scientist or Coordinator, if the group by consensus determines continued tracing is appropriate, the current Tracer will offer the case to another Tracer.

Receiving the Case

1. The Tracer who accepts the case will:
    a. Open the passing Tracer's tracing workbook.
    b. Locate the case by CCSSID or SIBIDNO.
    c. Copy the participant information in the cells (SI assigned and from ID number to last name) .

    d. Paste the copied information into the next available row in their tracing workbook.



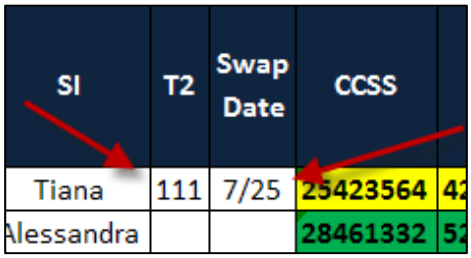
e. In the passing Tracer's tracing workbook, on the same row as the participant ID and under the column header "Case Pass Date," enter the current date using the keyboard shortcut "Ctrl + semicolon, Enter".

f. In the passing Tracer's tracing workbook, on the same row as the participant ID and under the column header "T2", enter their SI ID.

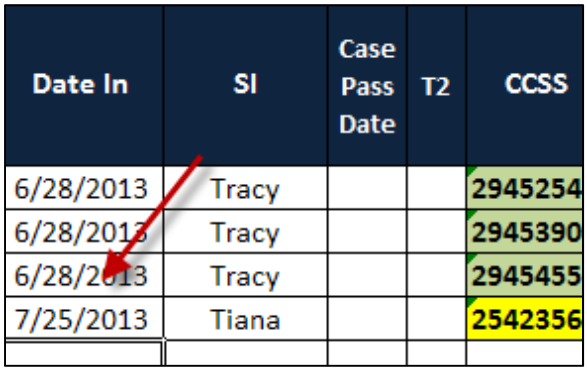
g. Save and close the passing Tracer's workbook.

h. In their own workbook, add the current date (using the keyboard shortcut "Ctrl + semicolon, Enter") on the same row under the column header, "Date In".

i. Save the workbook and begin tracing.



SI	T2	Swap Date	CCSS	
Tiana	111	7/25	25423564	42
Alessandra			28461332	52



Date In	SI	Case Pass Date	T2	CCSS
6/28/2013	Tracy			2945254
6/28/2013	Tracy			2945390
6/28/2013	Tracy			2945455
7/25/2013	Tiana			2542356

2. The passing Tracer will know from the entry in their workbook that the "Pass" process is complete and will discontinue tracing the case.

All questions, comments or concerns will be presented to the LSI team, Coordinator, and/or Research Scientist directly or submitted at the next available Tracing Board Meeting.

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Revision No.	Date	Responsible Author	Change Description
1	7/25/13	K. Rothammer, D. Rinehart, R. Massey	Initial Development

Tracing Sibling Cohort Permission/Survey Calls Guidance

Background

The first step in recruiting siblings for the LTFU Study is to obtain permission from the survivor to contact the potential sibling participant. The potential sibling is the full-blood sibling who would be *closest in age* to the case. A deceased sibling may be the appropriate sibling so long as the sibling lived to be at least five years old. After a survivor/case (or representative) has given the LTFU Study permission to contact their nearest-in-age full-blood sibling, we provide information to the sibling about participating in the LTFU Study. The sibling is asked to complete a sibling baseline questionnaire. We make follow-up phone calls to non-responders beginning approximately 3-weeks after the date the survey is mailed.

Participants who are lost to follow-up because of insufficient contact information (i.e. phone number, address, etc.) are referred to the Tracing Division of the Epidemiology and Cancer Control Department. Once current information is located and verified, the participant is removed from the tracing workbook for recruitment or follow-up.

Procedures

Overall Concept: Sibling Permission/Survey Tracing Calls

1. The LTFU Study *CRA Team* mails the Permission letters and forms to the case or LAR.
2. The LTFU Study *Survey Interviewers* (SIs) make calls to the case if no permission response is received. If permission is gained during the follow-up call, the SI gathers sibling data and asks the case to notify his or her sibling that the LTFU Study will be contacting them.
3. The LTFU Study *Survey Interviewers* make calls to the sibling participant if no response to the survey mailing is received. The Interviewers attempt to gain survey completion.
4. If at any point in the above process we lose contact with a case, sibling, LAR, or proxy, the participant is added to *Tracing*.
    a. If *Tracers* are able to CONFIRM that new contact information is valid, they update the database and send the participant back into the standard calling queue.
    b. If *Tracers* are NOT able to confirm new contact information, the case remains in tracing until the information is confirmed with a live person.

Tools You Will Need:

1. Excel Tracing Workbook 2. Expansion Tracking database *3.* MS Word **Phone Contact Logs** 4. **Call Outcomes Log** *5.* The (optional) **New Contact Data Form** 6. The **Expired Participant Information Sheet** 7. **Expansion Sibling Cohort Survey Calls** SOP 8. **Expansion Sibling Cohort Permission Calls** SOP	9. **Permission Stage** Support Materials a. Permission Forms A, B and D (several copies each, see individual forms for guidance) b. Permission Letters A1, A2, B1, B2, and D (one copy each for reference) c. The **Guide to Expansion Sibling Permission Forms, SI Packet** 10. **Survey Stage** Support Materials a. **Informed Consent Expansion Sibling** form b. The Survey Date Range table c. Sibling-Baseline Expansion Adult Survey for SI d. Sibling-Baseline Expansion Minor for SI e. Sibling-Baseline Expansion Expired for SI

Survey Interviewers

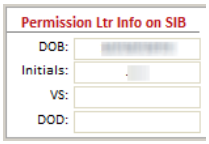
General Tracing Procedures for both Permission and Survey Tracing Needs

1. Open the Expansion Tracking database and choose "Siblings" from the main switchboard. Go back to the switchboard on the Main Menu tab, and choose "Cases". Now forms for both siblings and survivors/cases are available to you by using the tabs under the Access ribbon.
2. Search for the sibling record: click in the **SIBID** field, and then click the Find icon on the Access ribbon. (The sibling ID is exactly the same as survivor/case ID except last digit is 9. (*e.g. Case CCSSID=11122238, Sibling SIBID =11122239*)
3. Identify whether the trace will be for a survivor/case or their LAR/proxy (for permission calls) or a survivor's sibling or the sibling's LAR/proxy (for sibling survey calls):
   a. Review the **Trace Purpose** column of the sibling tracing assignments Excel worksheet. It will be set to "Permission" or "Survey".
   b. Check the **Outcome** field in the Permission Tracking box of the green Permission tab:
      i. If the **Outcome** field is blank, the trace is for a sibling <u>permission</u> call. (*i.e. The tracing team is searching for the case/parent of minor case or their LAR/proxy*.)
      ii. If the **Outcome** field has a value of "1", the trace is for a sibling <u>survey</u> call. (*i.e. The tracing team is searching for the sibling/parent of minor sibling or their LAR/proxy*.)
      iii. If the **Outcome** field has a value between "2" and "10", do not trace.
4. Follow standard tracing procedures prior to making telephone calls to the target party or associates.
   NOTE: If tracing a sibling participant for a sibling survey call, remember we may already have documented and confirmed contact information for survivor/case in case's record.
5. If you encounter an answering machine, follow the guidelines provided in the document "Phone Message Guidance" (revised 6-30-2010), located at: *Z:.. \Interviewers\Calling Tools*.

Pre-Call Procedures

<u>Tracing for PERMISSION</u>

1. Open the MS Word **Phone Contact Log** for the survivor/case. If none exists, create one. (See the SOP **Using and Creating Participant MS Word Call Logs (Phone Contact Log)** located in the SOP Library.) Review all previous recorded activity.
2. Build a profile of the survivor/case by reviewing all available data in the case/survivor's database record, noting the applied **Tracing Status** and **Tracing Date**.
3. After reviewing the case record, review the sibling form:
   a. Review any previous history in the **TRACE Log/History** of the Expansion Tracking database (both blue case and green sibling records).
   b. Confirm no permission outcome is posted in the **Outcome** field of the **PERMISSION TRACKING** box on the green Permission tab to confirm you are correctly preparing for a permissions call.
   c. Check the **Date Sent** field to determine if a permission packet has been mailed to the case/LAR/proxy.
      i. If <u>not</u>, be prepared to explain sibling study and request permission to contact sibling.
      ii. If it <u>has</u> been mailed, then note what letter and form TYPES were mailed.
      Note: The **Letter Type** and **Form Type** displayed in the Permission Tracking box is for informational purposes only.
   d. Review the **Permission Ltr Info on SIB** box within the Permission Tracking box on the Permission Tab:



      i. **DOB**
      ii. **Initials**
      iii. **VS** = Vital status
      iv. **DOD** = Dt of death reported by case on baseline survey (Avoid calling around any death anniversary.)
4. Be prepared to complete a permission form by having blank copies of all form types ready, or be prepared to transfer a successful trace to the assigned Survey Interviewer if he/she is in the office.
5. See **Pre-Post Checklist - Expansion Sibling Permission** for a brief checklist.

<u>Tracing for SURVEY</u>

1. Confirm the **Outcome** field of the Permission Tracking box on the green Permission tab is populated with "1", to confirm you are correctly preparing for a <u>survey</u> call.
2. Check the Sib Baseline tab:
   a. **Ineligible for Study** field should be blank. If this field is populated, do not trace.
   b. **Baseline Outcome** field should be blank. If this field is populated, do not trace.
3. Check the **Sib Reg** tab, **Sibling Study Outcome** box, to ensure the **Study Outcome** field is blank. If this field is populated, do not trace.
4. Build a profile of the sibling by reviewing all appropriate fields in the sibling's database record, noting the applied **Tracing Status** and **Tracing Date**.
5. Review any previous call history in the **CALL Log/History** and **TRACE Log/History** of the Expansion Tracking database in both the blue case and green sibling records. See the **Pre-Post Checklist - Sibling Survey Calls** for a brief checklist of what to review.
6. Be prepared to complete the expansion sibling survey by having a blank copy of the **Informed Consent Expansion Sibling** form and a blank paper copy of the appropriate paper survey (in case of technical issues with the online survey) ready, or be prepared to transfer a successful trace to the assigned Survey Interviewer if he/she is in the office.

Call Procedures

1. If the **phone is answered**, use identity verification to confirm the correct party and/or family has been reached.
2. Confirm all appropriate contact information for the trace target including mailing address, all contact phone numbers, email address, parent/spouse/LAR/proxy contact information, additional contact information, etc. Optionally, document this information on the **New Contact Data Form** to be entered into the database during the post-call procedures.
3. If trace target **has been reached**, proceed with permission (See the **Expansion Sibling Cohort Permission Calls** SOP.) or survey (See the **Expansion Tracking Sibling Cohort Survey Calls** SOP.) call OR transfer the participant to the assigned Survey Interviewer (SI) if he/she is in the office.
4. If the trace target is newly found to be expired, complete the **Expired Participant Information Sheet** with as much information as the party is able to provide. Attempt to obtain the permission or the sibling survey from an available, appropriate proxy.

Post-Call Procedures: PERMISSION Trace Calls

1. Update the MS Word **Phone Contact Log** with the outcome of the trace. IMPORTANT: Always preface notes in the **Comments** column with the project identifier (e.g. "SIB", "Sibling", "(SIB PERM)", etc.).
2. Update the **TRACE Log** in the green sibling record of the Expansion Tracking database.
3. Update the Excel tracing workbook.
4. If any information for the case/survivor was confirmed:
   a. And permission/refusal was **NOT** obtained:
      i. Update the confirmed information in the blue case/survivor record (See the SOP **Expansion Baseline Survey Calls** for details.) AND in the Permission tab of the green sibling record, both in the Expansion Tracking database.
      ii. If appropriate, update the **Tracing Status** and **Tracing Date** fields in the blue case/survivor record AND in the Permission tab of the green sibling record, both in the Expansion Tracking database.
      NOTE: If removing a case from address tracing (**Tracing Status** is currently 13, 18, or 81) when the case or his/her representative was not contacted to obtain verbal permission or refusal, resend permission materials by updating the **Tracing Status** field to "82" in the Permission Tracking box on the Permission tab of the green sibling record, as described in step 4aiii, below. If the tracing code was 13 and a confirmed telephone number was not found, update the **Tracing Status** field in the blue case record to be 19 and the **Tracing Status** field on the green Permission tab to 82.
      iii. If a resend of the permission packet was requested by the case or his/her representative:
         a) Populate the **Tracing Status** field in the Permission Tracking box on the Permission tab in the green sibling record with 82 - Resend Permission.
         b) Populate the **Tracing Date** field in the Permission Tracking box on the Permission tab in the green sibling record with the current date.
         c) Add a dated note with your SI ID in the **Comments** field of the Permission tab in the green sibling record. Indicate a resend has been requested.
         d) Confirm that the address on the Permission tab is accurate.
      iv. Email the Survey Interviewer assigned to this permission case to advise that new contact information was confirmed.
   b. And permission/refusal **WAS** obtained:
      i. Update the confirmed information in the blue case/survivor record. See the SOP **Expansion Baseline Survey Calls** SOP for details.
      ii. As long as the call resulted in updated phone and address information for the case, clear the **Tracing Status** and **Tracing Date** fields in the Permission Tracking box of the Permission tab in the green sibling record AND in the Quest tab in the blue case/survivor record. However, do NOT clear any tracing code values from the Sib Info tab in the green sibling record as these tracing values are for the sibling's contact information in pursuit of the sibling baseline survey.
      iii. Add the call that resulted in permission/refusal to the database call log in the green sibling record. See the SOP **Expansion Sibling Cohort Permission Calls** for details.
      iv. Record the appropriate information in the Permission Tracking box on the Permission tab of the green sibling record to reflect permission gained or denied. See the SOP **Expansion Sibling Cohort Permission Calls** for details.
      v. It is NOT necessary to update the name, address, phone, or email information on the Permission tab of the green sibling record if permission or refusal was obtained. The Permission tab of the green sibling record is active only as long as the permission effort remains unresolved.
      vi. On the Sib Info tab, enter the sibling's information per the **Expansion Sibling Cohort Permission Calls** SOP.
      ***IMPORTANT**: The sibling information needs to be entered in the database **in a specific order** to successfully update the print tables, which impacts both the print and online versions of the survey.*

Survey Interviewers

5. If the survivor/case or their target sibling was newly found to be expired:
   a. For expired siblings, enter a dated note in the **Comments** field of the Permission tab AND the Sib Info tab of the green sibling record.
   b. For expired cases, enter a dated note in the **Comments** field of the Quest tab of the blue case record and with a note in the **Comments** field of the Permission tab of the green sibling record.
   c. Log a request in the **Call Outcomes Log** to update the vital status of the case or sibling.
6. Update all applicable fields in the Excel tracing workbook.
7. File applicable forms properly.
   a. Place completed Permission forms (for permission granted or permission denied) in the hanging file folder labeled "Completed Permission Forms - Siblings". The file folder is located in the file cabinet by the Call Center printer.
   b. File the **Expired Participant Information Sheet**, if applicable, in the hanging file folder labeled "Refusals and Deceased". The file folder is located in the file cabinet by the Call Center printer.
   c. Place the **New Contact Data Form**, if used, in the shredder.

*Post-Call Procedures: **SURVEY** Trace Calls*

1. Update the **TRACE Log** in the green sibling record of the Expansion Tracking database.
2. Update the Excel tracing workbook.
3. If contact information for the *sibling participant* or his/her associates was obtained:
   a. Update the green Sib Info tab:
      i. Update the appropriate fields with any confirmed contact information. See the SOP **Expansion Sibling Cohort Survey Calls** for details.
      ii. Update the **Tracing Status** and **Tracing Date** fields, as appropriate.
   b. Update the Sib Reg tab:
      i. Update the appropriate fields with any confirmed contact information. See the SOP **Expansion Sibling Cohort Survey Calls** for details.
      ii. If updating any information in this tab that would otherwise be lost, document the information being removed in the **Parent Comments** field. There is no archive feature for this tab.
      iii. Update the **OK to Contact FATHER** and/or **OK to Contact MOTHER** fields to indicate whether or not the sibling participant gave permission to use either parent as an additional contact. Update the **OK Date** field to indicate the date permission to use the parent as an additional contact was given or denied.
      iv. Determine if the confirmed parent information also applies to the case. If so, update the Reg tab in the blue case record.
   c. Update the Sib AddlContact tab if the sibling participant provided an additional contact other than one or both of his/her parents. See the SOP **Expansion Sibling Cohort Survey Calls** for details.
      i. If information for an existing contact has changed, document the information being removed in **Additional Contact Comments** field. There is no archive feature in this tab.
      ii. If a new party is provided as an additional contact, create a new record without deleting any old ones.
4. If contact information was confirmed or updated for the *survivor/case* during your tracing calls, access the blue case record by going to the CCSS_ET Main Data Entry tab located just under the Access ribbon. Update the confirmed information per the **Expansion Baseline Survey Calls** SOP.

   NOTE: The **Archive Contact Info** button on the Quest tab of the blue case record *does not work* when accessed through the Case tab of the green sibling record and clicking on the **Open Sibling's Case** button. Access the record through the main switchboard to make updates.
5. If survivor/case or their target sibling was newly found to be expired:
   a. For expired *siblings*, enter a dated note in the **Comments** field on the Sib Info tab of the green sibling record.
   b. For expired *cases*, enter a dated note in the **Comments** field on the Quest tab of the blue case record.
   c. Log a request in the **Call Outcomes Log** to update the vital status of the case or sibling.
6. If a survey was gained, follow all appropriate post-call procedures per the **Expansion Tracking Sibling Cohort Survey Calls** SOP.
7. File applicable forms properly.
   a. Place completed informed consent forms in the hanging file folder labeled "Sibling Consent Completed Forms". The file folder is located in the file cabinet by the Call Center printer.
   b. File the **Expired Participant Information Sheet**, if applicable, in the hanging file folder labeled "Refusals and Deceased". The file folder is located in the file cabinet by the Call Center printer.
8. Place the **New Contact Data Form**, if used, in the shredder.

Revision Record Printed 11/4/2013 2:30 PM

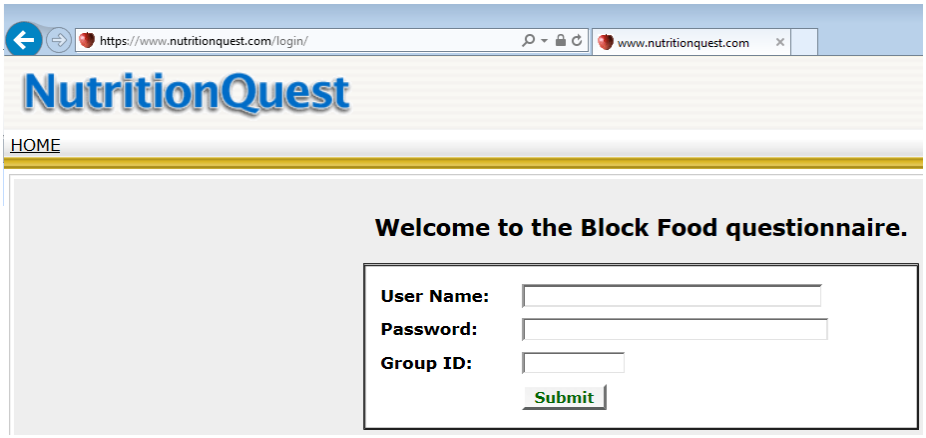
[247] Current Filename:		Tracing Sibling Permission and Survey Calls ver 1_2.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	5/28/2013	D. Bowen, R. Massey, D. Rinehart	Initial Development
1.1	5/29/2013	D. Bowen, D. Rinehart	Content revision
1.2	11/3/2013	R. Massey	Content revision: Directives to enter resend after address traced/ confirmed, log permission gained/refused calls in db call log, access case record through switchboard to make updates.

Transcribing St. Jude Life FFQ Paper Surveys into Online Surveys

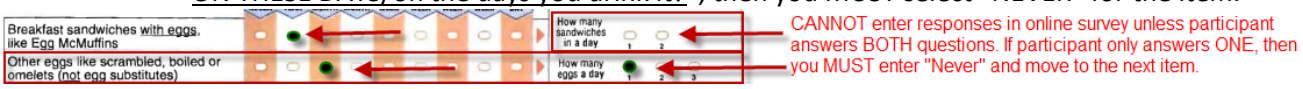
Background

Participants complete an online Food Frequency Questionnaire (FFQ) as part of their St. Jude Life visit. However, at times the online system is down or there is a technical issue with the computer. In situations such as this, a paper copy of the FFQ is completed. Once the online survey is available, the paper copy must be logged-in to the online system.

1. Go to: https://www.nutritionquest.com/login/
   a. Enter the participant's User Name: Participant's Medical Record Number (MRN)
   b. Enter Password: sjlife
   c. Enter Group ID: 245

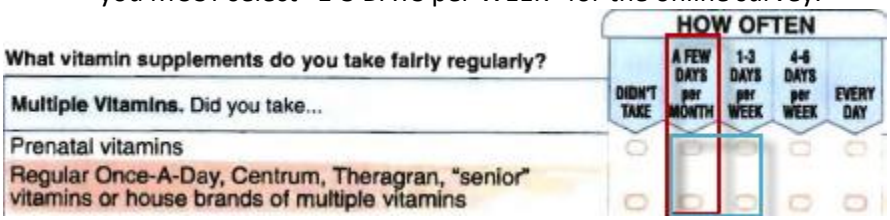


2. As you work your way through the online system, you will notice that the online survey design is slightly different than the design of the paper survey. Below are examples of these differences and instructions on how to address them.
   a. For items that ask "HOW OFTEN IN THE PAST YEAR" & "HOW MUCH ON THESE DAYS/on the days you drink it?", the online system forces you to enter values for EACH item. However, on the paper survey, participants may not answer each question. If a participant ONLY answered "HOW OFTEN IN THE PAST YEAR" and ignored "HOW MUCH ON THESE DAYS/on the days you drink it?", then you MUST select "NEVER" for the item.



   b. For certain items that ask "HOW OFTEN IN THE PAST YEAR" & "HOW MUCH on the days you drink it?", the online system immediately asks for the type of drink, whereas these question are in a separate section of the paper survey. In order to accurately enter the data in the online system, you MUST refer to page 6 or 7 of the paper survey to find the corresponding type of drink and response.

c. In the vitamin supplements section of the paper survey, the participant is offered 5 response options (DIDN'T TAKE, A FEW DAYS per MONTH, etc.). However, in the online system, the participant is only offered 4 options (DIDN'T TAKE, 1-3 DAYS per WEEK, 4-6 DAYS per WEEK, EVERY DAY).
    i. If a participant selected "A FEW DAYS per MONTH" on the paper survey, then you MUST select "1-3 DAYS per WEEK" for the online survey.



3. If you have any questions about the process, then see Janna Lipford (x7363), Aaron McDonald (x6177) or Jenny Lanctot (x5916).

Revision Record Printed 11/26/2014 7:59 AM

Current Filename:		Transcribing St. Jude Life FFQ Paper Surveys into Online Surveys.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	11/24/14	J. Ford & J. Lipford	Initial Development

Triaging Incoming LTFU App Calls

Background:

An LTFU software application (or "app") has been developed that can be accessed via smartphone, tablet, or PC. The app cannot be downloaded from an app store. Rather, it is a web app, which is a website that can be added to the home screen of your smartphone so that it looks like an app. For privacy protection, the participant creates a unique password during registration.

No outgoing calls will be made regarding the LTFU app, but the Call Center may receive incoming calls from participants who have questions or problems registering and logging into the app. All participants with questions should be transferred directly to Nicole Wilson, Clinical Research Assistant, with a high priority on assuring a direct transfer to Nicole rather than leaving a message. This procedure outlines how to triage these calls.

Tools:

- **Transferring Calls 101** (located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools*)
- **LTFU Participant Database Data Entry** (located in the SOP Library)

Procedure:

Step 1. Transferring the Call to Nicole Wilson, Clinical Research Assistant (x 6014)

1. Thank the participant for their call and for their participation.
2. Confirm the participant's contact information.
3. Attempt to transfer the call directly to Nicole Wilson, available Monday-Friday, 8am-5pm. See the guidance document **Transferring Calls 101** for instructions.
    A. If the transfer is successful, update the database. Refer to the SOP, **LTFU Participant Database Data Entry**.
    B. If the transfer is unsuccessful, move to **step 2**.

