St. Jude Children's Research Hospital
ALSAC • Danny Thomas, Founder

EPIDEMIOLOGY
AND CANCER CONTROL

SURVEY INTERVIEWER

TRAINING AND ORIENTATION

Revised 08/25/2020

St. Jude Children's Research Hospital
ALSAC • Danny Thomas, Founder

Finding cures. Saving children.

Welcome to the Call Center Team!

We are delighted to have you joining our team as a Survey Interviewer. Your role is critical in fulfilling the mission of our department, our research studies, and St. Jude Children's Research Hospital. The importance of our research is far-reaching and encompasses the well-being of the cancer survivor, the practice of the pediatric oncologist, and the diverse research questions of the cancer investigator.

The information in this book is designed to serve as an introduction to our department and provide many valuable resources that will help you make a smooth transition into your new role. In the next several weeks, you will receive intensive training in all aspects of your position. Please do not hesitate to ask questions if anything is unclear to you at any time.

The Call Center team and I are here to support your transition, and you can call on any of us to assist you. We are looking forward to your joining our team and your successful career in Epidemiology and Cancer Control.

Sincerely,

Dayton R. Rinehart
Coordinator-Survey Interviewers

THE SURVEY INTERVIEWER

Approximately one in every 350 individuals living in the United States develops a cancer before the age of 20. In the 1940s and 1950s, few children survived cancer. In the 1960s however, researchers discovered ways to design therapies using combinations of chemotherapy drugs and different treatment modalities. With current therapies, more than 80 percent of children diagnosed with cancer can be expected to be long-term survivors. As a result, there now exists for the first time a large and rapidly growing population of individuals who have been cured of childhood cancer. Unfortunately, as a consequence of their disease and treatment these long-term survivors now face significant, largely uncharacterized, risks to their health and well-being. Researchers now have an opportunity and an obligation to:

- Gain new knowledge about the long-term effects of cancer and therapy to help design treatment protocols and intervention strategies that will increase survival and minimize harmful health effects
- Educate survivors about the potential impacts of cancer diagnosis and treatment on their health, provide follow-up care, create and implement programs for the prevention and early detection of late effects

Job Description

The **Survey Interviewer** in Epidemiology supports the implementation of the overall program of data collection for the Department of Epidemiology; contacts and schedules interview appointments with participants; conducts telephone interviews; performs data entry, electronic data collection, and tracing to support clinical research and ensures efficient, timely delivery; prepares files for the various studies; and works a flexible schedule (e.g. nights and weekends) to accommodate research participant schedules.

There are four key areas of responsibility for Survey Interviewers:

1. Recruitment: invite potential participants into the LTFU
2. Conducting surveys over the phone with participants
3. Tracing: intense, focused searching for lost potential participants
4. General Administration duties: filing, photocopying, typing, data entry, digital communications

Funding

- Position is funded by the National Cancer Institute, guaranteed only for 12 months

Benefits – See the St. Jude Human Resources website for details.

Overview

There is a saying, “What gets measured gets done.” Public health works this way, too. But before we can improve the public’s health and save lives, we need information from the public—we need to collect it, analyze it, and measure it. Only then can we do something about it.

As a St. Jude Children's Research Hospital interviewer, you will be on the front lines of the public health crusade because you are handling the first step: collecting information. This training will show you how to do this and will help you improve your skills as an interviewer.

In section 1, you will learn more about three steps:

1. Collecting Information: Why your job is so important
2. Analyzing and Measuring Information: How the data you collect are used
3. Making Positive Changes: How your data can save lives

Step One: Why Is Your Work As An Interviewer Important?

When you make telephone calls as a St. Jude Children's Research Hospital interviewer, you will be asking people about their medical and health information. Many people don't realize the late effects that they are at risk for because of their cancer treatment.

Getting the Word Out

The information gathered by interviewers is eventually used by researchers throughout the country to help people understand the issues that cancer survivors face. In fact, data collected by interviewers are heard on the news and seen in medical journals and newspapers throughout the United States.

Your Role Is Critical

You are interviewing a sample of cancer survivors from states across the country. Since a large number of those involved in the study do not return the survey via mail, you will be the voice of St. Jude and will call those who have not returned the information. One of the most important jobs in the process is yours—the interviewer. The interviewer is the eyes and ears of the research team, serving as the link between those who seek the information and the respondents who provide it. It is crucial that we have information from as many individuals as possible so that we can better understand the issues that these survivors face. A survey is only as good as the interviewer who works on it. These days, when so many private and public agencies depend on accurate surveys to make decisions that affect people in all walks of life, the interviewer's job is especially important and meaningful.

Step Two: How the Data Are Used

After you have collected information, your data are analyzed by statisticians. Scientists can use the data in many ways, including:

1. Tracking trends over time
2. Categorizing the data into subgroups
3. Comparing one treatment to another
4. Helping people understand what late effects they are at risk of developing

Step Three: How Your Data Can Save Lives

As you heard earlier, "What gets measured gets done." So, once your data are collected and measured, what actually gets done with it? These data are used to help physicians recognize late effects and provide a better quality of life for survivors. These data are also used to help researchers in the current battle for children who are fighting cancer.

Background

What is a Survey?

A survey usually involves collecting data from a group of people selected to accurately represent the population under study. This group of people is called a sample. People in the sample are asked a series of questions (a questionnaire). The answers obtained are put together in an organized way so that conclusions can be drawn. This information is then used in planning, research, and solving particular problems. Skillful interviewing procedures are used to ensure full and accurate information. Careful methods are followed so that the data gathered from the sample of respondents can be confidently used to represent the total population.