Step 2. Transferring the Call to Chris Vukadinovich, Director – Databases & Systems, Epidemiology (x4686)

1. If Nicole Wilson is unavailable, attempt to transfer the call to Chris Vukadinovich.
2. If the transfer is successful, update the database.
3. If the transfer is unsuccessful, move to **step 3**.

Step 3. Gathering Best Callback Time/Day from the Participant and Sending the Information to Nicole Wilson. – If unable to transfer the call:

1. Gather the best time(s) and day(s) for the participant to receive a callback.
2. Email the applicable information to Nicole Wilson *and copy Chris Vukadinovich, Aaron McDonald, James Ford, Dayton Rinehart, and the Lead Survey Interviewer (LSI) team*. All emails must include:

A. The participant's CCSSID number
B. The participant's preferred contact name
C. A summary of the issue or question
D. The participant's contact information
E. The best day(s) and time(s) to return the participant's call

Sample Email:

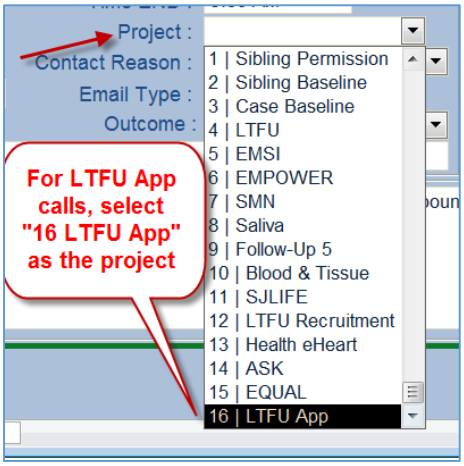
Subject bar: CCSS Pt 15123456, MRN 1234, Requests Call Regarding LTFU App

Email body:

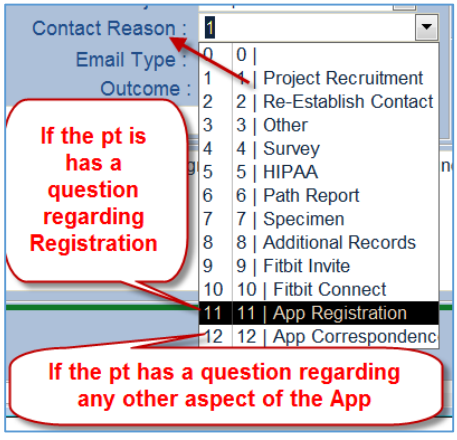
Nicole:
CCSS Pt 15123456, MRN 1234, Nora Jones, is having trouble registering on the LTFU app.
Contact phone: 901-555-5555
Best day/time to call is on Monday or Wednesday, before 1pm (EST)
Please let me know if you have any questions.
Thank you.

Step 4. Updating the LTFU Participant Database

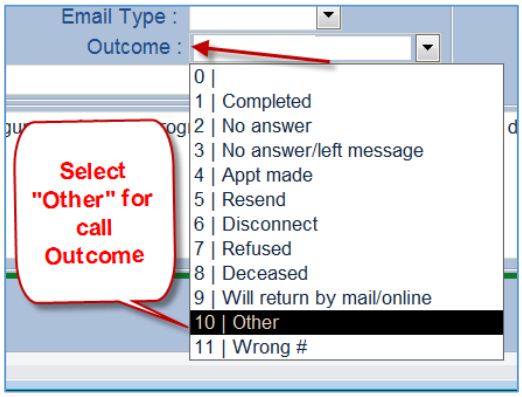
1. **Participant** (and **Associates**, if possible) tab(s): Update the contact information, dates, and source fields. See the SOP titled **LTFU Participant Database Data Entry** for details.
2. **Contact Log**: Update the following fields:
   A. **Project**: 16-LTFU App



   B. **Contact Reason**:
      i. 11-App Registration: Select for questions regarding registration
      ii. 12-App Correspondence: Select for questions regarding any other aspect of the app

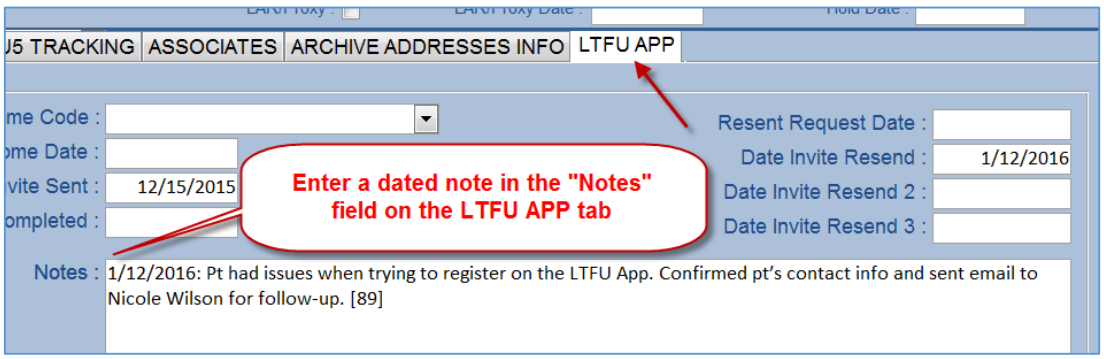


C. **Outcome**: 10-Other



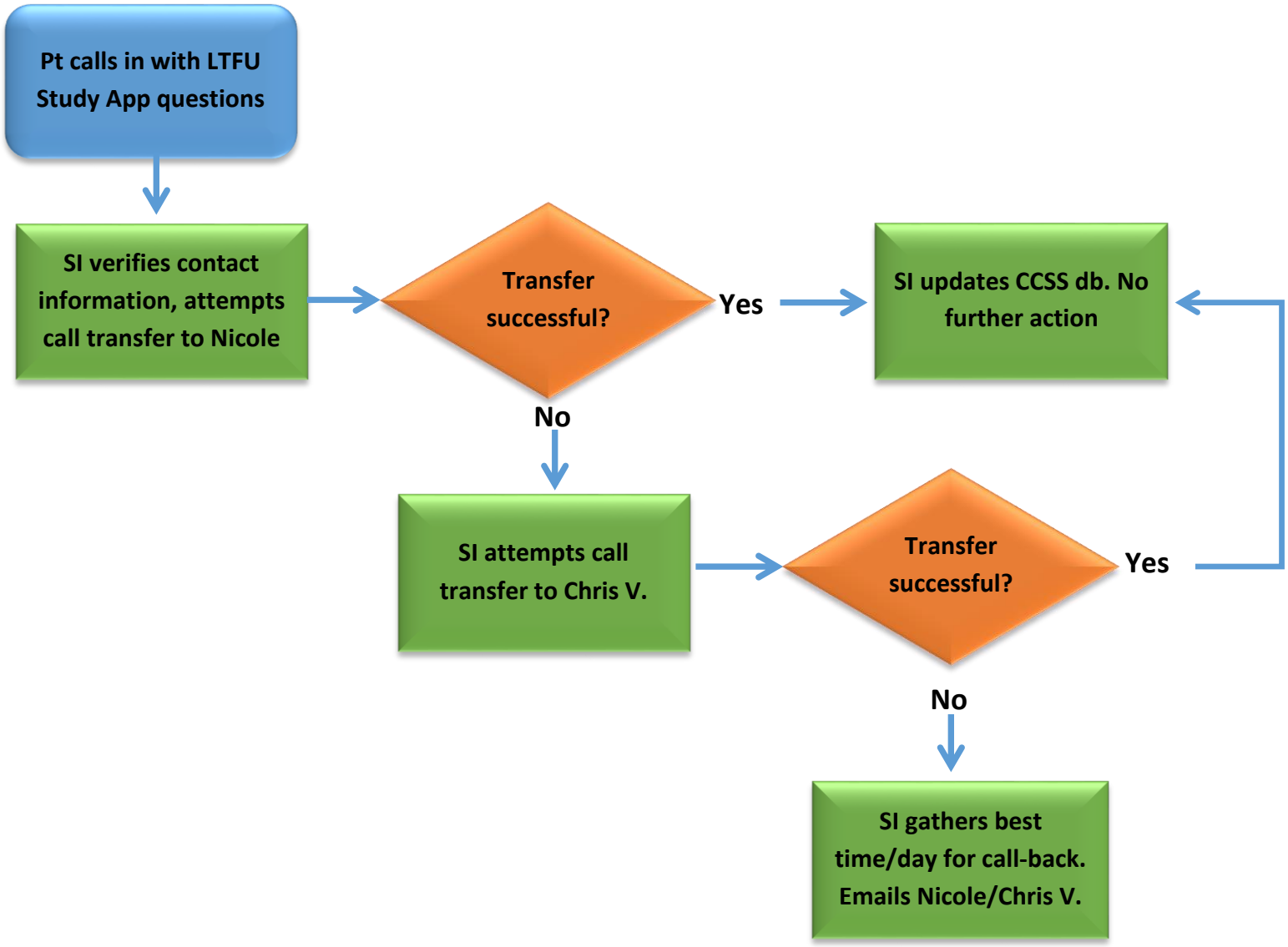
D. **Notes**: Enter a clear, concise and complete note.
Example: Pt had issues when trying to register on the LTFU App. Confirmed pt's contact info and sent email to Nicole Wilson for follow-up.

3. **LTFU APP** tab: Add a dated note with SI ID in the **Notes** field.



Consult with a Lead Survey Interviewer or the Coordinator if you have any questions or need further assistance.

Triaging Incoming LTFU App Calls Flow Diagram



Revision Record Printed 8/10/2016 2:24 PM

[312] Current Filename:		Triaging Incoming LTFU App Calls ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	4/29/2016	G. Armstrong, C. Vukadinovich, A. McDonald, D. Rinehart, N. Wilson, A. DiScenza, A. Cobble, J. Ford	Initial Development

Type and Institution Codes

Reg Institutions		Expansion Tracking Institutions
University of Minnesota	01	University of Minnesota
The Children's Hospital of Denver	02	The Children's Hospital of Denver
Children's Hospital of Pittsburgh	03	Children's Hospital of Pittsburgh
Children's Hospital at Stanford University	04	Children's Hospital of at Stanford University
Dana-Farber Cancer Institute	05	Dana-Farber Cancer Institute
Emory University	06	Emory University
Children's National Medical Center	07	Children's National Medical Center (DC)
U.T.M.D. Anderson Cancer Center	08	U.T.M.D. Anderson Cancer Center
Memorial Sloan-Kettering Cancer Center	09	Memorial Sloan-Kettering Cancer Center
Texas Children's Hospital	10	N/A (see inst 28)
University of California at San Francisco	11	University of California at San Francisco
Seattle Children's Hospital & Medical Center	12	Seattle Children's Hospital & Medical Center
Toronto Hospital for Sick Children	13	Toronto Hospital for Sick Children
St. Jude Children's Research Hospital	15	St. Jude Children's Research Hospital
Children's Hospital of Columbus	16	Children's Hospital of Columbus
Roswell Park Cancer Institute	17	Roswell Park Cancer Institute
Mayo Clinic	18	N/A
Minneapolis Children's Medical Center	19	Minneapolis Children's Medical Center
Children's Hospital of Philadelphia	20	Children's Hospital of Philadelphia
St. Louis Children's Hospital	21	St. Louis Children's Hospital
Children's Hospital of Los Angeles	22	Children's Hospital of Los Angeles
UCLA Mattel Children's Hospital/Miller/Orange County	23	UCLA Mattel Children's Hospital
Riley Hospital for Children, Indiana University	24	Riley Hospital for Children, Indiana University
UAB/The Children's Hospital of Alabama	25	UAB/The Children's Hospital of Alabama
Univ of Michigan - Mott Children's Hospital	26	Univ. of Michigan-Mott Children's Hospital
Children's Medical Center of Dallas	27	Children's Medical Center of Dallas
	28	Texas Children's Hospital*
	29	City of Hope
	30	Children's Hospital Orange County
	31	University of Chicago
	32	Northwestern Children's Memorial Hospital
	33	Cook Children's Hospital (Fort Worth)
		*TX Children's inst code changed

	Type Code
1	Leukemia
2	Central Nervous System (CNS)
3	Hodgkin's
4	Non-Hodgkin's Lymphoma
5	Kidney
6	Neuroblastoma
7	Soft Tissue Sarcoma
8	Bone
9	***Case Control - Sibling*** *(last digit of CCSSID)*

Revision Record

Printed 7/9/2012 3:17 PM

Current Filename:		Type and Institution Codes ver1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	10/5/09	A. McDonald	Initial Development
1.1	10/7/09	J.Bates	Add code reference list
1.2	11/16/10	J.Bates	Add original cohort Inst codes

Undeliverable and Forwarding Address Updates for Recruitment

Background

Recruitment packets that cannot be delivered or are forwarded to a new address by the post office are logged in the Recruitment database. Packets sent with an institution-specific business reply mailer are sent to the PI's institution, and the data manager returns these in bulk to the recruiting center for further processing.

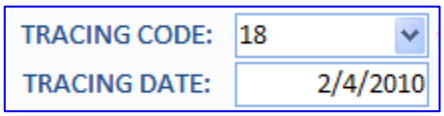
Procedure

1. In the Recruitment database, locate the record for the CCSSID. (CCSSID will be on the mailing label) Make sure the name on the returned item matches the participant's name in the database.

2. If the package is returned to us as **undeliverable**:

   a. If Tracing Code is already 19 (Disconnect/Wrong Number),
      i. *Change* the TRACING CODE to 13 (Tracing)
      ii. Enter the date in TRACING DATE.

   b. If Tracing Code is blank:
      i. Select 18 (Undeliverable) in the TRACING CODE field.
      ii. Enter today's date in the TRACING DATE field.



      iii. Annotate the return in the RECRUIT NOTES field. E.g., "2/4/10: init pkt ret to sender[jb]. Include info gleaned from USPS stamp such as no such number, no such street, fwd order expired; moved left no adrs; attempted not known.

      iv. [NOTE: Code 18 is the signal for the interview team to research the address. When they locate a viable/verified address, they remove the tracing code and date, and code the RESEND REQUEST (and DATE RESEND REQUEST) as needed. If they discover existing phone numbers are all bad, they enter a 13 as the TRACING CODE, which is the signal for the tracing team to initiate a trace.

   c. Open the package and put the contents in the appropriate location.
      i. Check the package contents to see if everything is there. If anything is missing, add a notation in the NOTES field.
      ii. Return the pen, the participant copy, and the blue BRE to the appropriate stock in the supply room.
      iii. Turn the $2 in to the CRA2.
      iv. SHRED the survey, cover letter, and white mailing envelope.

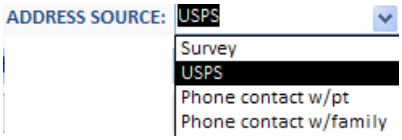
3. If the USPS notification provides us with a **forwarded address**:

   a. Click the **Archive Address** button. This will place a copy of the CURRENT address in the archived address file. (You can view archived addresses on the Archive Addresses tab.

   b. Make the appropriate corrections to the address, using ADDRESS, CITY, STATE, ZIP5 fields.

   c. Type today's date in the ADDRESS DATE field.

   d. Select the "USPS" from the ADDRESS SOURCE dropdown list.



   e. Enter an explanatory COMMENT. E.g., "2/16/10: USPS fwd resend2 to new adrs; updated in db. [JB]"

   f. On the Quest tab, click the **Update Print Table Address** button. (Be sure you do not click Update Print Table NAMES by mistake.)

   g. SHRED the notice from the post office.

Revision Record — Printed 7/16/2012 9:19 AM

Current Filename:		Undeliverable and address changes for Recruitment ver 1_4.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	2/24/10	J.Bates	Initial Development
1.1	5/4/10	J.Bates	Prior tracing code
1.2	6/28/11	J.Bates	Update print table
1.3	8/29/11	J.Bates	USPS return notes
1.4	7/5/12	J.Bates	Clarify background

Unsubmitting/Deleting DatStat Surveys

Background

If a survey that was submitted online in the DatStat system needs to be recalled, the following procedure outlines how this can be done. These actions are permanent and should therefore be undertaken only when authorized and necessary. Contact the IT department for additional clarification.

Procedures

1. You will need the DATSTATSUBMISSIONID, DATSTATSESSIONID, and DATSTATENDDATETIME (date the survey was submitted) for the survey(s) you need to review. (These can be found in the DatStat tables in CCSSREG.)
2. Once logged in to the Web Console, click on CCSS Project.
3. Click on the appropriate survey.
4. Under the General tab, click on the date the survey was submitted.
5. Click the number under Row that corresponds to the correct DATSTATSUBMISSIONID.
6. Now you should be in the participant's results. Here, I usually click on PRELOAD VARIABLES and look at the IMPORTNAME to make sure I'm in the correct patient. (You can also scroll down until you get to the IMPORTNAME if you prefer.)
7. Click Unsubmit. If it has been determined that a survey needs to be deleted, click Delete here.

To access participant's survey:

1. Copy and Paste the appropriate link (see below) into the Address bar.
2. Copy and Paste the participant's DATSTATSESSIONID after the '=' and press Enter.
3. Note: You can also use the patient's log-in info to get in if you prefer.
4. When finished reviewing, you'll need to Submit the survey. Be careful when navigating through the surveys. It would be easy to accidentally click a response instead of Previous or Next.

Links Used for Accessing Surveys in DatStat

FU2007:
https://live.datstat.com/STJUDE-Collector/survey.ashx?Name=CCSS_Follow-Up_2007&DATSTAT.SESSIONID=

FU2007 Sibling:
https://live.datstat.com/STJUDE-Collector/survey.ashx?Name=CCSS_Follow-Up_2007_Sibling&DATSTAT.SESSIONID=

CCSS Men's Health Questionnaire:
https://live.datstat.com/STJUDE-Collector/survey.ashx?Name=Men's_Health_Questionnaire&DATSTAT.SESSIONID=

CCSS Men's Health Questionnaire Sibling:
https://live.datstat.com/STJUDE-Collector/survey.ashx?Name=Sibling_Men's_Health_Questionnaire&DATSTAT.SESSIONID=

Expansion Baseline Adult:
https://live.datstat.com/STJUDE-Collector/survey.ashx?Name=CCSS_Expansion_Baseline&DATSTAT.SESSIONID=

Expansion Baseline Minor:
https://live.datstat.com/STJUDE-Collector/survey.ashx?Name=CCSS_Expansion_Baseline_Minor&DATSTAT.SESSIONID=

Revision Record Printed 7/10/2012 2:14 PM

Current Filename:		UnsubmittingDeleting DatStat Surveys ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	11/5/09	unknown	Initial Development
1.1	7/10/12	J.Bates	Background added

Updating Database for Name Changes

Background

When the study team is notified that a CCSS participant's legal name has changed due to marriage, divorce, adoption, etc., the appropriate database is updated to reflect the name change. This ensures mailings are sent to the correct name, ensures survey booklets and forms are printed with the correct name, and assists Survey Interviewers in verifying identity and establishing rapport when calling participants.

The database with the most current record is the appropriate database to update. For example, if the participant has rolled over from the Recruitment database to the Expansion Tracking database and later to the LTFU Participant database, only the record in the LTFU Participant database is updated.

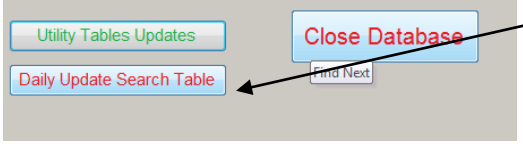
While the address fields may contain a participant's preferred first name, record headers always contain the participant's *legal* first, middle, and last name.

Procedure

LTFU Participant Database – Cases and Siblings

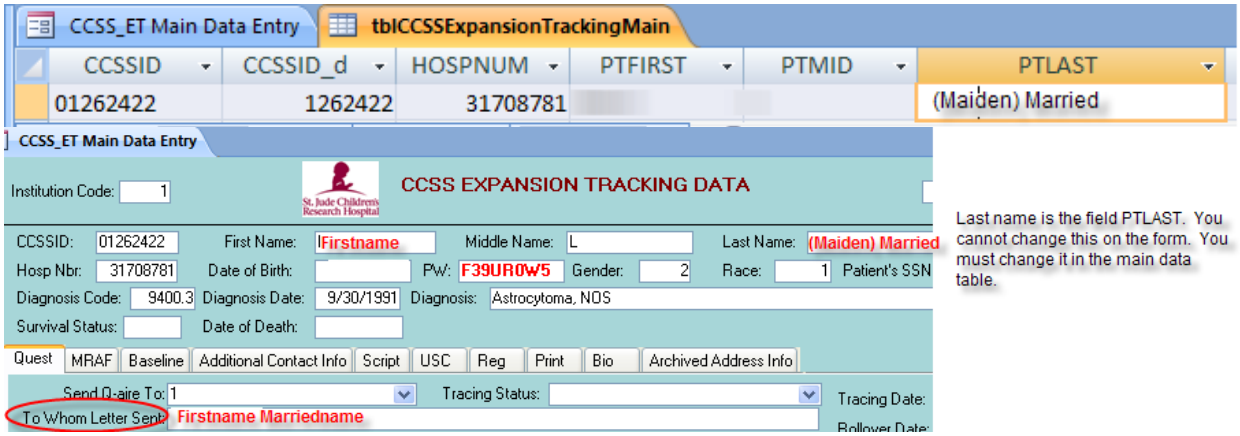
1. Open the LTFU Participant database and find the participant's record using the Search feature. See the SOP titled **LTFU Participant Database Data Entry** for details.
2. On the Participant tab, log a dated comment with initials or SI ID in the **Notes** field. Document the source of the information, the reason for the name change, the former legal name, the updated legal name, and any preferred name that is different than the legal name. *Example: 2/17/15: Case advised her last name has changed from Jones to Smith due to divorce. Legal first name is Carlita but prefers to go by "Carlie". [158]*

3. Click on the **Archive Name** button.
4. In the header, click on the **Admin** button to open the frmPatientBasicInformation form.
5. Update the **Last Name** field with the participant's current legal last name.
6. Move the cursor to a new field (e.g. **DOB**, etc.) in the form, and then close the frmPatientBasicInformation form.
7. Press the F5 key on your keyboard to see the changes in the record's header.
8. Edit the **Preferred Name** field to the new preferred first and legal last name. *Example: Carlie Smith*
9. Move to the cursor to a new field (e.g. **Preferred Contact info/time**, etc.).
10. Click the **Update Print Tables** button.
11. On the LTFU screen, click the **Daily Update Search Table** button



Expansion Tracking Database – Case Records

1. Open the Expansion Tracking database. Choose **Cases** at the main switchboard.
2. Open the Navigation Pane, and choose Tables from the drop-down category menu. Search for the table named **tblCCSSExpansionTrackingMain**, double click on the table name to open it, then locate the participant:
    a. Select the **CCSSID** column.
    b. Click the binoculars on the Home tab of the Access Ribbon (or press <Ctrl> and <F>).
    c. Type the CCSSID in the **Find What** field of the Find and Replace window.
    d. Click the **Find Next** button.
    e. In the row for the CCSSID in question, navigate to the column labeled **PTLAST**. Update the value in the **PTLAST** cell as follows:
        i. For name changes due to marriage where the participant did not indicate a hyphenated last name, add parentheses around the maiden name, insert a space, and then type the new/married last name. For example, the **PTLAST** field may look like: *(Smith) Jones* or *Smith-Jones*.
        ii. For name changes due to divorce, jot down the married last name to include in your note (See below.), then update the field to include *only* the maiden name.
        iii. For name changes due to adoption, jot down the birth surname to include in your note (See below.), then update the field to include *only* the adopted surname.
    f. Arrow up to the previous record to save your change.
    g. Close the table.



3. Find the case's record using the Find feature. If the **Last Name** field in the header does not reflect the change just made in the table, click on the **Refresh** drop-down from the Home tab on the Access Ribbon, and then choose the **Refresh** option (*not* **Refresh All**).
4. On the Quest tab:
    a. Edit the name appearing in the **To Whom Letter Sent** field to show the preferred first name and new legal last name. For name changes due to marriage, do *not* enclose the maiden name in parentheses or otherwise keep the maiden name unless the participant

indicated a hyphenated last name. For example, the **To Whom Letter Sent** field may look like: *Mary Jones* or *Mary Smith-Jones*.

b. SAVE the changes to the record, either by (1) moving to the next record in the database and then back again or by (2) moving the cursor to a new field then clicking the **Save** icon on the Home tab of the Access Ribbon.

c. Click the **Update Print Table Names** button. This updates the name that will be imprinted in the survey booklet.

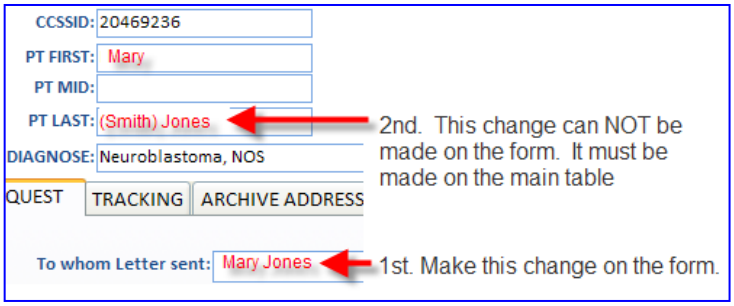
d. Enter a dated note with initials or SI ID in the **Comments** field. Document the source of the information, the reason for the name change, the former legal name, the updated legal name, and any preferred name that is different than the legal name. *Example: 11/19/2014: Per case's LAR, case's surname is now Jones due to adoption. Birth surname was Smith. Updated db. [jf]*

Expansion Tracking Database – Sibling Records

Survey Interviewers have access to edit names for sibling participants in the Expansion Tracking database. See the SOP titled **Expansion Sibling Cohort Survey Calls** for instructions.

Recruitment Database

1. Open the Recruitment database, and search for the case using the Find feature in Access.
2. Edit the **To whom Letter sent** field of the Quest tab to show the preferred first name and new legal last name. For name changes due to marriage, do *not* enclose the maiden name in parentheses or otherwise keep the maiden name unless the participant indicated a hyphenated last name. (e.g., *Mary Smith* becomes *Mary Jones* or *Mary Smith-Jones*.)



3. Go to the next record to save the change.
4. Open the Navigation Pane, and choose Tables from the drop-down category menu. Search for the table named **tblCCSSRecruitmentMain**, double click on the table name to open it, then locate the case:
    e. Select the **CCSSID** column.
    f. Click the binoculars on the Home tab of the Access Ribbon (or press <Ctrl> and <F>).
    g. Type the case's CCSSID in the **Find What** field of the Find and Replace window.
    h. Click the **Find Next** button.
    i. In the **PTLAST** field, update the name as follows:
        i. For name changes due to marriage where the participant did not indicate a hyphenated last name, add parentheses around the maiden name, insert a space, and then type the new/married last name. For example, the **PTLAST** field may look like: *(Smith) Jones* or *Smith-Jones*.

ii. For name changes due to divorce, jot down the married name to include in your note (See below.), and update the field to include *only* the maiden name.
iii. For name changes due to adoption, jot down the birth surname to include in your note (See below.), and update the field to include *only* the adopted surname.

j. Arrow up to the previous record to save the change.
k. Close the table.

5. In the CCSS Recruitment Data Entry form, go back to the case's record. If the **PT LAST** field in the header does not reflect the change just made in the table, click on the **Refresh** drop-down from the Home tab on the Access Ribbon, and then choose the **Refresh** option (*not* **Refresh All**).
6. Click the **Update Print Table Names** button on the Quest tab.
7. Enter a dated note with initials or SI ID in the **Comments** field. Document the source of the information, the reason for the name change, the former legal name, the updated legal name, and any preferred name that is different than the legal name. *Example: 11/14/2014: Per case, her last name is Jones due to marriage. Maiden name is Smith. Updated db. [123]*

REG Database: Name changes should not be made in REG database; use LTFU for original cohort cases and siblings.

Revision Record Printed 9/19/2014 12:51 PM

[96] Current Filename:		Updating Database for Name Changes ver 2_10.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	11/14/2013	R. Massey	Initial Development – Replaces SOP titled *Changing Maiden Name to Married Name*
1.1	11/20/2013	J. Ford	Updating with new directives concerning REG database headers
2.0	9/9/2014	R. Massey, J. Ford	Format Update and Content Revision – updated Background, added directives for LTFU Pt db, removed SIs from audience
2.1	9/19/2014	L.Harrison	Added directive for updated search field; removed directives for updating REG

Updating Databases with Post-Recruitment Death Notices

Background

When the study team is notified that a participant has expired, the appropriate database is updated to reflect the change in vital status. This minimizes the opportunity for inappropriate communication to or regarding a deceased party, which may cause undue distress to the family.

The database with the most current record is the appropriate database to update. For example, if the participant has rolled over from the Recruitment database to the Expansion Tracking database and later to the LTFU Participant database, only the record in the LTFU Participant database is updated.

For cases that have not yet been recruited, use the SOP titled **Change of Vital Status – Recruitment** to make the updates in the Recruitment database.

If the case was treated at St. Jude (institution 15), also see the SOP titled **Death Notifications about St Jude Cases**. *NOTE: If notification is received via MILLI, search the Recruitment, Expansion Tracking, and LTFU Participant databases by MRN (hospnum) since MILLI would not indicate if the notice is for the original cohort, the expanded cohort, or someone who is not a CCSS participant at all.

Procedures

LTFU Participant Database

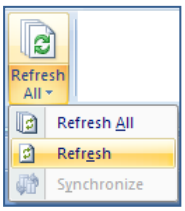
1. Open the LTFU Participant database and find the participant's record.
2. On the Participant tab:
   A. Click the **Death Data Form** button.
      i. **Vital Status** – Populate with "2" (2 = Deceased).
      ii. **Date of Death**, **State of Death**, **Reason for Death**, **Did participant have cancer at time of death** – Populate with any known information.
      iii. Generally, leave all other fields in the Death Data form blank.
      iv. Close the Death Data form.
   B. **Notes** – Enter a dated note with initials or SI ID documenting the change in vital status and the source of this information.
   C. **Use Email for Newsletter** – If the checkbox is checked, uncheck it.
   D. **Date News Letter** – If the field is populated, clear it.
3. On the FU5 Tracking tab, review the **Date Intro Letter Sent** field.
   A. If it is BLANK (i.e. the intro letter HAS NOT been sent), no action is necessary.
   B. If it is NOT BLANK (i.e. the intro letter HAS been sent), review the **Date Survey Returned** field.
      i. If **Date Survey Returned** IS blank (i.e. the survey WAS NOT returned), populate the **FU5 Outcome Code** with 4-Deceased, and enter the current date in the **FU5 Outcome Date** field.
      ii. If **Date Survey Returned** IS NOT blank (i.e. the survey WAS returned), leave the **FU5 Outcome Code** and **FU5 Outcome Date** fields blank.
4. In the record's header:
   A. **CCSS Study Outcome** – Populate with 38-Deceased.
   B. **CCSS Outcome Date** – Enter the current date.

C. NOTE: If these fields are already populated, LSIs/designees should consult with the Coordinator or CRA2 team for advice on how to proceed.

5. Review the death notice (e.g. **Expired Participant Information Sheet**) for evidence of a **subsequent malignancy** (e.g. the participant had cancer at the time of death). If such evidence is noted, notify the Subsequent Malignant Neoplasm (SMN) project coordinator for possible pursuit.
6. If the participant was a St. Jude (institution 15) case, see also the SOP titled **Death Notifications about St Jude Cases**.

Expansion Tracking Database – CASE Participant

1. Open Expansion Tracking database, and choose **Cases** from the main switchboard.
2. Locate the case's record using the Find feature in Access.
3. On the Quest tab of the correct record:
   A. Click the **Open Death Data Form** button (right side of screen).
      i. **Alive/Dead Status –** Update to be "2" (2 = Deceased).
      ii. **Date of Death**, **State of Death**, **Parent's reason for Death**, **Did pt have cancer at time of death (according to parents) –** Populate with any known information. NOTE: If notification was received via MILLI, enter the note, "Notified via MILLI on <*date*>."
      iii. Generally, leave all other fields in the Death Data form blank.
      iv. In the Records group of the Ribbon's Home tab, click the Refresh drop-down arrow. Select "Refresh" (*not* Refresh All).
      v. Close the Deathdata form.

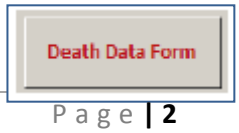


   B. **Comments** – Enter a dated note with initials or SI ID documenting the change in vital status and source of the information.
   C. **Send Q-Aire To** – Update to be 5-parent (pt. has died).
   D. **Use Email for Newsletter** – If the checkbox is checked, uncheck it.
4. Click on the Baseline tab and review the **Date Survey Returned** field.
   A. If the field IS NOT blank(i.e. case HAS returned a Baseline questionnaire):
      i. Click on the Reg tab.
      ii. **Outcome** – Populate with 38-Deceased.
      iii. **Outcome Date** – Populate with the current Date.
      iv. NOTE: If these fields are already populated, LSIs/designees should consult with the Coordinator or CRA2 team for advice on how to proceed
   B. If the field IS blank (i.e. case HAS NOT returned a Baseline questionnaire), leave the **Outcome** and **Outcome Date** fields in the Reg tab blank.
5. Review the death notice (e.g. **Expired Participant Information Sheet**) for evidence of a subsequent malignancy (e.g. the participant had cancer at the time of death). If such evidence is noted, notify the Subsequent Malignant Neoplasm (SMN) project coordinator for possible pursuit.
6. If the case was treated at St. Jude (institution 15), see also the SOP titled **Death Notifications about St Jude Cases**.

Expansion Tracking Database - SIBLING Participant

CAUTION: Do NOT open the Death Data form UNLESS sibling is deceased!

1. Open Expansion Tracking database, and choose **Siblings** from the main switchboard.
2. Locate the participant's record using the Find feature in Access.
3. On the Sib Info tab of the correct record:
   A. Click the **Death Data Form** button on the right side of the page.



i. **Alive/Dead Status –** Update to be "2" (2 = Deceased).
ii. **Date of Death** – Populate if the date is known.
iii. Click the **SAVE** button, then close the Deathdata form.

B. The **Survival Status** field (and **Death Dt**, if entered) will now display in the header of the sibling's record.
C. **Comments** – Enter a dated note with initials or SI ID documenting the change in vital status and the source of the information.
D. **Send Q-Aire To** – Update to be 5-Parent(Sib has died).
E. **Use Email for Newsletter** – If the checkbox is checked, uncheck it.

4. Click on the Sib Baseline tab and review the **Date Survey Returned** field.
   A. If the field IS NOT blank (i.e. participant HAS returned a Baseline questionnaire), then:
      i. Click on the Sib Reg tab.
      ii. **Sibling Outcome** – Populate with 38-Deceased.
      iii. **Sibling Outcome Date** – Populate with the current date.
      iv. NOTE: If these fields are already populated, LSIs/designees should consult with the Coordinator or CRA2 team for advice on how to proceed
   B. If the field IS blank (i.e. case HAS NOT returned a Baseline questionnaire), leave the **Sibling Outcome** and **Sibling Outcome Date** fields in the Sib Reg tab blank.
5. Review the death notice (e.g. **Expired Participant Information Sheet**) for evidence of a subsequent malignancy (e.g. the participant had cancer at the time of death). If such evidence is noted, notify the Subsequent Malignant Neoplasm (SMN) project coordinator for possible pursuit.

Recruitment Database

If the expired case has *NOT YET BEEN* recruited, see the SOP titled **Change of Vital Status – Recruitment** for instructions.

REG Database

Death notifications should not be entered into the REG database for cases or siblings. All notifications should be entered in the CCSS LTFU Participants database**.**

Revision Record — Printed 3/18/2015 4:17 PM

[98] Current Filename:		Updating Databases with Post-Recruitment Death Notices ver3_3.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	6/5/09	A. McDonald	Initial Development
2.0	11/8/10	J. Bates	Recruiting cases
2.1	5/12/11	J. Bates	Refer recruitment to separate procedure
2.2	6/13/11	J. Bates	Cross reference
2.3	7/17/12	J. Bates	St Jude cases cross reference
2.4	2/8/13	J. Bates	Clear Newsletters via email option
3.0	10/18/13	R. Massey	Remove references to specific employee, add directives for sibling db.
3.1	9/10/14	R. Massey, J. Ford	Content Revision: Add directives for LTFU Pt database
3.2	9/19/2014	L. Harrison	Removed instructions for updating REG
3.3	3/18/2015	R. Massey	Content Revision: FU5 Tracking tab updates, notify of SMNs

Updating Date of Birth

Background

A participant's date of birth (DOB) is used to calculate his/her age at a series of points in time. The current age indicates whether the individual is a minor or an adult. For most institutions, DOB is also used for online access to survey instruments. Further, DOB impacts eligibility. It is critical that the correct DOB is maintained for each participant.

The DOB is part of the registration data received from an institution and uploaded into the Recruitment database. The DOB rolls over with the participant from the Recruitment database to the Expansion Tracking database and later to the LTFU Participant database, and it displays in the database records, the applicable print table (which is used to print on the survey booklet's medical release), and the DatStat system (which uses the DOB in the online login process). Note that Dana Farber does not provide us with the participant's DOB.

This procedure outlines how to update a participant's date of birth when we have confirmed it is not correct in our records. The LSI team will learn of a needed date of birth change when a Survey Interviewer (SI) has confirmed the correction by telephone and logged the request in the appropriate field of a contact or trace log.

Procedures

Confirming that a date of birth is incorrect

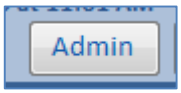
A date of birth may be properly confirmed as incorrect in the following ways:

1. A participant, parent, or LAR may provide a corrected DOB by phone, a returned survey, or medical release.
2. For cases, the data manager from a participating institution may correct the birth date originally provided in the institution's registration file. A CRA2 will correspond with the data manager for re-verification if we have *conflicting* information from a primary source (e.g. case, parent).
3. For cases, a data manager may provide a different DOB on a medical record cover sheet. The CRA2 will ask the data manager to re-verify the information before changing the database.

Once a DOB is confirmed to be incorrect in the database, a Lead Survey Interviewer (LSI) or Clinical Research Associate II (CRA2) will proceed to the sections of this document titled *LTFU Participant Database*, *Recruitment Database*, or *Expansion Tracking Database*, as appropriate.
NOTE: Conflicting information obtained from tracing is NOT used to update the database unless we have verification from a source close to the survivor. Conflicting information is documented in tracing notes.

LTFU Participant Database

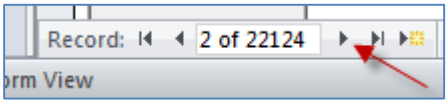
1. In the **Notes** field of the Participant tab, document the source of the information, the original/incorrect date of birth, and the new/correct date of birth with a dated comment, including SI ID or initials.
2. Click the **Admin** button in the header.



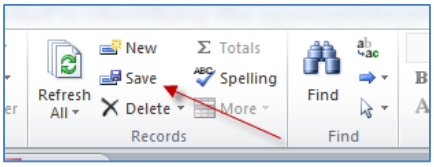
3. Update the **DOB** field in the frmPatientBasicInformation form.
4. Move the cursor to a different field in the form, and then close the frmPatientBasicInformation form.
5. Press the F5 keyboard key to view the change in the record.
6. Confirm the participant is still eligible based on age at diagnosis and years survived since diagnosis (for cases) or years survived since birth (for siblings).
7. If the participant is still eligible, determine if the FU5 survey has been submitted by reviewing the **Date Survey Returned** field on the FU5 Tracking tab.
   A. If the FU5 survey HAS been submitted (i.e. the **Date Survey Returned** field is populated), no additional action is necessary.
   B. If the FU5 survey HAS NOT been submitted (i.e. the **Date Survey Returned** field is blank), notify the CRA2 team so the DatStat form for the FU5 survey can be updated.

Recruitment Database

1. In the **Comments** field of the Quest tab, document the information source, the original/incorrect date of birth, and the new/correct date of birth with a dated note, including initials or SI ID.
   Example: 3/15/2015: Pt reports birthdate is 1/3/1985 and not DOB originally on file (10/3/1985). Corrected main and print tables. [inits or SI ID]

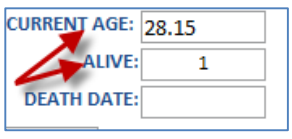


2. Save the changes either by (1) navigating to the next record or by (2) moving the cursor to a new field, then clicking the Save icon on the Ribbon.



3. Update the main table:
   A. Open the main table, *tblCCSSRecruitmentMain*.
   B. Locate the case by CCSSID, and filter the records to see only the target record.
   C. Locate the column **BIRTHDATE**, and key in the correct date of birth.
   D. Tab to the next column.
   E. Close the table. When prompted, do NOT save changes to the design of the table.

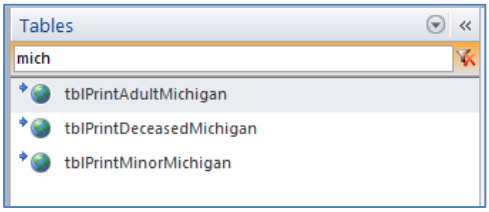
4. No print table needs to be updated *UNLESS* the participant was treated at institution 26 (University of Michigan/C.S. Mott Children's Hospital). For cases treated at institution 26:
   A. Determine if the individual is deceased. This is indicated by **Alive** =



2.

B. For alive cases, determine whether the case is an adult (18 years old or over) or a minor (under 18 years old) by reviewing the **Current Age** field in the record's header.

C. Open the age-appropriate/vital-status-appropriate print table from the list to the right.



D. Locate the record by CCSSID, and correct the field **DOB_HIPAA**.

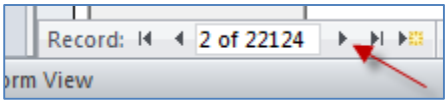
E. LSIs should contact the project CRA2 if assistance is needed in identifying the appropriate print table.

5. Confirm the case is still eligible based on age at diagnosis and years survived since diagnosis.
   A. **If the case *is* still eligible, LSIs should notify the CRA2 team so that the date of birth can be updated in DatStat.**
   B. If the case *is not* still eligible, update the record to indicate the ineligibility. See the SOP titled **Documenting Ineligibility** for details.

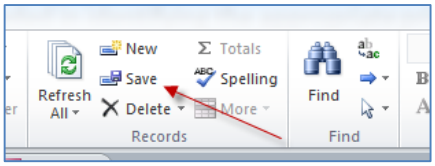
Expansion Tracking Database

NOTE: The following procedure is for survivor participants in the Expansion Tracking database. For changing dates of birth for sibling participants in the Expansion Tracking database, see the SOP titled **Expansion Sibling Cohort Survey Calls**.

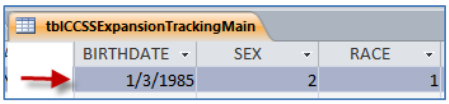
1. In the **Comments** field of the Quest tab, document the information source, the original/incorrect date of birth, and the new/correct date of birth with a dated note, including initials or SI ID.
   Example: 3/15/2015: Pt reports birthdate is 1/3/1985 and not DOB originally on file (10/3/1985). Corrected main and print tables. [inits or SI ID]



2. Save the changes by (1) navigating to the next record or (2) moving the cursor to a new field and clicking the Save icon on the Ribbon.

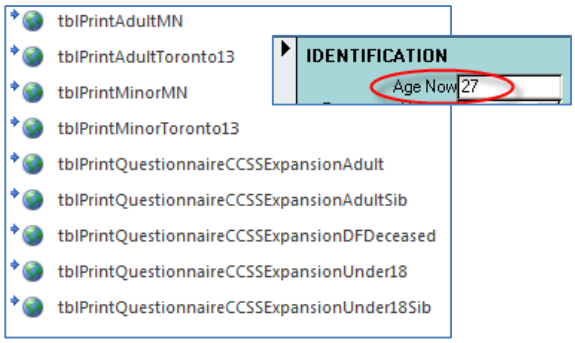


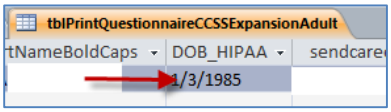
3. Update the main table:
   A. For initial DOB entry for Dana Farber (institution 05) cases, use the SOP titled **Processing LTFU Expansion Baseline Dana Farber**, following the instructions for *Date of Birth and Gender*. Then proceed to step 4 of this document to update the print table.
   B. Otherwise:
      i. Open the main table, *tblCCSSExpansionTrackingMain*.
      ii. Locate the case by CCSSID, and filter the records to see only the target record.
      iii. Locate the column **BIRTHDATE**, and key in the correct date of birth.



      iv. Tab to the next column.
      v. Close the table. When prompted, do NOT save changes to the design of the table.

4. If the case has <u>not yet</u> completed the baseline survey, update the appropriate print table:
   A. Determine if the individual is deceased, indicated by **Survival Status** = 2.
      i. If the case is deceased and <u>was not</u> treated at Dana Farber, <u>do not</u> update a print table.
      ii. If the case is deceased and <u>was</u> treated at Dana Farber, <u>do</u> update a print table.
   B. For alive cases, determine whether the case is an adult (18 years old or over) or a minor (under 18 years old). Refer to the **Age Now** field on the AgeOfMajority tab.
   C. Open the institution-appropriate and age-appropriate/vital-status-appropriate print table from the list to the right. If the alive case is from an institution other than 01 or 13, use the general adult or minor table.
   D. Locate the record by CCSSID, and correct the field **DOB_HIPAA**.
   E. LSIs should contact a CRA2 if help is needed to identify the appropriate print table.





5. Confirm the case is still eligible based on age at diagnosis and years survived since diagnosis.
   A. **If the case *<u>is</u>* still eligible, LSIs should notify the CRA2 team so the date of birth can be updated in DatStat.**
   B. If the case *<u>is not</u>* still eligible, update the record to indicate the ineligibility. See the SOP titled **Documenting Ineligibility**.

Revision Record — Printed 5/1/2015 10:42 AM

224 Current Filename:		Updating Date of Birth ver 3_2.docx	
Revision No.	Date	Responsible Author	Change Description
1	11/29/12	J. Bates	Initial Development
2.0	1/22/13	J. Bates	Add information for Original Cohort (Reg database)
2.1	5/3/13	J. Bates	Expansion Cohort Case Print Table Reference
3.0	5/27/14	R. Massey, L. Harrison, J. Ford	Updated sequencing, added sibling directives,
3.1	10/15/14	R. Massey, D. Rinehart, J.Ford	Content Revision: Added directives for LTFU Participant database
3.2	4/24/15	R. Massey	Content Rev.: Corrected ref'ed SOP title to "Documenting Ineligibility"

Updating Gender

Background

Correct documentation of LTFU Study participant gender is essential for identification verification, establishing rapport when contacting participants, and for obtaining responses to the correct gender-specific questions during LTFU Study surveys.

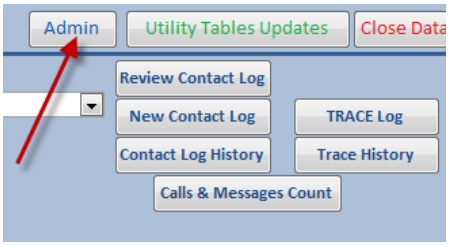
On occasion, a potential participant, participant, parent, or LAR may provide information by telephone to a Survey Interviewer (SI) or via a returned survey that a gender has been recorded incorrectly in the LTFU Study database. In these circumstances, the CRA2, LSI, Coordinator, or Coordinator's designee will update the participant's gender in the database. SIs will document this correction in the **DB Change** field of the appropriate call, contact, or trace log, and the LSI team or Coordinator's designee(s) will harvest this information to be processed, preferably daily.

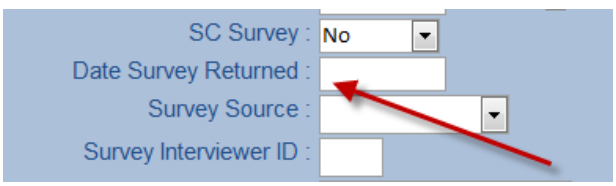
Note that Dana Farber does not provide us with the gender of participants recruited through that institution.

Procedures

LTFU Participant Database

1. Locate the participant's record. See the SOP titled **LTFU Participant Database Data Entry** for details on using the Search screen.
2. Log a dated note with SI ID or initials in the **Notes** field of the Participant tab. Document the source of the information, the wrong gender, and the correct gender.
3. Click the **Admin** button in the header.
4. Update the **Sex** field (1 = Male, 2 = Female) in the frmPatientBasicInformation form.
5. Move the cursor to a different field in the form, and then close the frmPatientBasicInformation form.
6. Press the F5 key on the keyboard to view the change in the record.
7. Review the **Date Survey Returned** field on the FU5 tracking tab:
    a. If the field *IS* populated, no further action is required.
    b. If the field *IS NOT* populated, LSIs should notify the CRA2 of the gender change so that the DatStat application for the FU5 survey can be updated.

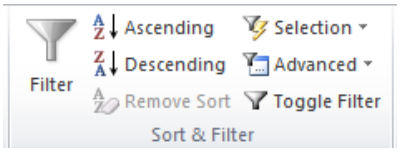




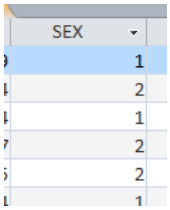
Expansion Tracking Database

1. Locate the participant's record in the Expansion Tracking database.

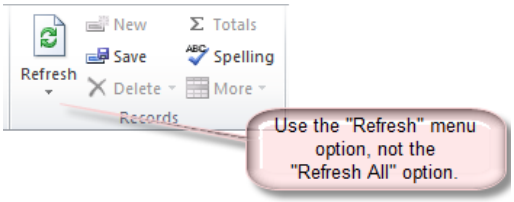
2. Add a dated note with SI ID or initials in the **Comments** field of the Quest tab (for cases, blue records) or of the Sib Info tab (for siblings, green records). Document the source of the information, the wrong gender, and the correct gender.
3. Navigate to the next record in the database.
4. Update the main table.
    A. For initial gender entry for Dana Farber (institution 05) cases, use the SOP titled **Processing LTFU Expansion Baseline Dana Farber**, following the instructions for *Date of Birth and Gender*. Then proceed to step 5 of these instructions.
    B. Otherwise:
        i. Open the table named tblCCSSExpansionTrackingMain (for cases) or tblSiblings (for siblings).
        ii. Locate the record for the CCSSID (for cases) or SIBID (for siblings) in question, then filter the table to show only that participant's record.



        iii. Tab or scroll to the column for Sex, and enter the correct gender code for the participant.
            a. 1 = male
            b. 2 = female

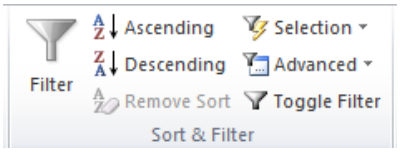


        iv. Release the filter on the table, and navigate to the previous record.
        v. Close the table.
5. Return to the participant's record in the Expansion Tracking database. Use the Refresh command on the Access Ribbon to refresh the record and see the corrected gender.

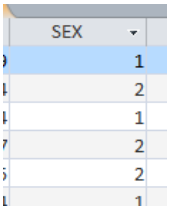


Recruitment Database

1. Locate the case's record in the Recruitment database.
2. Add a dated note with SI ID or initials in the **Comments** field of the Quest tab. Document the source of the information, the wrong gender, and the correct gender.
3. Navigate to the next record in the database.
4. Open the table named tblCCSSRecruitmentMain.
5. Locate the record for the CCSSID in question, and then filter the table to show only that case's record.

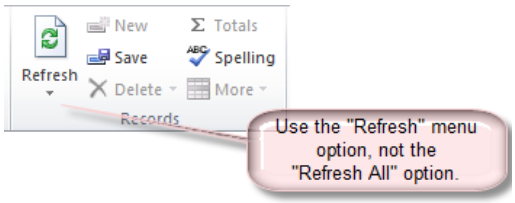


6. Tab or scroll to the column for Sex, and enter the correct gender code for the case.
    a. 1 = male
    b. 2 = female



7. Release the filter on the table, and navigate to the previous record.
8. Close the table.

9. Return to the case's record in the Recruitment database. Use the Refresh command on the Access Ribbon to refresh the record and see the corrected gender.



Revision Record

Printed 11/17/2014 8:35 AM

Current Filename[281]:		Updating Gender ver1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	10/30/2014	R. Massey	Initial Development

Updating Michigan Recruitment Print Table Assignments

Background

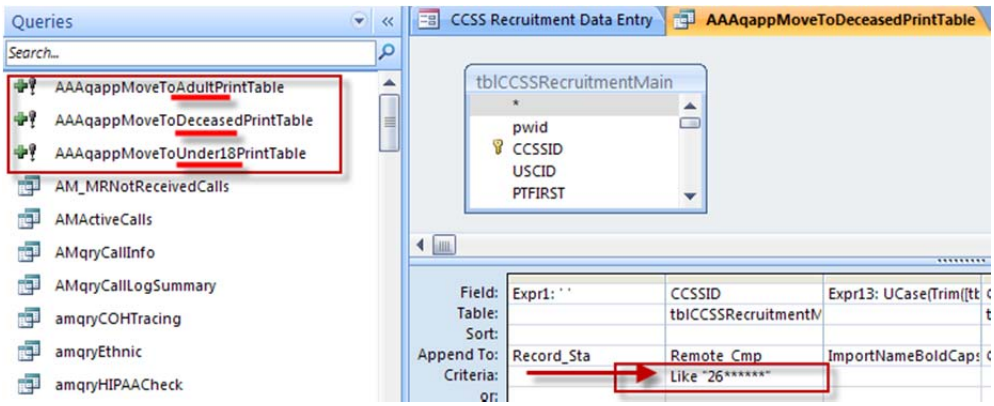
In the recruitment database, when a Michigan participant's status changes (for example alive to deceased or minor to adult), the participant will need to be removed from the current print table and put into the appropriate print table.

Procedures

1. In the Recruitment database, you will open the query that corresponds with the NEW print table for the participant:
   a. **AAAqappMovetoDeceasedPrintTable** to add a participant to the deceased print table
   b. **AAAqappMovetoAdultPrintTable** to add a participant to the adult print table
   c. **AAAqappMovetoUnder18PrintTable** to add a participant to the minor print table

2. Open the query in design view.
   a. In the Criteria field for the CCSSID field, key in the CCSSID of the pt you need to add to that print table. (This will write over the existing criteria.) Double-check to be SURE YOU typed the CCSSID accurately.

   b. Save the query.



3. Run the query. This appends the individual to the appropriate Michigan print table. To be certain, open the table and search by CCSSID.
4. After adding the participant to the appropriate table, remove the participant from its original print table.
   a. Open the original print table.
   b. Search for the CCSSID to locate the row. Once you locate the CCSSID, right click on the row and select the **Delete Record** option.
   c. Delete the row.

Revision Record Printed 7/10/2012 2:18 PM

Current Filename:		Updating Michigan Recruitment Print Table Assignments ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	12/20/11	L.Harrison	Initial Development

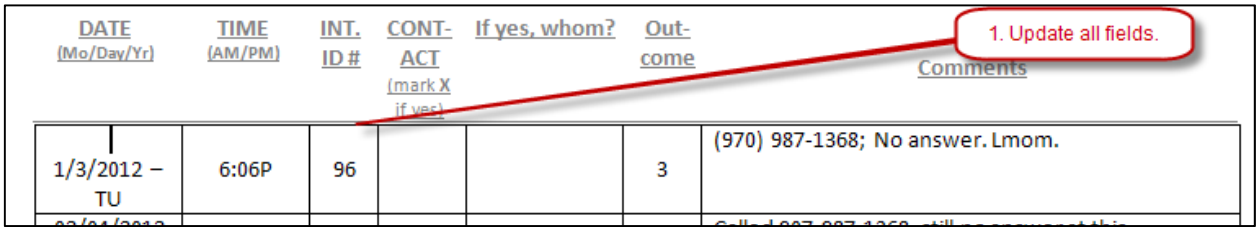
Updating Original CCSS Cohort Contact Information

Background

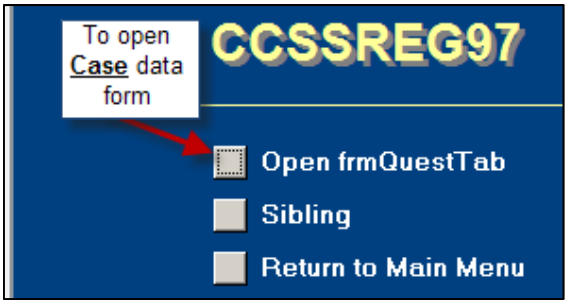
Whenever contact is made with an **Original Cohort** CCSS participant (case) or their sibling, the person handling the call will verify and update contact and additional contact information in both the REG database and applicable MS Word **Phone Contact Log**. In addition, if the participant provides new contact information and was treated at St. Jude Children's Research Hospital (institution 15), the information will be sent to the St. Jude Life Coordinator via email.

Procedures

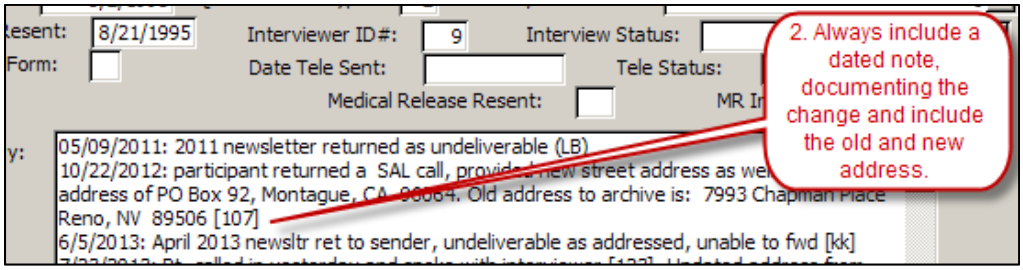
1. Update the MS Word **Phone Contact Log** -
   Complete all fields in a new row, and enter new contact information received from the participant, including address, phone, alternate phone, email address, parent or alternate contact information. (Preferably, you should verify all contact information directly from REG with the case or sibling.)



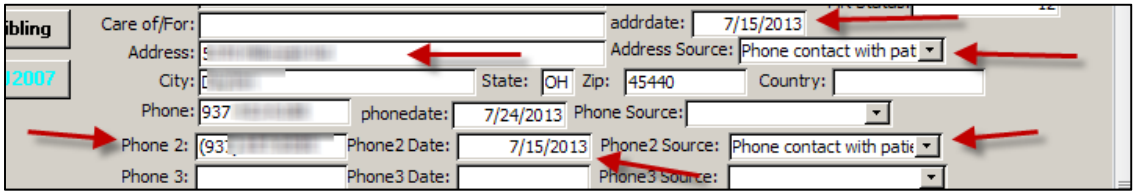
2. Update **REG: Case**
   a. Open the REG database, and select **Open frmQuestTab** from the switchboard.



   b. Use the search feature to locate the participant.
   c. Enter a dated note in the **Tracing history** field of the Page 1 tab indicating what the address was changed from (old address) and to (new address).



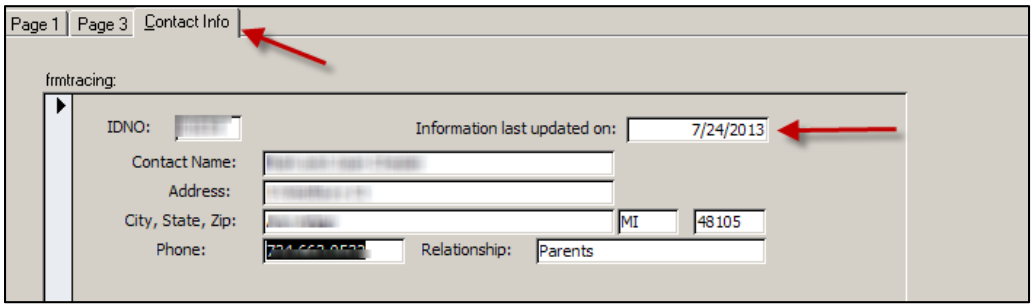
d. Enter the new address in the address fields, update the **addrdate** and **Address Source** fields



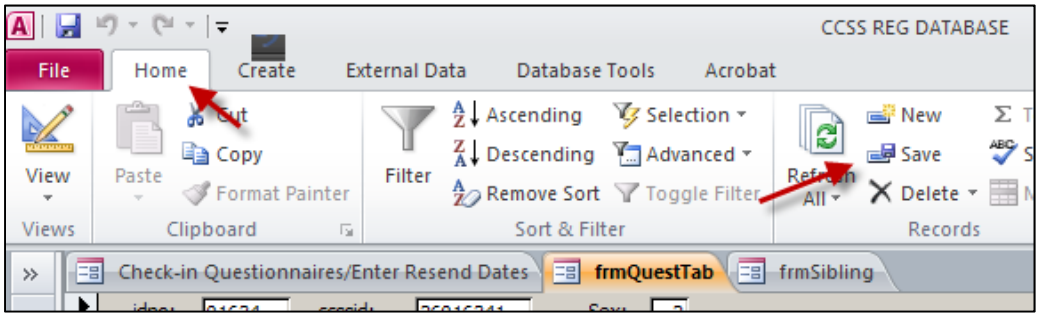
e. Verify the phone and email fields and the phone and email date/source fields.

f. If all available phone fields are populated with invalid phone numbers, refer to the **Handling Additional Phone Numbers** SOP in the SOP Library.

g. Confirm additional contact information on the "Contact Info" tab. If changing the contact information for any **existing** contact, document the information being removed in the **Tracing history** field of the Page 1 tab before making the change.

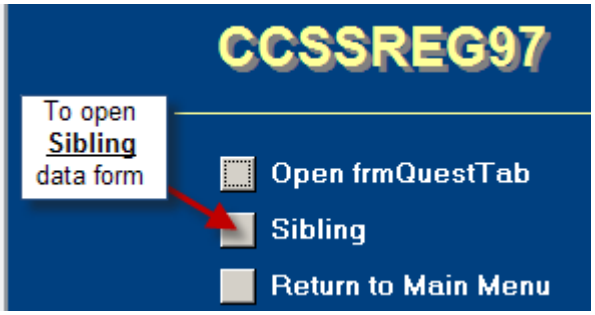


h. Move to a new **field**, then click the **Save** icon in the **Records** section of the Access. Home tab.

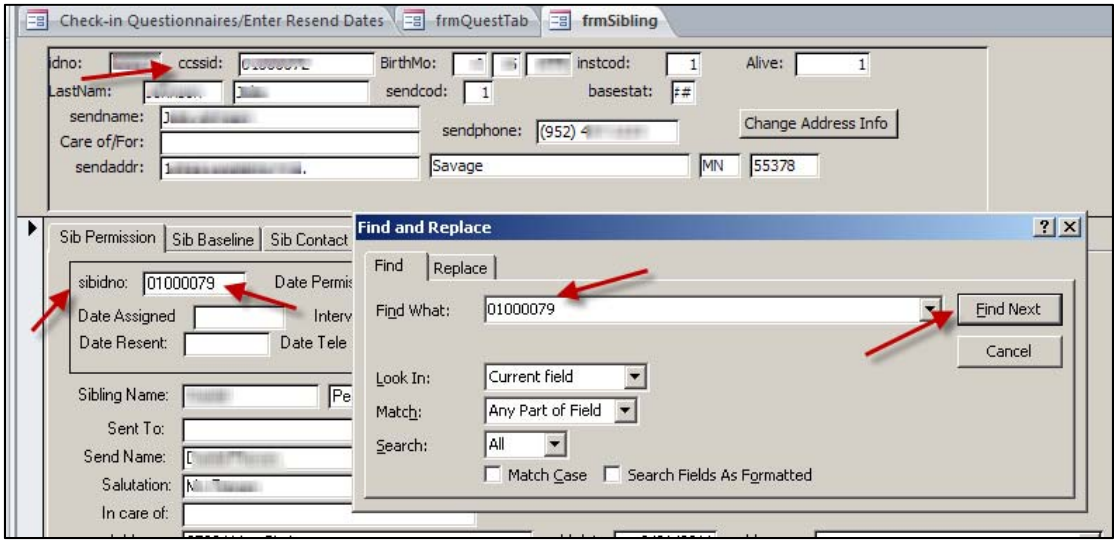


3. Update **REG: Sibling**

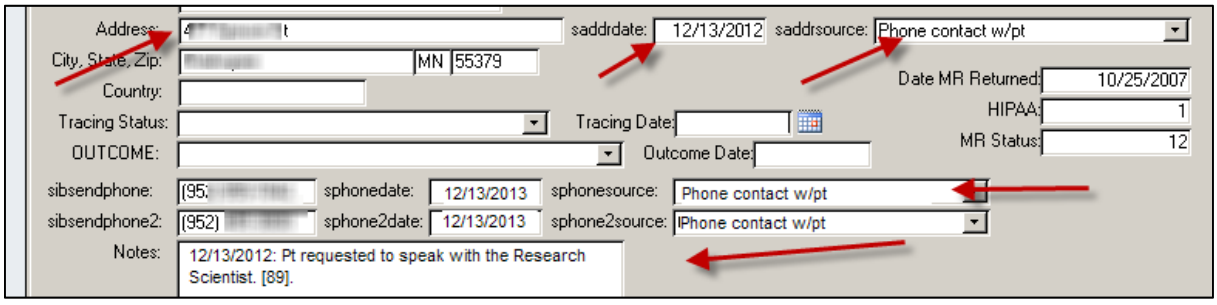
a. Open the REG database, and select **Sibling** from the switchboard.



b. Use the search feature to locate the sibling participant by **sibidno**. (NOTE: The sibling's CCSS case information is displayed at the top of the screen and the sibling's information is displayed below.)



c. Update the sibling's address and phone contact information on the Sib Permission tab in the same manner as the case's Page 1 tab, including dates and sources.



d. Update the sibling's additional contact information on the Sib Contact tab and the sibling's email information on the Sib email address tab.

e. Move to a new field in the record, then click the **Save** icon in the **Records** section of the Access Home tab.

4. <u>All other updates</u>
   a. Name changes, vital status changes, gender, date of birth changes are updated by the Lead Survey Interviewers (LSIs) by adding a request in the **Call Outcomes Log**.
   b. Additional requests, questions, or concerns need to be sent via email to the Coordinator and copied to the Research Scientist and LSI team.

Revision Record
Printed 7/26/2013 11:52 AM

[255] Current Filename:		Updating Original CCSS Cohort Contact Information ver 1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/24/13	D. Rinehart, R. Massey	Initial Development

Updating Print Tables

Background

When we print Expansion Baseline surveys, the Teleform program inserts personalized information (participant name, date of birth, mailing address, and phone number). This personalized information is stored in special "print tables" in the Expansion Tracking database. Information that we update on the Quest tab of the database does NOT automatically get updated in the print tables. Therefore, it is necessary to take additional steps after updating the name and/or address to ensure the print table is updated so that the survey will have the correct information inserted.

Procedures

1. Locate the participant record in the database, follow applicable procedures for confirming or updating the mailing ADDRESS/PHONE numbers. (E.g., to CONFIRM the address/phone, record the current date and information source. To UPDATE the address, FIRST use the Archive Contact Info button to archive existing information. THEN record the new address/phone information and information source and date.) (See **Notifications from Mail Carrier about Participant Correspondence**)

2. If the NAME needs to be changed, follow the applicable procedure for making the changes to the name. (See **Changing Maiden Name to Married Name**).

3. AFTER making the changes on the Quest tab, SAVE the changes. *If you fail to do this, then the Update Print Table operations WILL FAIL!* So either:
   a. Move to the next record in the database, and then move back to the record you updated; or
   b. Click the Save icon on the Records section of the Home ribbon

4. If you have either UPDATED or CONFIRMED any address or phone numbers for the participant record, click the Update Print Table Address button.

5. If you have updated the NAME for the participant, click both the Update Print Table Names button and the Update Print Table Address button.

Special notes:

1. The Update Print Table functions use the **participant's Birth Date** to determine which print table needs to be updated (e.g., minor or adult).
   a. If the date of birth is incorrect (or was initially missing as is typical for **Dana Farber** cases), the update print table functions may NOT work until we have updated the Date of Birth.
   b. To update the Date of Birth, notify the CRA2 or the LeadSI.
2. Each week work day the CRA2 runs a procedure to check for individuals who just turned 18, so they can be moved from the minor print table to the adult print table. On the outside chance that this procedure has NOT been run yet, it is possible the update print table will not work. Thus, we recommend waiting until 10 a.m. before updating the print tables.
3. For deceased cases, you only need to update print tables for cases from Inst 05/Dana Farber.

Revision Record — Printed 2/4/2013 8:40 AM

(223) Current Filename:		Updating Print Tables ver 1_1.docx	
Revision No.	Date	Responsible Author	Change Description
1	11/27/12	J.Bates	Initial Development
1.1	2/4/13	J.Bates	Date of birth info

Updating the FU5 iPad Letter Master List

Background

The **FU5 iPad Letter Master List** has been developed for use when the LTFU Participant database is unavailable to provide support for FU5 incoming calls from LTFU Study participants who have been mailed the advance letter (or "iPad intro letter"). This list must be updated weekly upon receipt of the CRA's emailed notification that the week's batch of advance letters has been mailed.

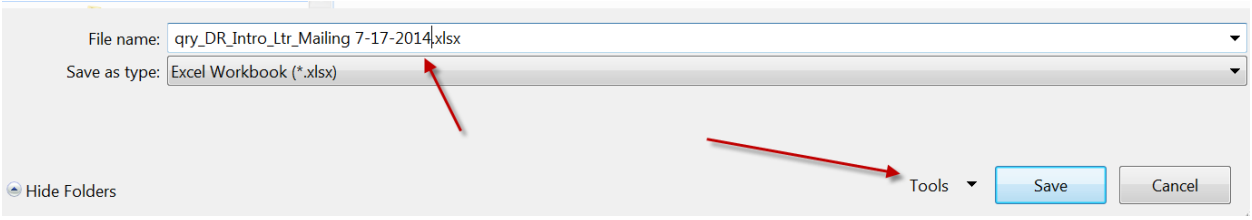
Procedures

Tools Needed:

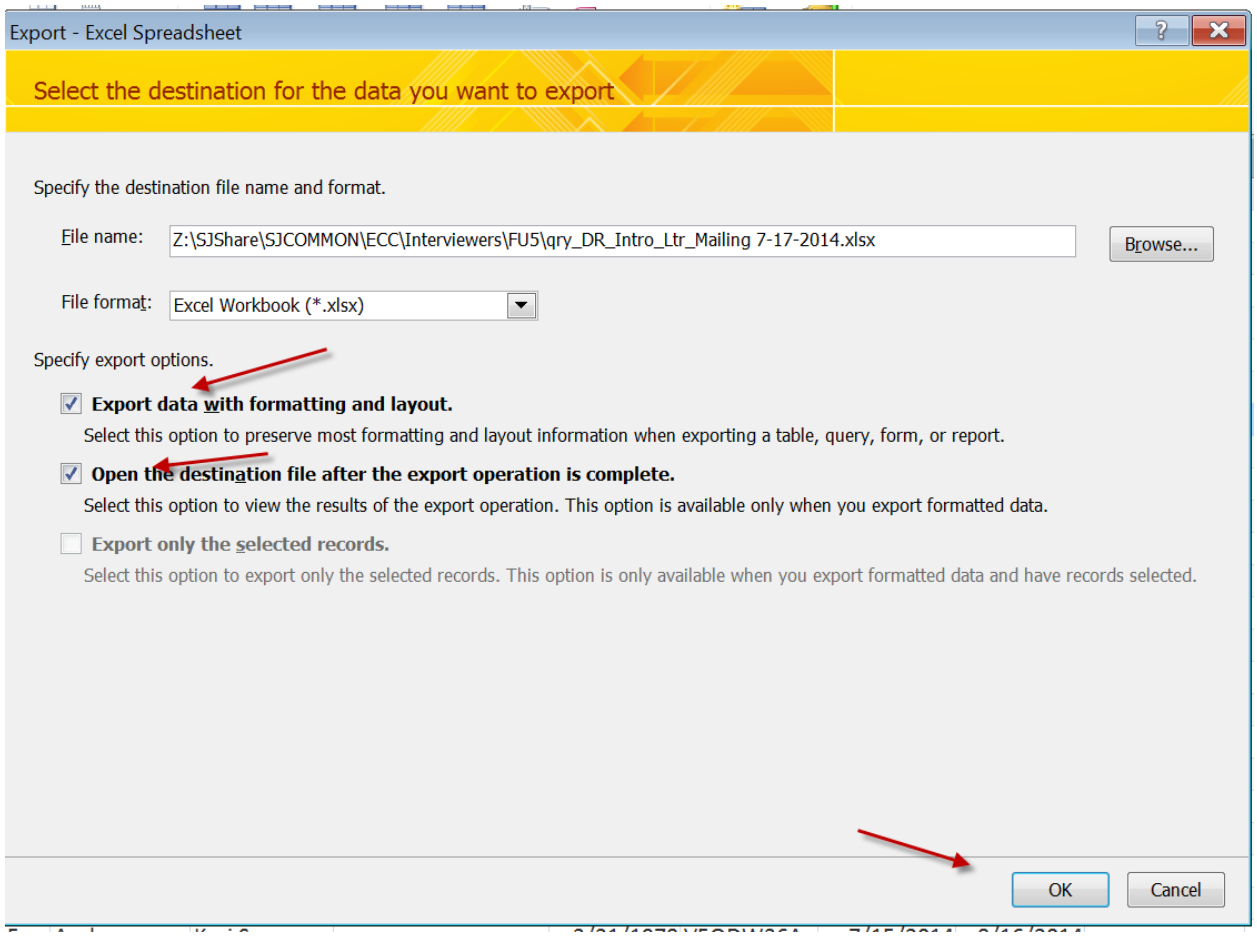
- File name: **FU5 iPad Letter Master List_[mm-dd-yyyy]**, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\FU5*
- Query name: qry_DR_Intro_Ltr_Mailing, located in the CCSS Call Center Admin Database at Z:\SJShare\SJCOMMON\ECC\Interviewers\LSI\Tech\CCSS Call Center Admin DB

Steps:

1. Open the most recently dated Excel file **FU5 iPad Letter Master List_[mm-dd-yyyy]**.
2. Open the CCSS Call Center Admin Database.
3. Run the query named qry_DR_Intro_Ltr_Mailing, then export the results as an Excel file:
    a. From the Navigation pane of the CCSS Call Center Admin Database, locate the query named qry_DR_Intro_Ltr_Mailing.
    b. Double-click on the query name to run the query.
    c. Export the query results as an Excel file:
        i. From the Access Ribbon, select the External Data tab.
        ii. In the Export group, click the Excel icon.
        iii. In the Export-Excel Spreadsheet window, click the **Browse** button.
        iv. In the File Save window, drill down to the folder FU5 folder, located at *Z:\SJShare\SJCOMMON\ECC\Interviewers\FU5*.



        v. In the **File Name** field, add the current date to the existing Excel file name.
        vi. Click the **Save** button.
        vii. Check the **Export data with formatting and layout** and **Open the destination file after the export operation is complete** checkboxes.



viii. Click the **OK** button.

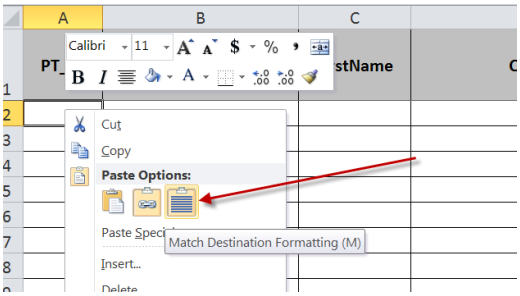
ix. Close the Export-Excel Spreadsheet dialogue box WITHOUT checking the **Save export steps** checkbox.

x. Close the qry_DR_Intro_Ltr_Mailing query results in the database.

4. Update the file **FU5 iPad Letter Master List_[mm-dd-yyyy]**:
    a. Prepare the Excel file **FU5 iPad Letter Master List_[mm-dd-yyyy]**:
        i. On the Excel Ribbon's File tab, choose "Save As" from the menu. In the Save As window:
            1. Ensure the file is being saved in *Z:\SJShare\SJCOMMON\ECC \Interviewers\FU5*.
            2. In the **File Name** field, change the date in the file name to the current date.
            3. Click the **Save** button.
        ii. On the Excel Ribbon's Review tab, unshare the workbook.
        iii. Click cell A2, scroll to the last row with data, hold down the Shift key, and click in column L in that last row. This should highlight the list. Press Delete on the keyboard to clear the cells.

b. Copy the data from the Excel file **qry_DR_Intro_Ltr_Mailing [mm-dd-yyyy]** from cell A2 to column L in the last row with data.

c. Click in cell A2 in the Excel file **FU5 iPad Letter Master List_[mm-dd-yyyy]**, then right-click in the same cell and paste the data using the "Values" or "Match Destination Formatting" paste option.



d. Save the file.

e. On the Excel Ribbon's Review tab, share the file.

f. Close the file. Close the **qry_DR_Intro_Ltr_Mailing [mm-dd-yyyy]** file.

g. Archive the *previous week's* version of **FU5 iPad Letter Master List_[mm-dd-yyyy]**.

h. Archive all versions of **qry_DR_Intro_Ltr_Mailing [mm-dd-yyyy]**.

5. Send an email to the Survey Interviewer team that the **FU5 iPad Letter Master List** file has been updated.

Revision Record

Printed 9/4/2014 9:07 AM

Current Filename:		Updating the FU5 iPad Letter Master List 1_2.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/17/14	D. Rinehart	Initial Development
1.1	7/29/14	D. Rinehart, R. Massey	Content Revision
1.2	8/27/14	R. Massey, D. Rinehart	Remove information regarding tracing list, updated title, updated database where query is located

Updating the Subsequent Neoplasm Status Reports

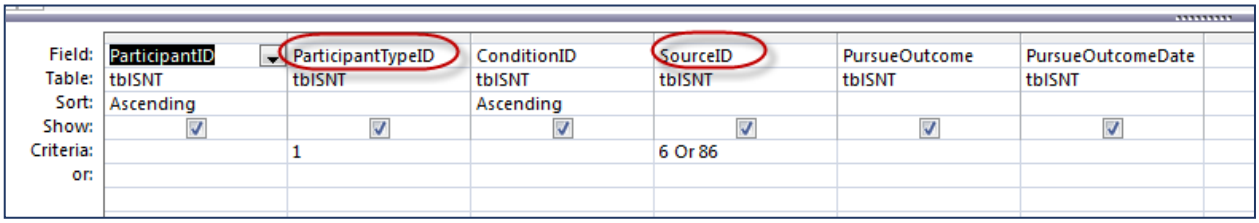
Background

In order for Childhood Cancer Survivor Study (CCSS) leadership to direct use of the subsequent neoplasm (SN) project resource for publications and ancillary research projects, the leadership team must understand the current state of the project. Status reports for each active source of SNs (e.g. FU7 survey) are produced on a regular basis and provided to the leadership team including the CCSS Principal Investigator, the CCSS Project Director, and the CCSS Research Scientist. This procedure explains how to update the SN status reports for each source.

Procedure

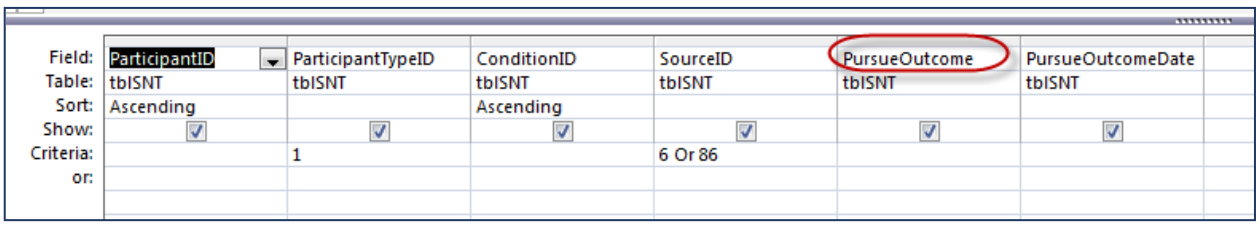
1. Resolve as many condition-level requests for project manager action as possible .
2. Open the appropriate SN status report template and resave the document in the same location with the current date in the document name. For example, **FU7 SN Status – CASES – TEMPLATE** becomes **FU7 SN Status – CASES – 091920**.
    A. Expansion Baseline cases – **ExpBase SN Status – CASES – TEMPLATE**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\Expansion Baseline*
    B. Expansion Baseline siblings – **ExpBase SN Status – SIBLINGS – TEMPLATE**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\Expansion Baseline*
    C. FU5 cases – **FU5 SN Status – CASES – TEMPLATE**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\FU5*
    D. FU5 siblings – **FU5 SN Status – SIBLINGS – TEMPLATE**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\FU5*
    E. FU6 cases – **FU6 SN Status – CASES – TEMPLATE**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\FU6*
    F. FU6 siblings – **FU6 SN Status – SIBLINGS – TEMPLATE**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\FU6*
    G. FU7 cases – **FU7 SN Status – CASES – TEMPLATE**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\FU7*
    H. FU7 siblings – **FU7 SN Status – SIBLINGS – TEMPLATE**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\FU7*
3. Update the document's heading to include the current date.

4. Open the SNT database, located at https://workspaces.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx.
5. Using the Navigation Pane, open **qry_SNStatusRpt_RM** in Design View. Update the criteria for the following fields:
   A. **ParticipantTypeID**
      i. Cases – Specify "1".
      ii. Siblings – Specify "2".
   B. **SourceID**
      i. Expansion Baseline – Specify "41 or 84".
      ii. FU5 – Specify "5 or 75 or 85".
      iii. FU6 – Specify "6 or 86".
      iv. FU7 – Specify "7 or 87".



Field:	ParticipantID	ParticipantTypeID	ConditionID	SourceID	PursueOutcome	PursueOutcomeDate
Table:	tblSNT	tblSNT	tblSNT	tblSNT	tblSNT	tblSNT
Sort:	Ascending		Ascending			
Show:	☑	☑	☑	☑	☑	☑
Criteria:		1		6 Or 86		
or:						

6. Run **qry_SNStatusRpt_RM**.
   A. Export a copy of the query results.
      i. Save the results as an Excel file in the instrument-appropriate folder at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports*. For example, results for FU7 cases would be saved at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN\SN Status Reports\FU7*.
      ii. When naming the exported Excel file, add either "CASES" or "SIBLINGS" followed by the 6-digit date after the query name. For example, results for FU7 cases exported on 1/2/2021 would be saved as **qry_SNStatusRpt_RM CASES 010221.xlsx**.
   B. In the SN status report document, update the **Self-Reported Conditions** text box with the total number of query results.
7. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "1". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Rejected at 1st Screening** text box with this total.

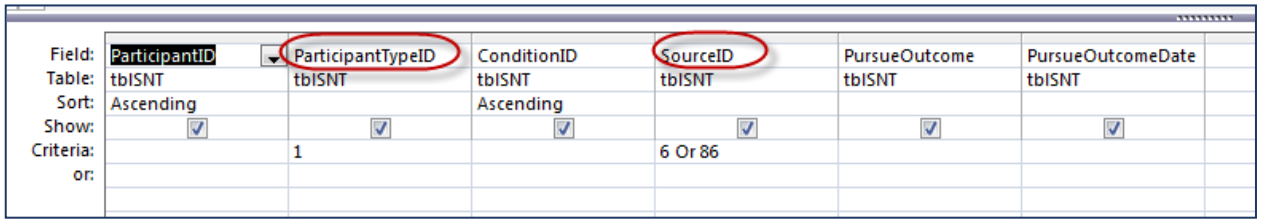


Field:	ParticipantID	ParticipantTypeID	ConditionID	SourceID	PursueOutcome	PursueOutcomeDate
Table:	tblSNT	tblSNT	tblSNT	tblSNT	tblSNT	tblSNT
Sort:	Ascending		Ascending			
Show:	☑	☑	☑	☑	☑	☑
Criteria:		1		6 Or 86		
or:						

8. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "Is Null". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Pending Pursue Decision** text box with this total.
9. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "<>1 And <>22". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Pursue Path Report** text box with this total.
10. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "22". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Participant Ineligible** text box with this total.
11. Ensure all totals on the 2nd row sum to the total number of self-reported conditions in the first row.
12. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "5 or 7 or 8". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Pursuing 1st HIPAA** text box with this total.
13. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "3 or 6". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Need More Info From Pt** text box with this total.
14. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "2". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Rejected During Pursuit** text box with this total.
15. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "<>1 And <>2 And <>3 And <>5 And <>6 And <>7 And <>8 And <>11 And <>13 And <>14 And <>22". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Path Report Requested** text box with this total.
16. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "13". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Pt Refused** text box with this total.
17. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "11". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Pt Denied SN At Re-Contact** text box with this total.
18. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "14". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Pt Non-Responder** text box with this total.
19. Ensure all totals in the 3rd row sum to the figure in **Pursue Path Report**.
20. Close **qry_SNStatusRpt_RM** but *do not save the changes*.
21. Open **qry_SNStatusRpt_Facilities_RM** in Design View. Update the criteria in both rows for the following fields:
    A. **ParticipantTypeID**
        i. Cases – Specify "1".
        ii. Siblings – Specify "2".
    B. **SourceID**
        i. Expansion Baseline – Specify "41 or 84".

ii. FU5 – Specify “5 or 75 or 85”.
iii. FU6 – Specify “6 or 86”.
iv. FU7 – Specify “7 or 87”.

22. Run **qry_SNStatusRpt_Facilities_RM** to obtain the total number of query results. In the SN status report document, update the **Facility Response Pending** text box with this total.
23. Open **qry_SNStatusRpt_Facilities_RM** in Design View.
    A. Delete the second row of criteria.
    B. Update the RequestStatus field in the first row to have criteria “3”.
    C. Re-run the query to obtain the total number of query results.
    D. In the SN status report document, update the **Facility-Specific Form Sent to Pt** text box with this total.
24. Close **qry_SNStatusRpt_FacilitiesRM** but *do not save the changes*.
25. Open **qry_SNStatusRpt_RM** in Design View. Update the criteria for the following fields:
    A. **ParticipantTypeID**
        i. Cases – Specify “1”.
        ii. Siblings – Specify “2”.



    B. **SourceID**
        i. Expansion Baseline – Specify “41 or 84”.
        ii. FU5 – Specify “5 or 75 or 85”.
        iii. FU6 – Specify “6 or 86”.
        iv. FU7 – Specify “7 or 87”.
    C. Update the PursueOutcome field to have criteria “10 or 40 or 41 or 50 or 51 or 53 or 54 or 55 or 56 or 57 or 58”.
    D. Run the query to obtain the total number of query results.
    E. In the SN status report document, update the **Records Obtained** text box with this total.
26. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria “15 or 16 or 17 or 20 or 21 or 52”. Re-run the query to obtain the total number of query results. In the SN status report document, update the **Unable to Obtain Records** text box with this total.
27. Ensure all totals in the 4th row sum to a total greater than or equal to the figure in **Path Report Requested** box. (Note that the figure could be greater than the **Path Report Requested** figure if multiple facilities are being pursued for one or more conditions.)
28. Update the **Pending 1st Adjudication** text box:
    A. Open **qry_SNStatusRpt_RM** in Design View.
        i. Update the PursueOutcome field to have criteria “40”.

ii. Run the query to obtain the total number of query results.

B. Open **qry_RecsReceived_SendtoPathMD_Cases_RM** or **qry_RecsReceived_SendtoPathMD_SIBs**, as appropriate, in Design View.
   i. Update the SourceID field to have the appropriate criteria for the survey in question.
      a. Expansion Baseline – Specify "41 or 84".
      b. FU5 – Specify "5 or 75 or 85".
      c. FU6 – Specify "6 or 86".
      d. FU7 – Specify "7 or 87".
   ii. Run the query to obtain the total number of query results.
   iii. Record the total in the single-asterisk note at the bottom of the document.
      a. If there are **no qualifying conditions**, update the note with "0".
      b. If there is **only one qualifying condition**, correct the grammar of the sentence.
   iv. Close the query, but *do not save the changes*.

C. In the SN status report document, update the **Pending 1st Adjudication** text box with the total results from both queries. *For example, if **qry_SNStatusRpt_RM** has 25 conditions and **qry_RecsReceived_SendtoPathMD_Cases_RM** has 6 conditions, update the Pending 1st Adjudication text box with "31".*

29. Update the **Pending Final Adjudication** text box:

A. Open **qry_SNStatusRpt_RM** in Design View.
   i. Update the PursueOutcome field to have criteria "41".
   ii. Run the query to obtain the total number of query results.

B. Determine if there are any **conditions that have been reviewed by the CCSS pathologist but not yet sent for final review**. Record this number in the double-asterisk note at the bottom of the document.
   i. If there are no qualifying conditions, update the note with "0".
   ii. If there is only one qualifying condition, update the grammar of the sentence.

C. In the SN status report document, update the **Pending Final Adjudication** text box.
   i. If there are no pathologist reviews that need to be sent for final review, update the **Pending Final Adjudication** text box with the total query results from **qry_SNStatusRpt_RM**.
   ii. If pathologist reviews need to be sent for final review and the adjudications HAVE been entered into the database, update **Pending Final Adjudication** with the total query results from **qry_SNStatusRpt_RM**.
   iii. If pathologist reviews need to be sent for final review and the adjudications HAVE NOT been entered into the database:
      a. Update **Pending Final Adjudication** with the total query results from **qry_SNStatusRpt_RM** plus the number of conditions that have been reviewed by the CCSS pathologist but not yet entered into the database. *For example, if **qry_SNStatusRpt_RM** has 25 conditions and there are 15 conditions that have been reviewed by the pathologist but not yet sent*

for final review, update the Pending Final Adjudication text box with "40".

b. Subtract the number of conditions that have been reviewed by the CCSS pathologist but not yet entered into the database from the number in the **Pending 1st Adjudication** text box. They would have been included in the query results as pending pathologist review but should be pending final review.

D. NOTE: The figure in the **Pending Final Adjudication** text box may not match the total figure from **SN Batch Tracking**, located at *Z:\ResearchHome\Departments\EpidemiologyCancerControl\common\CCSS\SMN*. Unlike this report, the **SN Batch Tracking** workbook (1) includes conditions entered by the CCSS pathologist that have not been entered into the SNT database and (2) may include conditions whose records were embedded with records for conditions from another source.

30. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "50". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Accept By Path** text box with this total.
31. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "51 or 53". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Accept by Med Records** text box with this total.
32. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "54 or 56 or 57 or 58". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Reject on Evidence** text box with this total.
33. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "55". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Reject – Lack of Evidence** text box with this total.
34. Ensure totals on the final row sum to a figure equal to the **Records Obtained** figure. NOTE: If final row totals sum to a figure less than the **Records Obtained** figure, it is likely there is a condition with Pursue Status = 10-Recs Obtained (which qualifies it for the **Records Obtained** text box) but whose **Date Sent Path Review** field in the condition record is not null (disqualifying it for the **qry_RecsReceived_SendtoPathMD** query). Consider whether any text boxes should be updated based on the unique circumstances discovered.
35. Open **qry_SNStatusRpt_RM** in Design View. Update the PursueOutcome field to have criteria "52". Re-run the query to obtain the total number of query results. In the SN status report document, update the **Accept by Self-Report** text box with this total.
36. Ensure the **Accept by Self-Report** total is less than or equal to the **Unable to Obtain Records** figure.
37. Close **qry_SNStatusRpt_RM** but *do not save the changes*.
38. Save the report.
39. Compare all figures to the most recent previous report to ensure they appear logical.
40. Archive the previous report(s).

Current Filename:		Updating the Subsequent Neoplasm Status Reports ver1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	9/29/17	R. Massey	Initial Development
1.1	8/26/19	R. Massey	Add FU7 directives, update network paths, improve flow, correct query name typo, add directive to save self-rpted condition results, add directive to compare to prior rpt before archiving

Uploading Sibling Participant Lists to DatStat

Background

In order for an expansion sibling baseline survey to be completed online (either alone or with the assistance of a survey interviewer), the individual's participant information must be uploaded to the DatStat participant list for the study. Since this information is not available until after we obtain permission to contact the sibling, the LeadCRA must take care of posting the record for the newly permitted sibling to the DatStat system. This will be done in a batch on a prearranged schedule. After permission has been obtained to contact the sibling, and the sibling's name, address, and date of birth have been entered into the Sibling Tracking system, AND THE SIBLING PRINT TABLE HAS BEEN UPDATED, the CRA2 will extract the data needed for DatStat and perform the upload process.

Procedures

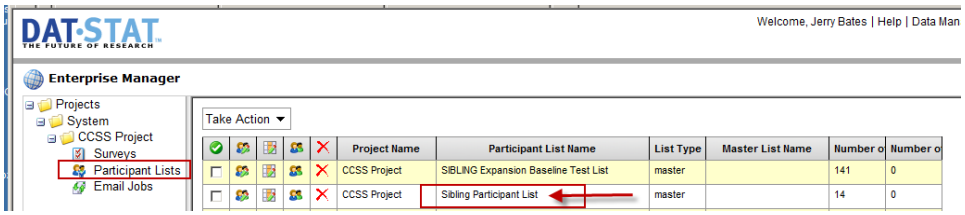
1. Ensure that the print table has been updated. To do this, run both
   a. quppSiblingPrintTableAdultSib-All
   b. quppSiblingPrintTableUnder18Sib-All

2. Run the query qmakCCSSExpansionSibDatStat. This query builds (and replaces) the local table tblCCSSExpansionSibDatStat, using the values that are in tblPrintQuestionnaireCCSSExpansionAdultSib

3. Export the tblCCSSExpansionSibDatStat as an Excel file. Store the Excel file **in**
   Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Expansion Tracking\DatStat Participant Lists\Sibling Participant List

4. Open the Excel file (Do a cursory check. If there are records with no addresses, you can manually edit them later, if needed, when there IS an address on file in the database.)
5. Save the Excel file as **tab delimited**. Then CLOSE the Excel file

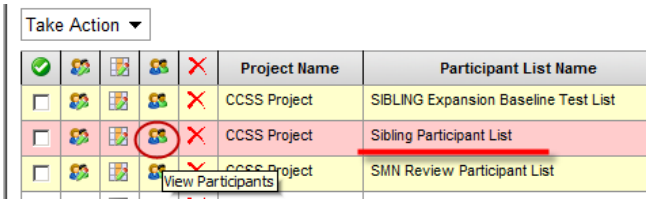
6. Open DatStat (https://live.datstathost.com/STJUDE/) and log in. In order to perform these functions, you must use the Enterprise Manager section (vs Data Manager)



7. Navigate to Projects, System, CCSS Project, Participant Lists, Sibling Participant List

8. Click the **View Participants** icon on the Sibling Participant List row

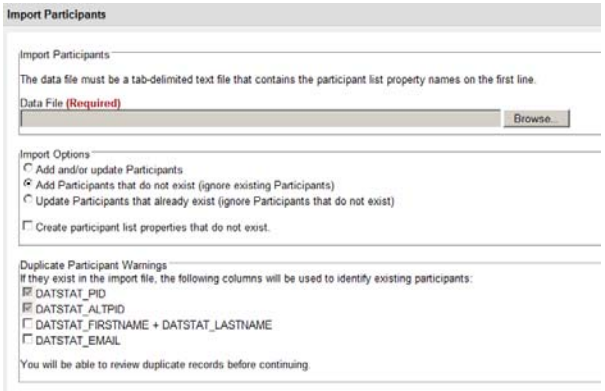
9. This will bring up the current Sibling Participant List as it is in DatStat.



10. If there are no data showing for the records, follow instructions for **(re)selecting columns** (below).

11. Click the **Take Action** drop down and select **Import Participants**

12. In the Import **Participants dialog** box:
    a. Select the Import Option "**Add Participants that do not exist (ignore existing Participants)**"
    b. NOTE: If we need to update EVERYBODY in addition to adding new participants, use the first option "Add and/or update Participants"
    c. Use the **Browse**… button to browse to the folder containing the tab delimited file you exported from Access earlier.



    d. Click the **SAVE** button, and then **OK**
    e. You may see a message that tells the number of participants successfully imported and a list of "errors". The errors are the records that would have been duplicates. This is NOT an error, so ignore and click OK.

To EDIT an individual Participant from the participant list:

1. Find the participant in the list
2. Click the Edit Participant icon
3. On the Edit Participant screen, select the tab for Custom Participant Info
4. You may now "edit in place" the fields for the selected participant.
5. Click the **Save** button.
6. When the Changes Saved message appears, click the **OK** button
7. The participant's record should now refresh to reflect the edits.

Reselecting columns to be displayed. *If the list of participants does NOT display*, you may need to rebuild the currently selected columns.

1. From the **Take Action** dropdown, select **Choose Columns**.
2. Beneath "Currently Selected Columns," click **Remove All**.
3. Then drag the following columns from the "Available Columns" list to the Currently Selected Columns. (These are the same columns that are in the xls/txt file.)

SIBID	sendcareof	sendstate	PW	FAFNAM
NameImport	sendaddr	zipsort	MOFNAM	FALNAM
DOB	sendcity	sendphone	MOLNAM	DATSTAT_ALTPID

4. **Save** and **OK**.

Revision Record — Printed 5/16/2013 12:18 PM

[234] Current Filename:		Uploading Sibling Participant Lists to DatStat ver 1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	5/1/13	J.Bates	Initial Development
1.1	5/3/13	J.Bates	Refresh columns; Import Participant "error"
1.2	5/16/13	J.Bates	Refresh column list to import

Use of "Care of" Field

Background

The U.S. Postal Service has guidelines for sending mail in the care of another person:

> *If you would like to send mail to an individual (John Doe) in care of another person (Robert Smith), use the following format:*
>
> *JOHN DOE*
> *C/O ROBERT SMITH*
> *123 APPLE WAY*
> *CITY ST 99999*
>
> http://faq.usps.com/eCustomer/iq/usps/request.do?create=kb:USPSFAQ&view()=c%5Bc_usps0910%5D&varset(source)=sourceType:embedded

In the LTFU study, the Expansion Tracking, REG, and Recruitment databases have been set up to accommodate requests that mail be sent in the care of someone else. The **Care of** field is found with the address information (Quest tab for Expansion and Recruitment; Page 1 for REG) and is used when a participant or a participant's legal guardian requests their mail be sent in care of someone else.

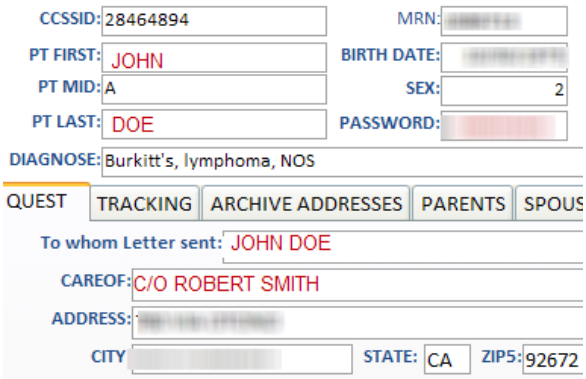
The **Care o**f field is not automatically used in mailings to the parents of minors or the families of deceased participants (automated queries will add "the parents of" or "the family of" when addresses are generated). For minors or deceased participants, the **Care of** field is used when a participant's legal guardian does not have the same last name as the participant.

Procedure

Data files for mail merge mailing labels (Expansion and Recruitment): Expansion Recruitment and Expansion Tracking queries used to generate production data files for mailing labels will include the **CAREOF** or **Care of** field. The mailing label will show the "care of" value on the second line of the mailing label. The following procedures outline how to populate the Care Of field correctly so the mail merge labels are produced consistently and accurately and a historical reference is maintained for future mailings:

Recruitment Database

In the Recruitment database, populate the **CAREOF** field in the Quest tab with "C/O Firstname Lastname".

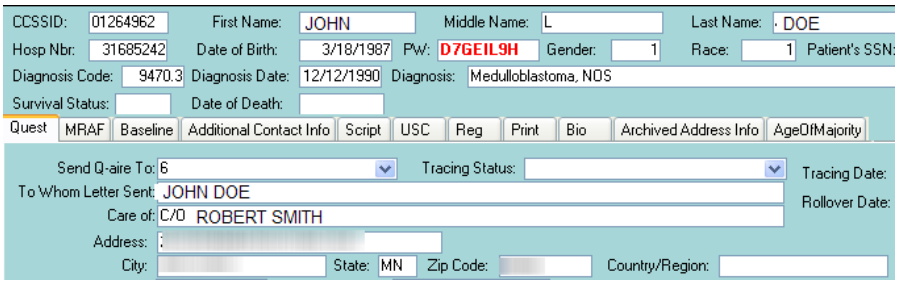


- Always start the entry with "C/O".
- Use the first and last name of the person in whose care the mail is being sent. "Robert Smith" is used as an example. In the Comments/Notes section, document the relationship between the participant and the person in the care of field and any clarifying information.
- Ensure the capitalization format matches the t of the address. (e.g. If the rest of the address is in ALL CAPS, the **CAREOF** field should also be in ALL CAPS.)

- If t the person in the Care Of field has a preferred name different from his/her legal name, document the legal name and preferred name in the **COMMENTS** field of the Quest tab using a dated note with your initials or SI ID. Record the preferred name in the **CAREOF** field. (e.g. Bob Smith in the **CAREOF** field and a dated note in the **COMMENTS** field indicating that Robert Smith prefers to be called "Bob".)
- The **To whom Letter sent** field should always contain the name of the case/survivor. (See the JOHN DOE example, noting the case/survivor's name at top of form.)
- When a recruited case rolls over to Expansion Tracking, the rollover procedure will put the **CAREOF** value in the Expansion Tracking database's **Care of** field.

Expansion Tracking Database - Cases

Populate the **Care of** field in the Quest tab with "C/O Firstname Lastname".



- Always start the entry with "C/O".
- Use the first and last name of the person in whose care the mail is being sent.
- In the Comments/Notes section, document the relationship between the participant and the person in care of field and any clarifying information.
- Ensure the capitalization format matches the rest of the address. (e.g. If the rest of the address is in ALL CAPS, the **Care of** field should also be in ALL CAPS.)
- If the person in the Care of field has a preferred name different from his/her legal name, document the legal name and preferred name in the **Comments** field using a dated note with your initials or SI ID. Record the preferred name in the **Care of** field. (e.g. Bob Smith in the **Care of** field and a dated note in the **Comments** field indicating that Robert Smith prefers to be called "Bob".)
- The **To Whom Letter Sent** field should always contain the name of the case/survivor. (See the JOHN DOE example, noting the case/survivor's name at top of form.)

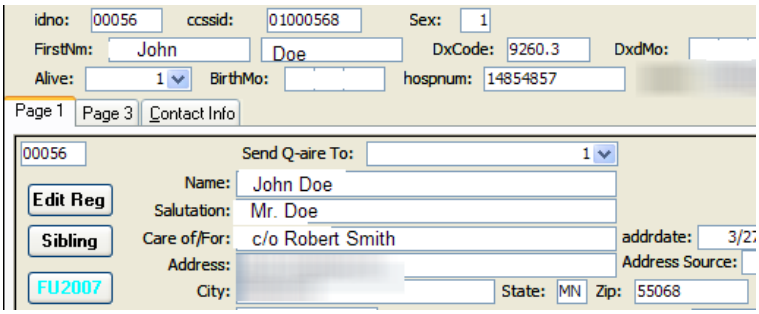
Expansion Tracking Database – Siblings

Populate the **Care of** field in the Sib Info tab with "C/O Firstname Lastname".

- Always start the entry with "C/O".
- Use the first and last name of the person in whose care the mail is being sent.
- In the Comments/Notes section, document the relationship between the participant and the person in care of field and any clarifying information.
- Ensure the capitalization format matches the rest of the address. (e.g. If the rest of the address is in ALL CAPS, the **Care of** field should also be in ALL CAPS.)
- If the person in the Care of field has a preferred name different from his/her legal name, document the legal name and preferred name in the **Comments** field of the Sib Info tab using a dated note with your initials or SI ID. Record the preferred name in the **Care of** field. (e.g. Bob Smith in the **Care of** field and a dated note in the **Comments** field indicating that Robert Smith prefers to be called "Bob".)
- The **Sibling Name** field should always contain the name of the sibling.

REG Database - Cases

The field to be updated in the REG database is titled Care of/For. Data entry in this field in the past has been used inconsistently, as "Care of" and as "For." These are outlined below.

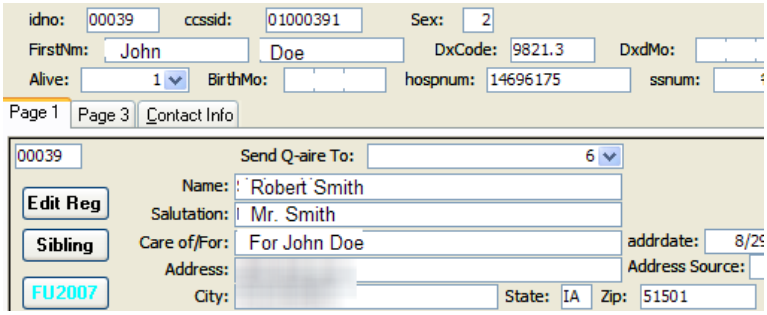


Please note, the upcoming combined database that will house both the original cohort and the expansion cohort will ONLY use the Care of field; participants' names will always be housed in the NAME field and Care of will house the name of who mail is to be directed.

Care of: The field may be used as a Care of directive, with the participant's name maintained in the Name field and the mail sent to a different name in the Care of field (as with Expansion tracking and Recruitment)

- Always start the entry with "C/O".
- Use the first and last name of the person in whose care the mail is being sent.
- In the Comments/Notes section, document the relationship between the participant and the person in care of field and any clarifying information.
- If the person in the Care of field has a preferred name different from his/her legal name, document the legal name and preferred name in the **Comments** field of the Sib Info tab using a dated note with your initials or SI ID. Record the preferred name in the **Care of** field. (e.g. Bob Smith in the **Care of** field and a dated note in the **Comments** field indicating that Robert Smith prefers to be called "Bob".)
- Ensure the capitalization format matches the rest of the address.

For: There are cases where the Name field does not contain the participant's name and instead has the name of the person the mail is been sent to *for* the actual participant. When this is the case, the Name field will not match the First and Last name found in the header (participant's name) and the participant's name will be listed in the Care of/For field as "For John Doe". In these cases:



- Populate the **Name** field with the name of the person in whose care the mail is being sent.
  - Ensure the capitalization format matches the rest of the address. (e.g. If the rest of the address is in ALL CAPS, the **Name** field should also be in ALL CAPS.)
  - If we know that the person in whose care the mail is being sent has a preferred name different from his/her legal name, document the legal name and preferred name in the **Tracing history** field of the Page 1 tab using a dated note with your initials or SI ID. Record the preferred name in the **Name** field. (e.g. Bob Smith in the **Name** field and a

dated note in the **Tracing history** field indicating that Robert Smith prefers to be called "Bob".)

- Populate the **Care of/For** field with "For" plus the first and last name of the participant. This is who the mail is for. Ensure the capitalization format matches the rest of the address. (e.g. If the rest of the address is in ALL CAPS, the **Care of/For** field should also be in ALL CAPS.) See the example screen shot.

Note, the For option will not be used in the upcoming combined database that will house both the original cohort and the expansion cohort.

REG Database – Siblings

In the sibling record, populate the **In care of** field in the Sib Permission tab with "C/O Firstname Lastname".

- Always start the entry with "C/O".
- Use the first and last name of the person in whose care the mail is being sent.
- In the Comments/Notes section, document the relationship between the participant and the person in care of field and any clarifying information.
- Ensure the capitalization format matches the rest of the address. (e.g. If the rest of the address is in ALL CAPS, the **In care of** field should also be in ALL CAPS.)
- If we know the person in whose care the mail is being sent has a preferred name different from his/her legal name, document the legal name and preferred name in the **Notes** field of the Sib Permission tab using a dated note with your initials or SI ID. Record the preferred name in the **In care of** field. (e.g. Bob Smith in the **In care of** field and a dated note in the **Notes** field indicating that Robert Smith prefers to be called "Bob".)
- The **Send Name** field should always contain the name of the sibling.

Revision Record Printed 3/7/2014 1:44 PM

[106] Current Filename:		Use of Care Of Field ver 2_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	3/29/2012	J.Bates	Initial Development
2.0	3/5/2014	R. Massey	Add directive for siblings, add directive for preferred names, added SIs to audience
2.1	3/7/2014	L.Harrison/J.Ford	Added further explanation to the REG options

Useful Websites

American Cancer Society	http://www.cancer.org/
Children's Oncology Group	http://www.childrensoncologygroup.org/
Drug Information	http://www.drugs.com/
Health and Human Services Office for Human Research Protections (OHRP)	http://www.hhs.gov/ohrp/
National Cancer Institute	http://www.cancer.gov/
National Childhood Cancer Foundation (Cure Search)	http://www.curesearch.org/
NIH Clinical Trials Information	http://www.clinicaltrials.gov/
PubMed (medical research journals and articles)	http://www.ncbi.nlm.nih.gov/sites/entrez?db=pubmed
Society of Clinical Research Associates (SoCRA)	http://www.socra.org/
Survivorship Guidelines (Cure Search; CoG)	http://www.survivorshipguidelines.org/
St. Jude File Transfer Application	https://fta2.stjude.org/courier/2645@/mail_user_login.html?
St. Jude Share Site	https://stjudeshare.stjude.org/index.php

Revision Record

Printed 7/16/2012 1:19 PM

Current Filename:		Useful Websites ver1_0.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development

Using and Creating Participant MS Word Call Logs ("PHONE CONTACT LOG")

Background

All calls to and from CCSS participants must be entered into a single "master" call log for the participant: the MS Word **Phone Contact Log**. Participants can be eligible for multiple studies at the same time, and this log allows Survey Interviewers (SIs) to see when the LTFU Study last called the participant as well as the outcome of each call. Reviewing a participant's call log is a critical pre-call step to build the participant profile and to ensure procedures are being followed regarding frequency of calls. Entering call results/information into the call log after the call is also necessary. (See **Decoding CCSSID** for tips on figuring out which cohort the case belongs to and what the institution codes are.)

Procedures

Locating and Using Existing Phone Contact Logs

1. Locate the logs:
   a. Open the folder containing the logs for the appropriate cohort for the participant:
      i. Expansion Cohort participants are in *Z:\SJShare\SJCOMMON\ECC\Interviewers \Expansion Survey Calls\Participant call logs*
      ii. Original Cohort participants are in *Z:\SJShare\SJCOMMON\ECC\Interviewers\Original Cohort Call Logs – Reg db*

   b. In the cohort folder, open the folder of the institution from which the CCSSID came. (The first 2 digits of the CCSSID are the key to the institution from which the participant came. For example, CCSSIDs beginning with 01 will be in the folder "01. Minnesota".)

   c. All files are named according to the CCSSID of the case.

   d. Locate the MS Word document named for the CCSSID.
   NOTE: If you do not find a log for the CCSSID, then you will need to create a new one. See the section of this document titled *Creating a New MS Word **Phone Contact Log***, below.

2. Open the MS Word **Phone Contact Log** for the participant and review all documentation as part of your pre-call procedures.

3. After completing a call to the participant, log all relevant information in the MS Word **Phone Contact Log**.

DATE (Mo/Day/Yr)	Day (i.e.: SU)	TIME (AM/PM)	INT. ID #	CONT-ACT (mark X if yes)	If yes, whom?	Out-come	Comments
4/19/13	FRI	4:40PM	111	X	PT	9	(832) 339-2442;spoke to pt, she said she has completed the survey and will mail next week.
7/9/13	Mo	2:33pm	111	X	Pt	9	(832) 339-2442; Spoke to pt, she said she's had a lot going on in her life, sick parents and busy with child. She promises to finish the survey and place in the mail. She verified her address.
9/23/13	MO	4:33 PM	152			3	832-339-2442; NO ANS, LEFT MSG

   a. Use the first empty row in the log to document the call you completed.

b. **DATE** column: Enter the date of the call.
NOTE: If making several calls on the same day to the same participant (e.g. calling additional contacts), use a new row to enter each subsequent call. Be sure to enter the date on each row, regardless of whether it is the same as the date on the previous call.

c. **Day** column: Enter the day of the week for the call using the indicated two-character abbreviated form. (See legend.)
NOTE: If the log you are using has no **Day** column, enter the day abbreviation after the call date in the **Date** column.

Day of the Week Legend:	
1. Sunday=	SU
2. Monday=	MO
3. Tuesday=	TU
4. Wednesday=	WE
5. Thursday=	TH
6. Friday=	FR
7. Saturday=	SA

d. **Time** column: Enter the time of the call, including "am" or "pm."

e. **INT. ID#** column: Enter your interviewer ID number.

f. **CONTACT** column: Enter "X" if contact was made with anyone.

g. **If yes, whom?** column: Populate this field if contact is made with anyone. Enter the identity of the party contacted. It is appropriate to use "Pt" to indicate you contacted the participant. Otherwise, be as specific as possible for other parties. (e.g., "Winston Churchill, father" or "Oprah Winfrey, aunt", etc.)

h. **Outcome** column: Enter the appropriate code to identify the outcome of the call. Use the outcome codes listed in the header.

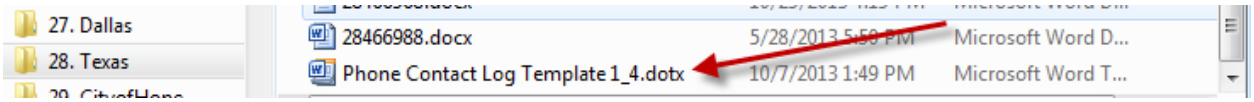
i. **Comments** column: Enter brief, clear, and complete notes detailing the results of the call.

Outcome:	**Outcome:**
1. Completed	6. Disconnect
2. No answer	7. Refused (enter comment)
3. No answer/left message	8. Deceased
4. Appointment made	9. Will return by mail/online
5. Resend	10. Other (enter comment)

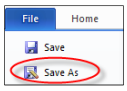
4. Save and close the document.

Creating a New MS Word Phone Contact Log

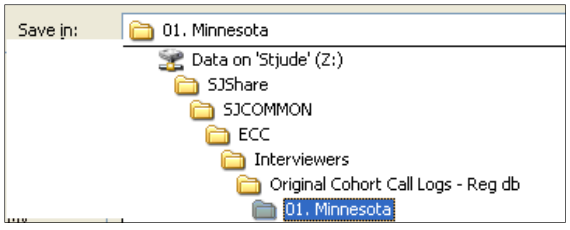
1. Open the template titled **Phone Contact Log Template 1_4** in the institution folder in which you searched when you tried to locate the log.



2. Select **File**, and then click **Save As**.



3. In the **Save As** dialog box:
   a. Drill down to *Z:\SJShare\SJCOMMON\ECC\Interviewers\Expansion Survey Calls\Participant call logs* and

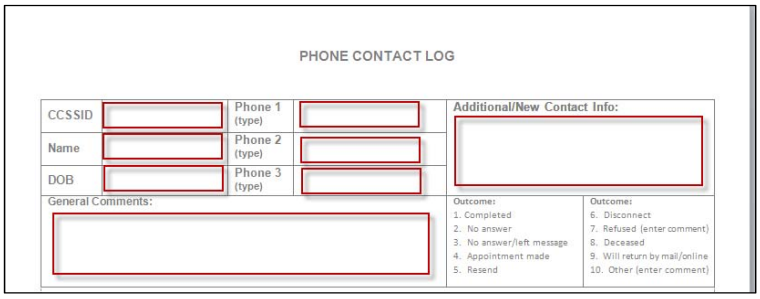


choose the appropriate institution folder for the CCSSID in question.

b. In the **File name** field (near the bottom of the window) enter the CCSSID number of the participant as the name of the call log file.

c. Click the **Save** button.

4. Fill out the top portion of the newly created MS Word **Phone Contact Log** for this CCSSID including the case's CCSSID number, name, DOB, phone number(s), additional or new contact information, and general comments. NOTE: General comments can be anything unusual or important for the next SI to know (e.g., "Case's LAR is George Washington." or "Only call after 2pm CT.")



5. Click the **Save** icon at the top of the form.

6. If appropriate, enter call information for the current call in the body of the new call log and save the log, as indicated in steps 3 and 4 under the section of this document titled *Locating and Using Existing* ***Phone Contact Logs***, above.

Revision Record — Printed 11/13/2013 8:15 AM

Current Filename:		Using and Creating Participant MS Word Call Logs ver1_4.docx	
Revision No.	Date	Responsible Author	Change Description
1	2/23/09	A. McDonald	Initial Development
1.1	5/4/12	Procedure Team	Content and formatting revisions
1.2	5/10/12	D. Rinehart	Updated form to add "day" column and legend
1.3	5/15/12	J.Bates	New file name includes "creating"
1.4	10/29/13	R. Massey	Update name of call log template, update screen shots.

Using Mail Merge and Labels

Background

Mail merges are frequently used to create cover letters and mailing labels for participant correspondence. There are several methods in Word to create mail merges and labels. The process for using the *Word Mail Merge Wizard* is discussed here.

Document

- Open Word
- Select Tools/Letters and Mailing/Mail Merge
- Choose Document Type – Letters
- Follow steps that are presented during the Mail Merge Set-up wizard

1. Select Document (current or from existing)
    a. Often use an existing document, but a new letter or Word template can be created/used here
2. Select Recipients
    a. Usually from an "existing" excel file that was created from a database query
    b. Choose "Browse" to find the file
    c. Make sure correct file was selected
3. Write your letter
    a. Click More Items to select needed fields or use existing fields in template if applicable
4. Preview the letter
    a. Can exclude recipients here if needed
5. Complete the merge
6. Print the letters

Labels

- Open Word
- Select Tools/Letters and Mailing/Mail Merge
- Choose Document Type – Labels
- Follow Steps in Mail Merge Set-up wizard

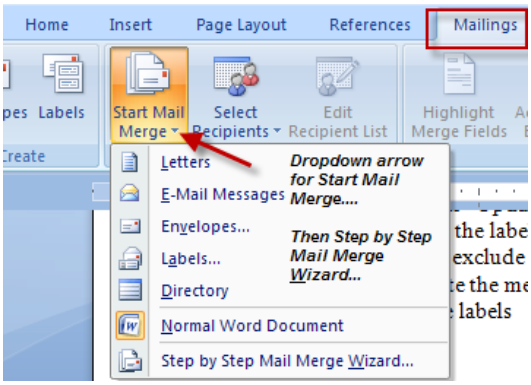
1. Select Label Options
    a. Change label size as appropriate for the label you are using (e.g. 5163)
2. Select Recipients
    a. Usually from an "existing" excel file that was created from database query
    b. Choose "Browse" to find the file
    c. Make sure correct file was selected
3. Arrange Label
    a. Click More Items to select needed fields (e.g., CCSID, Send Name, Send C/O, send address, send city, send state, zip sort, Sequence Number, envelope order number)
        i. Note: add country code if the address is outside of U.S.

   b. Manually format the spacing of the fields and lines of information, etc. if needed
   c. Click "Update all labels" if formatting changes were made
4. Preview the labels
   a. Can exclude recipients here if needed
5. Complete the merge
6. Print the labels

For Word 2007

The process is virtually the same as in Word 2003. The steps for getting to the *Step by Step Mail Merge Wizard…* are just a little different.

- Open Word
- Select the Mailings toolbar ribbon
- Select the dropdown arrow on the Start Mail Merge button



- Now, simply follow the steps presented during the Mail Merge Set-up wizard.

Revision Record

Printed 7/9/2012 2:47 PM

Current filename:		Mail Merge and Labels ver 1_1.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/2/09	A. McDonald	Initial Development
1.1	10/22/09	J.Bates	Formatting; Word 2007 screens

Using the Online Procedure Manual

Background

The standard operating procedures (SOPs) manual for the Childhood Cancer Survivor Study (CCSS) Coordinating Center and Call Center is available through the CCSS SOP Library. This online database is accessible through SharePoint. Users can browse a card catalog with brief descriptions of each procedure, search for procedures by key words or by user group, and retrieve the most updated version of any procedure. Each procedure indicates the user group(s) for the procedure (Survey Interviewers, Lead Survey Interviewers, CRAs, Lead CRAs, and/or Everyone). This document is a quick introduction to the features of the library.

Procedures

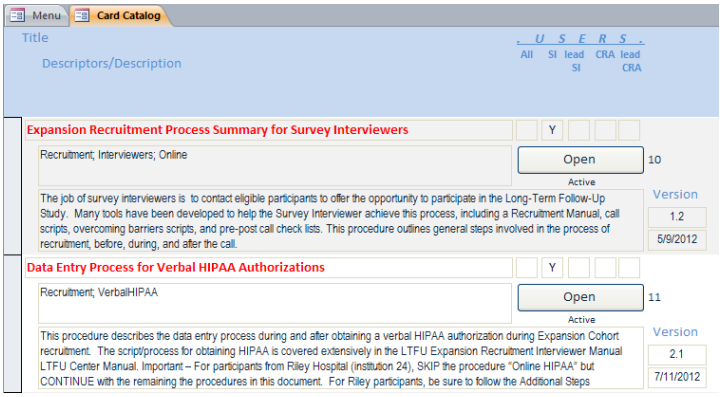
The opening screen for the library presents several action options.

1. **Card Catalog** – This button opens a list of every procedure in the library
2. Two search features open different search windows to assist in locating a specific procedure or group of procedures:
   A. **Search Key Words** – This button allows the user to key in the key word(s) or phrase on which the search will occur.
   B. **Search User Group** – This button allows the user to select user group(s) and displays all SOPs for the selected group(s).
3. Reports:
   A. **Report: CCSS SOP Library** – This button accesses a report that lists every procedure in the library.
   B. **New Procedures** – This button accesses a report that lists all procedures with version 1.0.
   C. **Recent Revisions** – This button accesses a report that lists recently updated procedures.
   D. **CCSS SOP Library-Expanded** – This button accesses a report of all procedures with full 'background' text.
   E. **INACTIVE Prodedures** – This button access a report listing procedures that are no longer active.
4. The **Exit** button closes the library.

Each procedure has a version number and revision date shown in the search results, in the procedure document's header, and in the procedure document's revision record.

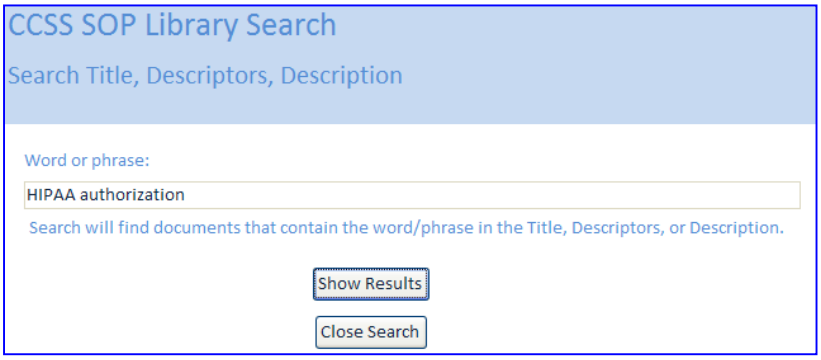
Card Catalog

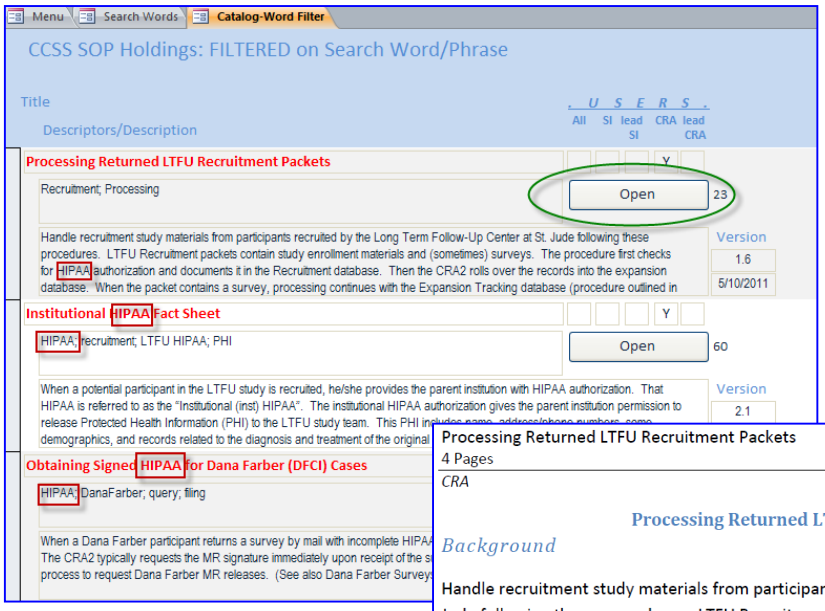
The card catalog allows the user to scroll through all procedures in the library. The **Open** button for each procedure opens the procedure in a pdf document. Printed copies of procedures should always be compared to the version available from the library to ensure the most recent revision is in use. See the version number and date shown both in the card catalog and in the header of each procedure.



Search Key Words

Enter a word or phrase and then click the **Show Results** button to see a list of all documents with that word/phrase in the title, descriptors, or description. Scan the displayed entries to locate the procedure in question, then click the **Open** button to view the full procedure. Use the **Close Search** button to close the search window and return to the menu.





Processing Returned LTFU Recruitment Packets — Ver. No. 1.6
4 Pages — Rev. Date: 5/10/11
CRA

Processing Returned LTFU Recruitment Packets

Background

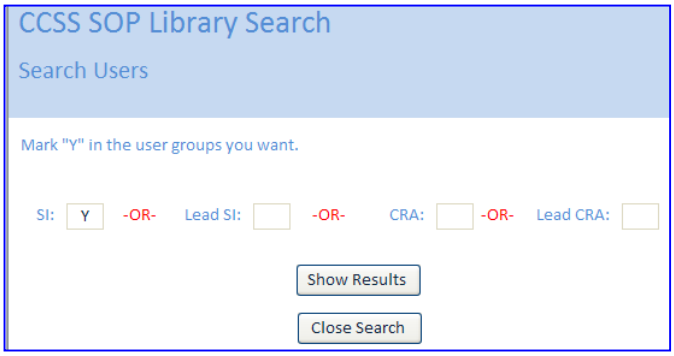
Handle recruitment study materials from participants *recruited by the Long Term Follow-Up Center* at St. Jude following these procedures. LTFU Recruitment packets contain study enrollment materials and (sometimes) surveys. The procedure first checks for HIPAA authorization and documents it in the Recruitment database. Then the CRA2 rolls over the records into the expansion database. When the packet contains a survey, processing continues with the Expansion Tracking database (procedure outlined in *Processing Expansion Questionnaires*).

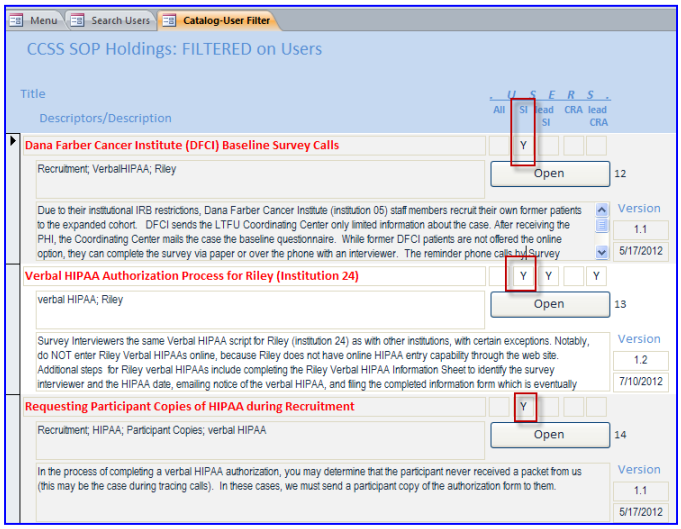
Procedure

1. Date-stamp the blue BRE with date received.

Search User Groups

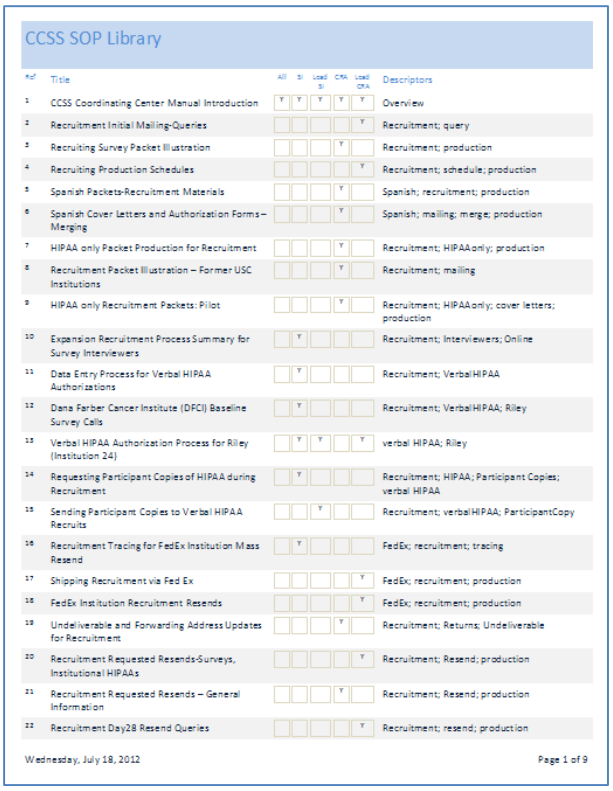
Type a capital "Y" in the box for each user group whose procedures you need. Select just one group if you want ONLY the procedures related to that group. When you select more than one group, the procedures you get will relate to ANY of the groups you selected. Use the **Close Search** button to close the search window and return to the menu.





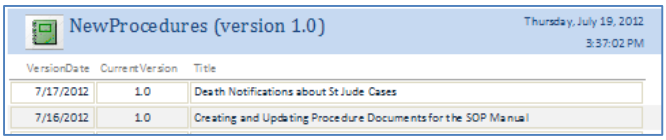
Report: CCSS SOP Library

The CCSS SOP Library report lists ALL (both active and inactive) procedures in the library by title and shows the user groups and descriptors.



New Procedures

The New Procedures report lists all procedures whose version is 1.0.

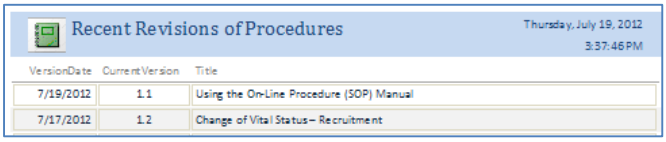

NewProcedures (version 1.0)

Thursday, July 19, 2012
3:37:02 PM

VersionDate	CurrentVersion	Title
7/17/2012	1.0	Death Notifications about St Jude Cases
7/16/2012	1.0	Creating and Updating Procedure Documents for the SOP Manual

Recent Revisions

The Recent Revisions report lists all procedures with a version date within a specified recent date range but does not include “new” (i.e. version 1.0) procedures.


Recent Revisions of Procedures

Thursday, July 19, 2012
3:37:46 PM

VersionDate	CurrentVersion	Title
7/19/2012	1.1	Using the On-Line Procedure (SOP) Manual
7/17/2012	1.2	Change of Vital Status – Recruitment

Revision Record

Printed 11/30/2015 3:12 PM

[202] Current Filename:		Using the Online Procedure Manual ver1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1.0	7/18/12	J. Bates	Initial Development
1.1	7/19/12	J. Bates	Add “new” procedure buttons, updated menu screen
1.2	7/25/13	J. Bates	Update menu; add new reports
1.3	11/30/15	R. Massey, J. Ford	Updated title, formatting

Verbal HIPAA Authorization Process for Riley (Institution 24)

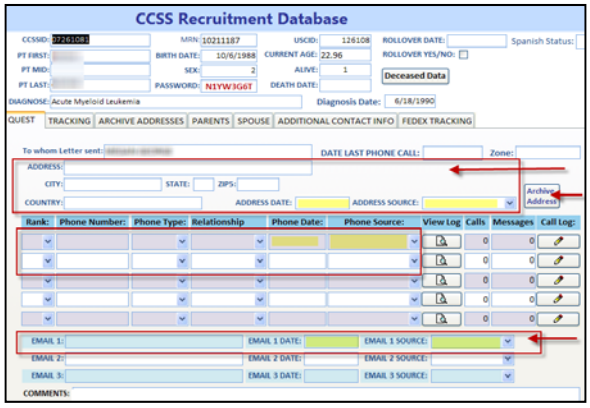
Background

The Survey Interviewer (SI) will use the same Verbal HIPAA script as with other institutions, with certain exceptions. This is necessary because Riley does not have online HIPAA entry capability through the web site www.longtermfollowup.org/logon. The *additional steps* include **completing** an additional information sheet to identify the survey interviewer and the HIPAA date, **emailing** notice of the verbal HIPAA, and **filing** the completed information form which is eventually sent to the study CRA2.

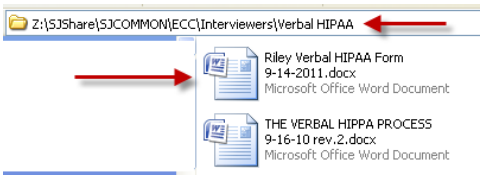
Procedure

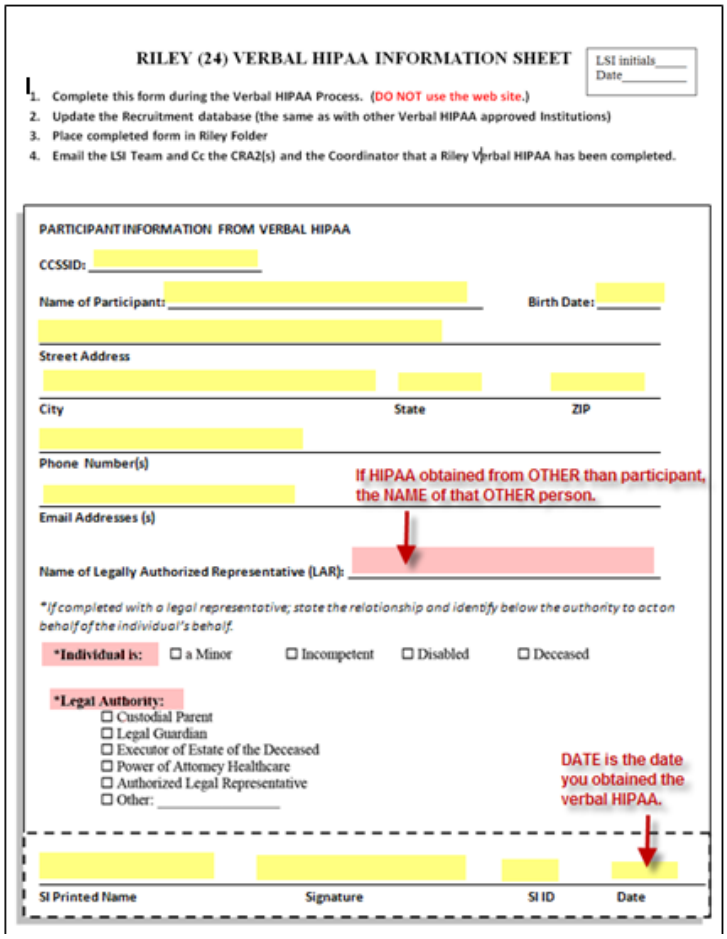
1. Obtain Verbal HIPAA using the standard verbal HIPAA script as with other institutions.

2. Confirm/ask for updated contact information. In the recruitment database, on the **Quest** tab, archive and update address information, add new phone contact numbers and email addresses (as with other institutions; remember to update the AddressDate and the AddressSource).

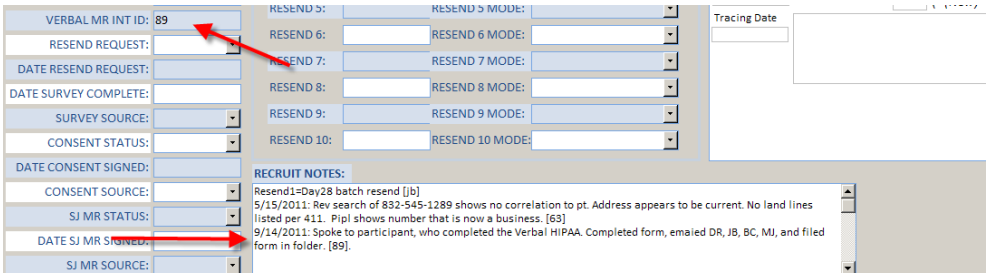


3. Fill out a hard copy (printed) of the Riley Verbal HIPAA Information Sheet with
   a. Participant's CCSSID
   b. Participant name, birth date, address, phone, email.
   c. If a legally authorized representative provided the verbal HIPAA, complete the designated sections (Name of the person from whom it was obtained, status of the individual, and relationship to the participant)
   d. At the bottom of the form:
      i. The SI's: printed name, signature and SI ID number
      ii. The date the verbal HIPAA was obtained





4. In the **Recruitment database**, on the **Tracking** tab: (as is currently the practice with all institutions eligible for Verbal HIPAA recruitment practices.)
    a. Enter your Interviewer ID in **VERBAL MR INT ID**,
    b. Enter a dated message with ID in **Recruit Notes**



5. Follow the standard verbal HIPAA steps regarding participant copies, survey completion, etc. (Refer to *Data Entry Process for Verbal HIPAA Authorizations*)
    a. If the individual wants to complete the survey with you over the phone, log in to the age-specific survey website using the Password and date of birth shown in the Recruitment database:
        i. Adults: www.stjude.org/expansionbaseline
        ii. Minors: www.stjude.org/expansionbaselineminor

    b. After entering the information into the Recruitment database, email the CRA2 and copy the LSI team and Coordinator, noting a Riley Verbal HIPAA for CCSSID # has been completed. Note: Without receipt of the email, the CRA2 will not know to complete the necessary data entry in the recruitment database, and *the case will not rollover* to Expansion Tracking.

6. Place the completed form in a file labeled Riley Verbal HIPAAs.

Revision Record
Printed 6/4/2013 3:31 PM

[13] Current Filename:		Verbal HIPAA Process for Riley v1_3.docx	
Revision No.	Date	Responsible Author	Change Description
1	9/12/11	A. McDonald	Initial Development
1.1	9/15/11	D. Rinehart	Illustrations, clarifications
1.2	7/10/12	Procedure Team	Updated background
1.3	6/3/2013	D. Rinehart, R. Massey, B. Carson	Content revision

Verifying Scanned Paper Questionnaires

Background

Paper questionnaires are processed, and as applicable, coded following initial receipt. The surveys are then scanned and verified. The scanning process creates a digital copy of the paper survey that can be "read" by the appropriate software in order to send the data in a standardized format to a database. Scanned data is visually inspected and verified to ensure accuracy and to record information written in the questionnaire text boxes.

This procedure describes the visual inspection and verification process. For instructions on the scanning process, which precedes verification, see the SOP titled **Scanning Paper Questionnaires**.

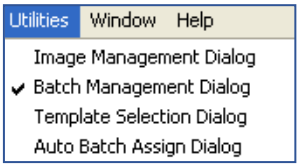
Procedure

During verification, TeleForm Verifier will ask the Clinical Research Associate (CRA) to manually record entries from text boxes, enter coded data, and confirm/correct any responses it may not have interpreted correctly. The CRA ensures the answers in TeleForm Verifier correctly match the answers indicated on the questionnaire. Discrepancies between the scanned and paper questionnaire that cannot be resolved (e.g., a participant marks more than one answer for a question) are recorded in the appropriate discrepancy log.

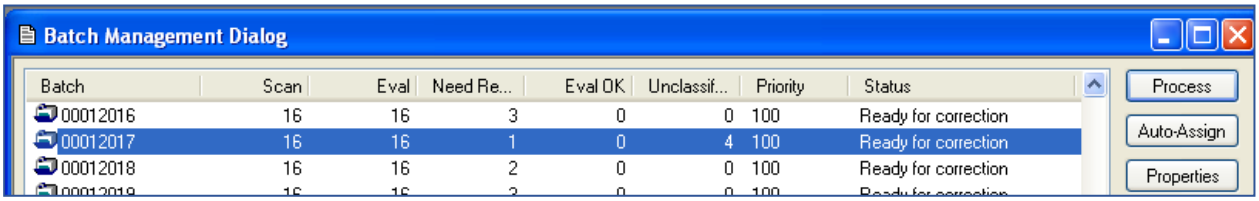
1. **Open TeleForm Verifier**.

2. Open the Options menu from the menu bar, and select "Correction Options." Uncheck all options except Form Mode, then click the **OK** button.

3. Open the Utilities menu from the menu bar. If the **"Batch Management Dialog"** option is not checked, select this option.



4. From the list of batches in the Batch Management Dialog box, locate the batch number to be verified. The batch number should be recorded on a sticky note on the front page of the first paper survey in the batch.

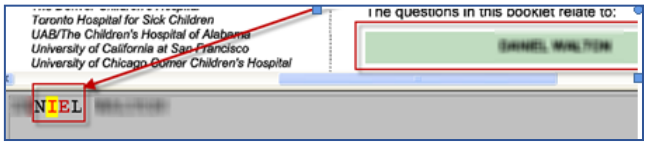


   A. Confirm the Status column indicates the batch is "Ready for correction."
   B. Select the row for the batch in question.
   C. Click the **Process** button or double-click the row to open the batch.

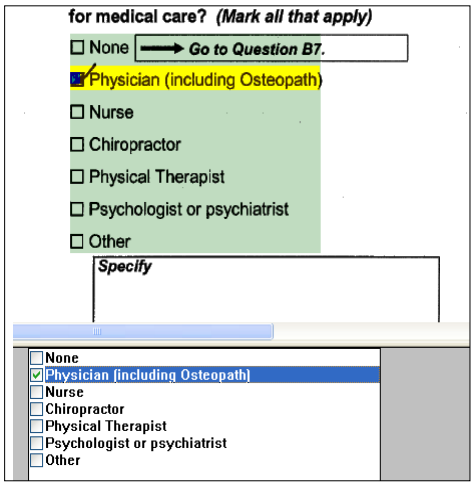
5. **Verify the data**. – TeleForm Verifier will "read" the survey data based on pre-defined templates and will stop at any field that requires the CRA's input. To confirm the data and move to the next item, press the <Tab> key. To confirm the data and move to the next section of items, press the <Enter> key. Use the Field List to navigate to any field in the survey. Record unclear items and all changes made to the survey in the appropriate discrepancy log.

A. Types of input required:

i. <u>Confirm Interpreted Text Data</u> – TeleForm Verifier will green-highlight the data in the context of the scanned survey, display the exact data being interpreted at the bottom of the screen, and wait for the CRA's correction or confirmation at the bottom of the screen. The yellow highlighted character is where any correction typing will begin, and the arrow keys can be used to move forward or backward in the text. Special attention should be given to interpretations displayed in red, as these are data that Verifier identified as particularly questionable. Refer to the hard copy of the survey if the scanned image is unclear.

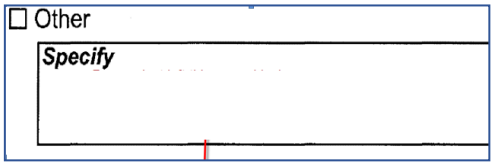


ii. <u>Confirm Interpreted Checkbox Data</u> - Compare what Verifier has interpreted at the bottom of the screen to the actual value highlighted in green (and on the hard copy of the survey, if necessary). Check or uncheck boxes, as needed, to match the participant's true response(s).

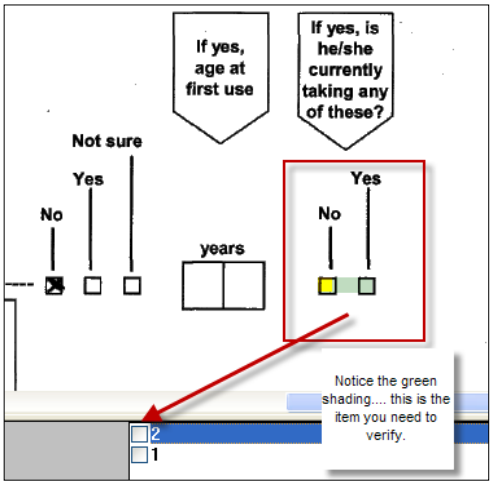


a. "Mark all that apply" – Confirm or correct each checkbox in the corresponding box in the gray area of the screen. It may be necessary to scroll the confirmation pane to see all available checkboxes.

b. "Other" checkbox's "specify" field – This may contain either text to be transcribed (see *Enter Written Text*, below) or text that has been coded (see *Enter Coded Data*, below). If the "specify" box is blank, do not type anything in the corresponding box in Verifier.



c. Multiple Yes/No checkboxes on the same question – TeleForm Verifier will green-highlight the set of checkboxes being reviewed. Ensure the verification entered is for the correct set.

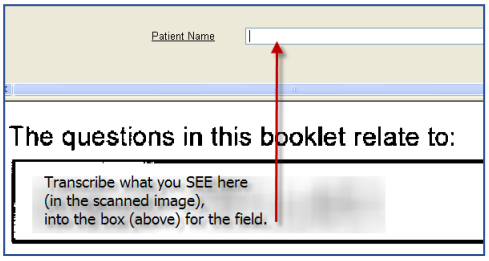


d. Consult the appropriate data dictionary, if needed:

1) <u>Expansion baseline adult case</u> – **QA Baseline Expansion 2007 Adult ANSWER KEY-with text box types-v3 4-12-2011** and **rptExpansionAdultTeleformKey**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\BASELINE ANSWER KEYS*

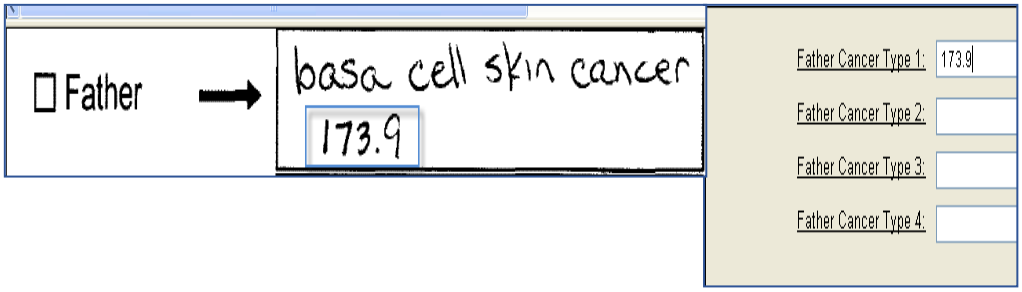
2) Expansion baseline minor case – **QA Baseline Expansion 2007 Minor ANSWER KEY-with text box types-v4 4-12-2011** and **rptExpansionMinorTeleformKey**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\BASELINE ANSWER KEYS*
3) Expansion baseline adult sibling – **Sibling-Baseline Expansion 2007 Adult Key-Expanded**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\BASELINE ANSWER KEYS-SIBLING*
4) Expansion baseline minor sibling – **Sibling-Baseline Expansion 2007 _Minor Key**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline SIBLING\BASELINE ANSWER KEYS-SIBLING*
5) Follow-Up 5 (FU5) adult case – **FU5 Adult Key**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5\Data Dictionary*
6) FU5 minor case – **FU5 Minor Key**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5 Minor\Data Dictionary*
7) FU5 adult sibling – **FU5 Sibling Key**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - FU5 Sibling*

iii. Enter Written Text – TeleForm Verifier will stop at any text field that requires the CRA's written transcription. Type the text exactly as it was written on the survey, even if it was misspelled.

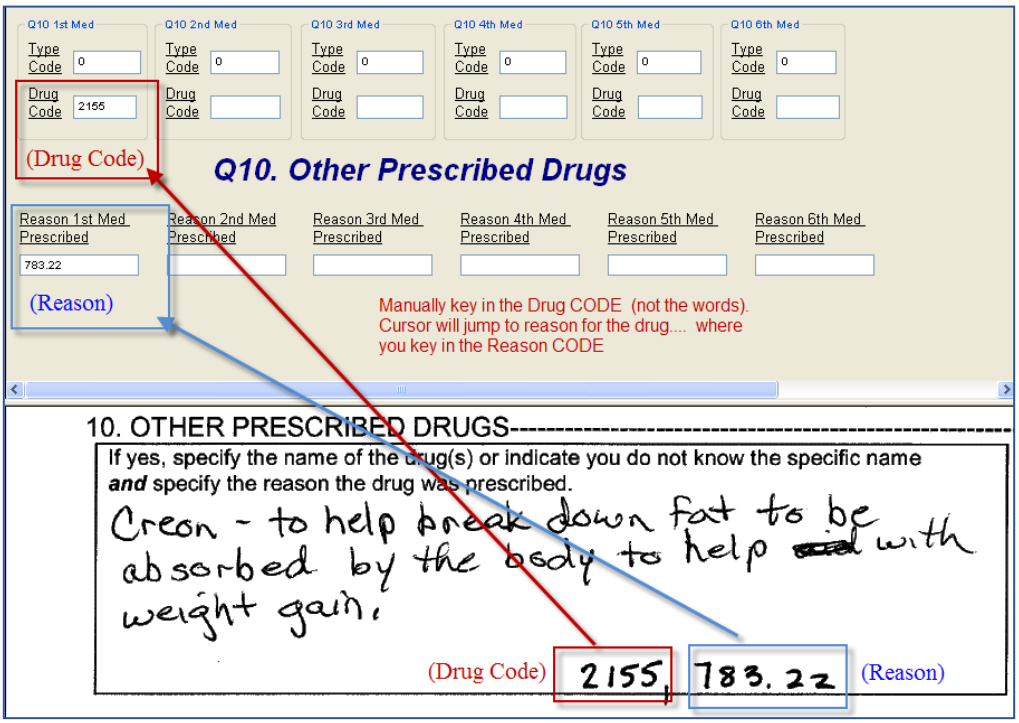


a. Refer to the hard copy of the survey if the scanned image is unclear. For text that is truly illegible, even after consulting colleagues, leave the field blank and note this change in the discrepancy log.
b. When the maximum number of characters for a field has been entered, TeleForm Verifier automatically advances to the next field (i.e., AutoTab). If this happens:
   1) Use the Field List to navigate back to the field in question and ensure all the text was accepted.
   2) If there is not enough space to type the entire entry:
      a) Give the paper survey to the TeleForm specialist with a request for additional space.
      b) When the needed space is added, complete the entry by typing the missing characters directly into the appropriate survey database.

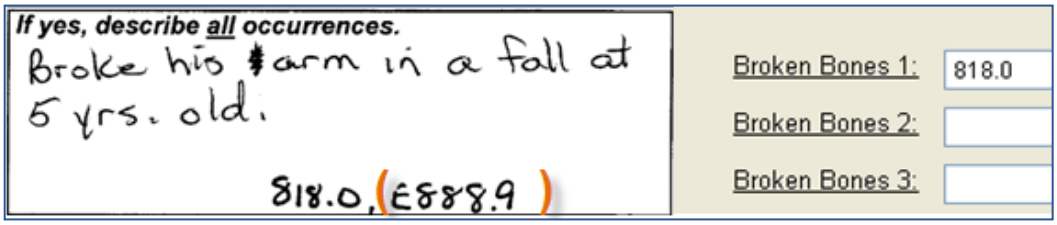
iv. Enter Coded Data - Coders convert certain survey responses to codes. TeleForm Verifier will stop at any field that requires coded data and will await the CRA's entry of these codes.



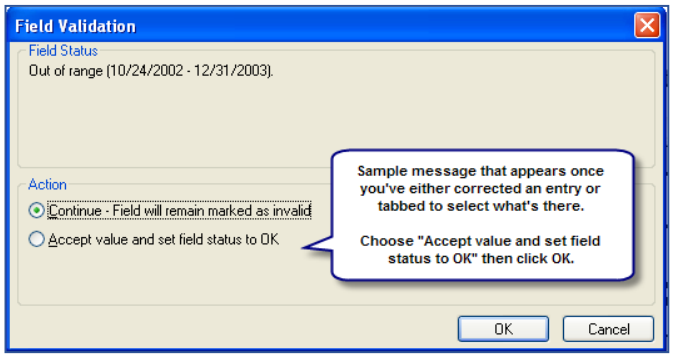
a. Certain entries have two codes. Prescribed drug entries are an example: both the drug and the reason are coded. For assistance differentiating between drug and reason codes, consult the coders, the Senior Coordinator-Clinical Research Operations, or the CRA2.



b. Do NOT enter codes that are in parentheses. In the below example, code 818.0 would be entered, but code E888.9 would NOT be entered since it is in parentheses.



v. Confirm Blank or Out-of-Range Items – TeleForm Verifier will green-highlight blank or out-of-range items in the context of the scanned survey, display the interpreted blank or out-of-range data, and wait for the CRA's correction or confirmation. If the blank or out-of-range item is confirmed, a Field Validation message may display. The Field Status group in the message displays the concern, and the Action group awaits the CRA's direction.



a. To accept the blank or out-of-range value:
   1) Select the **Accept**

value and set field status to OK radio button.

2) Click **OK**.

b. To come back to the field in question later in the verification process:

1) Select the **Continue – Field will remain marked as invalid** radio button.

2) Click **OK**.

B. Discrepancy Log – While verifying, you may find responses on the questionnaire that are not clear (e.g., more than one response selected, age given in months, height reported with fractions of inches). The participant ID, specific problem, page number, question number, and resolution to the issue should be entered in the appropriate Excel discrepancy log.

i. Network locations:

a. Expansion baseline adult case – **Expansion Baseline-Over18_Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

b. Expansion baseline minor case – **Expansion Baseline-UNDER18_Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

c. Expansion baseline adult sibling – **Expansion Baseline-Over18_SIBLING_Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

d. Expansion baseline minor sibling – **Expansion Baseline-UNDER18_SIBLING_Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

e. FU5 (one discrepancy log for all survey types) – **FU5 Survey Discrepancies**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS*

ii. General Guidelines – ANY change to the questionnaire should be noted in the discrepancy log.

a. If two answers are clearly marked, the answer should be changed to be blank/missing and noted in the discrepancy log.

b. If two answers are marked, but it is clear which answer was intended, choose the correct answer and note in the discrepancy log.

c. If a response is unclear, consult the Senior Coordinator-Clinical Research Operations or CRA2 for a decision on how to proceed.

d. If there is a decimal, fraction, or percentage value, round DOWN for *less than* 0.5 (½, 50%), and round UP for 0.5 (½, 50%) and above. Note this change in the discrepancy log.

e. If weeks or months are indicated for age (e.g. 2 weeks old, 3 months old), round DOWN for *less than* 6 months, and round UP for 6 months or above. Note this change in the discrepancy log.

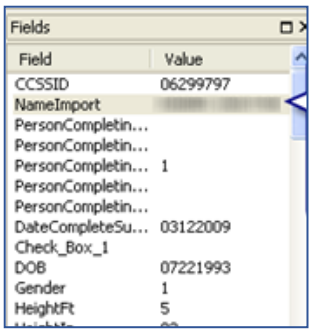
f. If it is suspected that a year is recorded instead of an age, check with the Senior Coordinator-Clinical Operations or CRA2 to confirm, then calculate the age based on the year indicated. Note the change in the discrepancy log.

g. If a month and day are left out of a date, use July 15th. If only the day is left out, use the 15th. Note this change in the discrepancy log.

h. If there is more than one age indicated AND the item asks for the earliest age, choose the younger age. Note this change in the discrepancy log.

C. Tips

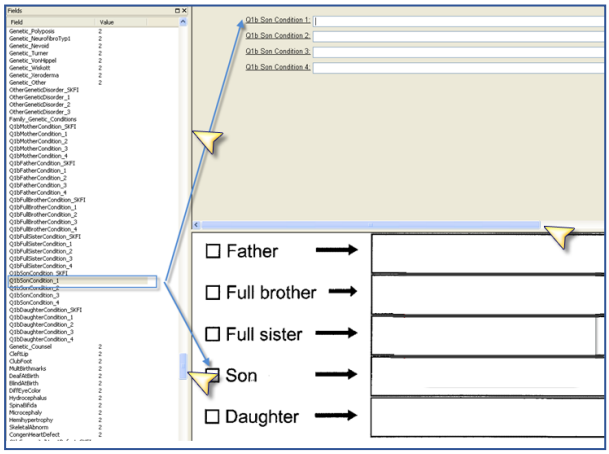
i. Field List – The Field List, located in a pane on the left-hand side of the screen when a batch is being verified, lists the names and values of the fields in the survey.



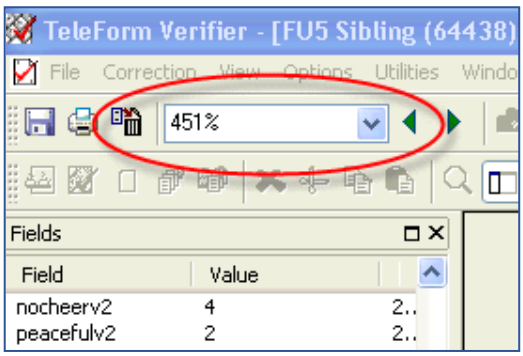
TeleForm Verifier will stop at those fields that need CRA input, but the user can navigate to any field by double-clicking the field in this list.

ii. Adjusting Displayed Fields – If the screen does not show enough of the scanned image to clarify which question is being verified:

a. Use the scroll bars to adjust what is viewed.



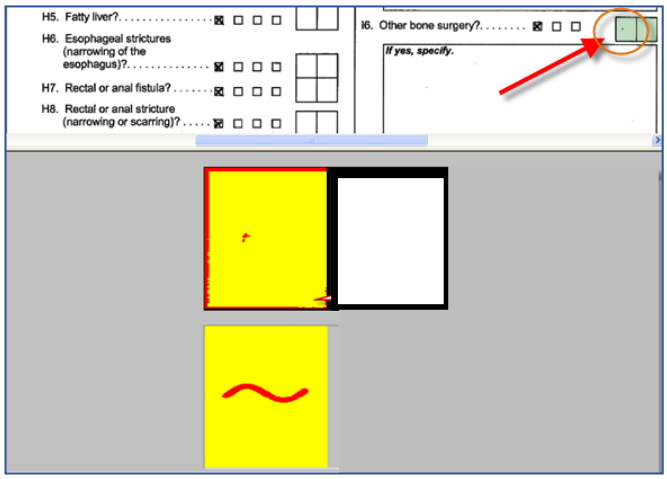
b. Adjust the zoom percentage.



iii. Stray marks – TeleForm Verifier is very sensitive and may attempt to interpret stray marks.

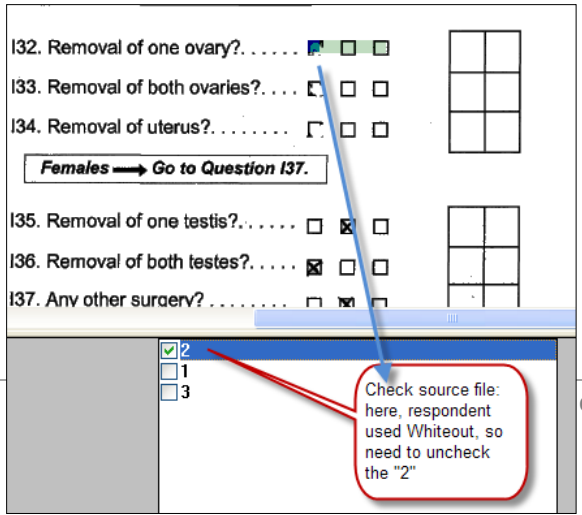
a. Consult the hard copy of the original survey to determine the true response.

b. If the entry is, in fact, a stray mark, click on the suggested answer in the yellow box at the bottom of the screen, then press the <Delete> key to delete the invalid data.



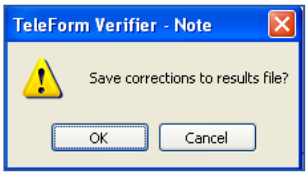
c. If the survey reveals data was entered, select the yellow box at the bottom of the screen, and type the response from the survey.

iv. Correction Fluid – When correction fluid is used on a



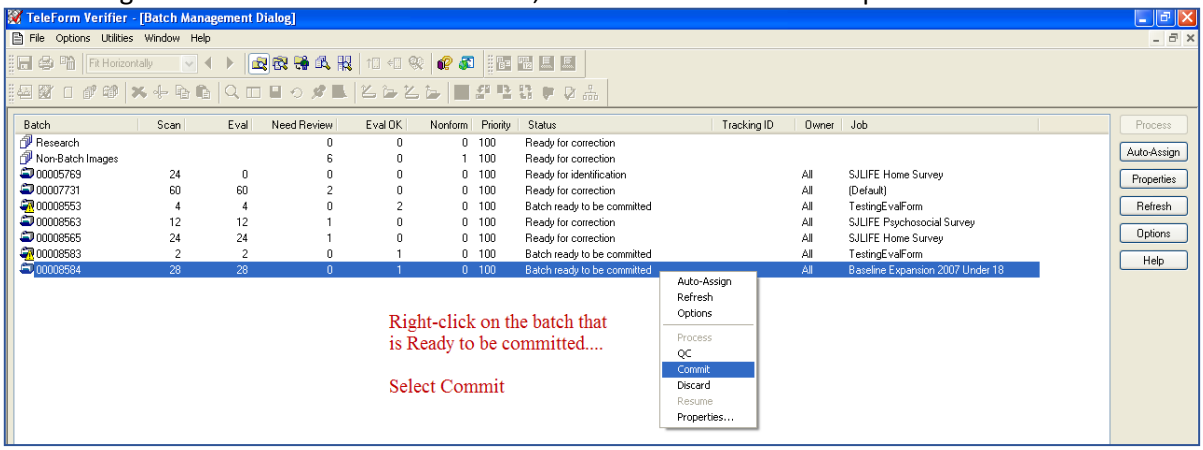
questionnaire, TeleForm Verifier may interpret the correction fluid as a response. Review the paper questionnaire to determine what answer, if any, is present, and verify accordingly.

6. When the end of the survey is reached, TeleForm Verifier asks, "Save corrections to results file?" Click the **OK** button to save your work.



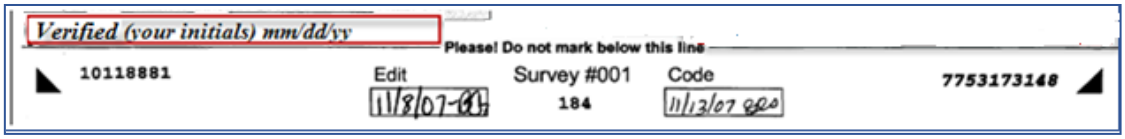
7. If the batch contains other surveys, TeleForm Verifier will begin the verify process for the next survey. Otherwise, the batch will close, and the status will display as, "Batch ready to be committed."

8. **Commit the Batch** – Committing the batch transfers the scanned and verified data to the appropriate database.
   A. Confirm the batch in question displays the status, "Batch ready to be committed."
   B. Right-click the correct batch number, and select the "Commit" option from the menu.



   C. Click the **Yes** button at the "Commit batch data?" prompt.
   D. If a batch fails to commit, *investigate immediately*. NEVER pass an uncommitted batch along as ready for QA.
      i. **Images Not Found** – Possible solution:
         a. Right click on the problem batch and select QC.
         b. Unclassify and reclassify (Evaluate as) any surveys in yellow.
         c. Click **Save**.
         d. When Reader is finished distributing and evaluating, try to process the batch.
         e. If problems with the batch continue, right-click the problem batch, select the QC option on the menu, and delete the problem surveys.
         f. Put the deleted surveys in another batch to be re-scanned.
      ii. **MISSING PAGES** – This means some of the pages did not verify correctly, may be out of order, or TeleForm cannot read the participant ID. Consult the TeleForm specialist for assistance addressing this problem.

9. **Write "Verified (initials) mm/dd/yy" in pen** in the lower left corner of the first page of each survey, just above the horizontal line.



10. **Update the appropriate Excel tracking spreadsheet** to indicate completion.
    A. Expansion baseline cases and siblings – **!TrackingBaselineScanning-QA**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Expansion Baseline\!ASSIGNMENTS*
    B. FU5 cases and siblings – **!FU5TrackingScanning**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Follow-Up 5*
    C. CARTOX II – **!CartoxIITrackingScanning**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Cartox II Tracking*
    D. CARTOX Functional Assessments – **!CartoxTrackingScanning**, located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Cartox Functional Tracking*

11. The batch is complete. Follow the procedures designated as "next steps" for the study in question (e.g. pass along for QA, file for review, etc.).

Revision Record — Printed 10/30/2015 8:36 AM

Current Filename:		Verifying Scanned Paper Questionnaires ver 1_2.doc	
Revision No.	Date	Responsible Author	Change Description
1	6/15/11	J. Bates	Initial Development
1.1	11/8/12	J. Bates	Caution about multiple users
1.2	10/30/15	R. Massey, J. Ford	Content Revision – Title change, rearranged for flow, merged another SOP

Viewing Breast Cancer Paper Survey Images

Background

Paper surveys from the Breast Cancer ancillary study have been boxed and moved from the CCSS Coordinating Center to an off-site storage facility. These paper surveys can be viewed digitally using the scanned images of the surveys. This procedure outlines how to locate and view these image files.

Procedures

1. Open the appropriate folder containing the survey image. The folder is located at *Z:\SJShare\SJCOMMON\ECC\CCSS\Ancillary Studies\Breast Cancer (Tara & Kevin)\Teleform Tiff Files*. Folder options are BC Alive, BC Deceased, No BC Alive, and No BC Deceased.
   NOTE: If unsure which folder is correct for the case in question, use trial and error to complete the process in each folder until the survey in question is located.

2. In the appropriate folder, locate the only .dat file (e.g. BC Alive.dat, BC Deceased.dat, etc.) among the .tif files.

3. Use Notepad to open the .dat file.

4. Search the .dat file for the CCSSID in question, and then locate the name of the .tif file at the end of the row. Make a note of the full .tif file name.

5. Search the current folder for the noted name of the .tif file. This file contains images of the survey in question.

Revision Record
Printed 11/30/2015 8:23 AM

Current Filename:		Viewing Breast Cancer Paper Survey Images ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	11/30/15	R. Massey, J. Ford	Initial Development

Viewing Follow-Up 4 Paper Survey Images

Background

Paper Follow-Up 4 (FU4) surveys, also known as Follow-Up 2007 (FU 2007) surveys, have been boxed and moved from the CCSS Coordinating Center to an off-site storage facility. These paper surveys can be viewed digitally using the scanned images of the surveys. This procedure outlines how to locate and view these image files.

Procedures

Most FU4/FU 2007 paper surveys can be viewed using Alchemy software. See the SOP titled **Accessing Records in Alchemy** for details on how to locate and view the files using Alchemy.

FU4/FU 2007 surveys that were scanned and verified before 3/14/08 were not recorded in the file system referenced by Alchemy. These surveys can still be viewed by manually locating the TIFF image file that was created during the scanning and verifying process. To manually locate the pre-3/14/08 image file:

1. Open the database titled "FU2007 survey data", located at Z:\SJShare\SJCOMMON\ECC\CCSS\Databases\Survey Data - Follow-Up 2007.

2. Open the table named Cover_Page by double-clicking on the table name in the Access navigation pane.

3. In the cover page table:
   A. Use Access's Find feature to locate the record for the participant ID in question.
   B. Note the value in the Time_Stamp field for the participant ID in question.

4. Go to Z:\Archive\ECC\CCSS\Alchemy Data\Follow-Up 2007\TeleForm TIFF files\TIFF files without .DAT file.
   A. Sort the files by "Date modified."
   B. Look for the first file whose time stamp is at or after the FU 2007 database time stamp.
   C. Using trial and error, open files at or after the noted time stamp to locate and view the survey in question.

Revision Record Printed 11/24/2015 1:53 PM

Current Filename:		Viewing Follow-Up 4 Paper Survey Images ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1.0	11/24/2015	R. Massey, J. Ford	Initial Development

ZIPCODE abbreviations, including US States (and Possessions), Military, and Canada

State/Possession	Abbreviation
ALABAMA	AL
ALASKA	AK
AMERICAN SAMOA	*AS*
ARIZONA	AZ
ARKANSAS	AR
CALIFORNIA	CA
COLORADO	CO
CONNECTICUT	CT
DELAWARE	DE
DISTRICT OF COLUMBIA	DC
FEDERATED STATES OF MICRONESIA	*FM*
FLORIDA	FL
GEORGIA	GA
GUAM	*GU*
HAWAII	HI
IDAHO	ID
ILLINOIS	IL
INDIANA	IN
IOWA	IA
KANSAS	KS
KENTUCKY	KY
LOUISIANA	LA
MAINE	ME
MARSHALL ISLANDS	*MH*
MARYLAND	MD
MASSACHUSETTS	MA
MICHIGAN	MI
MINNESOTA	MN
MISSISSIPPI	MS
MISSOURI	MO
MONTANA	MT
NEBRASKA	NE
NEVADA	NV
NEW HAMPSHIRE	NH
NEW JERSEY	NJ
NEW MEXICO	NM
NEW YORK	NY
NORTH CAROLINA	NC
NORTH DAKOTA	ND
NORTHERN MARIANA ISLANDS	*MP*
OHIO	OH
OKLAHOMA	OK
OREGON	OR
PALAU	*PW*
PENNSYLVANIA	PA
PUERTO RICO	*PR*
RHODE ISLAND	RI
SOUTH CAROLINA	SC
SOUTH DAKOTA	SD
TENNESSEE	TN
TEXAS	TX
UTAH	UT
VERMONT	VT
VIRGIN ISLANDS	*VI*
VIRGINIA	VA
WASHINGTON	WA
WEST VIRGINIA	WV
WISCONSIN	WI
WYOMING	WY

MILITARY ADDRESSES:

Three Military "States":

1. **AA**, which stands for Armed Forces (the) Americas
2. **AE**, which stands for Armed Forces Europe
3. **AP**, which stands for Armed Forces Pacific

Three "City" equivalents:

1. **APO**, which stands for Army Post Office
2. **FPO**, which stands for Fleet Post Office
3. **DPO**, which stands for Diplomatic Post Office

CANADA	Abbreviation
Alberta	AB
British Columbia	BC
Manitoba	MB
New Brunswick	NB
Newfoundland and Labrador	NL
Northwest Territories	NT
Nova Scotia	NS
Nunavut	NU
Ontario	ON
Prince Edward Island	PE
Quebec	QC
Saskatchewan	SK
Yukon	YT

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