Overview of the Study

The Childhood Cancer Survivor Study (CCSS) is being conducted by the Department of Epidemiology and Cancer Control at St. Jude Children's Research Hospital and roughly 30 other collaborative institutions in the U.S. and Canada. This study is also sometimes referred to as the Long-Term Follow-up Study (LTFU), and it is the study name to which participants are accustomed. Thus when speaking to participants, you should always refer to the study as the Long-Term Follow-Up Study. The purpose of this study is to investigate the possible association of cancer and treatment exposure with the risk of late-occurring events associated with health outcomes. The initial phase of the study consisted of interviewing either the case (patient), if over 18 years of age, or the parents of cases < 18 years of age. This initial phase included approximately 14,200 cases that completed a baseline questionnaire. Eligible participants are invited to continue their participation by completing and returning follow-up questionnaires sent to them in the mail. If participants do not return this questionnaire, they will be called by one of the telephone survey staff interviewers and will be asked to complete the questionnaire over the telephone. This procedure will be implemented for all follow-up questionnaires and ancillary studies.

The study subjects are individuals who have been identified from one of the collaborative institutions. They were diagnosed with leukemia, central nervous system tumor (restricted to medulloblastoma/PNET, ependymomas, and gliomas), non-Hodgkin's lymphoma, Hodgkin's disease, neuroblastoma, Wilms' tumor, rhabdomyosarcoma, osteosarcoma, Ewing's sarcoma, or retinoblastoma (expanded cohort only) before the age of 21 between 1970 and 1999. The study subjects are from all geographic regions of the U.S. and Canada. Eligible study subjects must have survived at least 5 years after diagnosis and are English or Spanish speaking.

Overview of Interviewer Responsibilities

This section will detail interviewer responsibilities. The rationale behind these responsibilities should be upheld every time you conduct an interview. You must follow protocol. Following protocol means doing things by the rules. There are five rules/responsibilities to remember. The five primary interviewer responsibilities are:

1. Ask all questions exactly as they are written, without modification
2. Ensure respondents' confidentiality
3. Make quality a priority in all aspects of interviewing
4. Maintain a courteous and friendly tone
5. Manage interview problems appropriately

Responsibility #1: All Interviewers Must Ask the Questions Exactly As They Are Written, Without Modification

***Reasons*:**

There are two reasons why it is important to ask all the questions as written.

- First, if all survivors are asked the questions the exact same way, the data collected are comparable across the entire cohort. If each interviewer modifies a question in a way s/he thinks will make it easier for a participant to understand, each interviewer has changed the question and the results may be different between participants due to the way the question was presented and not represent the response that would otherwise have been given.
- Second, all questions on the survey have been tested to ensure that people understand what they mean. Therefore, if you modify a question, you may get an answer that is incorrect for the intended question.

Here is an example of how an interviewer might get an incorrect answer. The entire question is presented for you first. Then, the example of how an interviewer might get an incorrect answer follows:

The question:

> **Interviewer:** (reading from questionnaire) "What type of health care coverage do you use to pay for most of your medical care? Is it coverage through:
>
> A. Your employer
> B. Someone else's employer
> C. A plan that you or someone else buys on your own
> D. Medicare
> E. Medicaid or Medical Assistance

F. The military, CHAMPUS, TriCare, or the VA
G. The Indian Health Service or the Alaska Native Health Service
H. Some other source"

Here is the example of how an interviewer might get an incorrect answer.

Interviewer: (reading from questionnaire) "What type of health care coverage do you use to pay for most of your medical care? Is it coverage through:

A. Your employer
B. Someone else's employer?"

Respondent: (interrupting) "Yes, it's B."

What's wrong with this scenario?

a) The respondent rudely interrupted
b) The interviewer did not read all the possible responses
c) The respondent intentionally gave the wrong answer

If an interviewer reads only part of the possible responses the person being interviewed may unintentionally give an incorrect or less accurate answer. The best thing to do is kindly tell the respondent you need to read all the responses. Here is the correct way to handle the question:

Interviewer: (reading from questionnaire) "What type of health care coverage do you use to pay for most of your medical care? Is it coverage through:

A. Your employer
B. Someone else's employer?"

Respondent: (interrupting) "Yes, it's B."

Interviewer: "Actually, there are several other choices for you to consider and I'm required to read all the choices to you. Is it:

A. Your employer
B. Someone else's employer
C. A plan that you or someone else buys on your own
D. Medicare
E. Medicaid or Medical Assistance
F. The military, CHAMPUS, TriCare, or the VA
G. The Indian Health Service or the Alaska Native Health Service
H. Some other source"

Respondent: "Well, actually, the answer is F, the military. My husband is a master sergeant over at the army base."

If respondents don't hear the correct choice, you may not get an accurate answer. It's important to take your time and read all the possible answers. Sometimes, respondents can't give you a response after the entire list is read. In this situation, choose don't know if the option is available or try to provide further clarification using the definitions in your manual.

Responsibility #2: Ensure Respondent Confidentiality

Most importantly, you must confirm you are talking with the patient or patient's proxy.

Reasons

Persons working in jobs and professions dealing with the experiences, thoughts, actions, and feelings of people have an ethical responsibility to these people. Survey research interviewing is one of these occupations, and interviewers must, therefore, accept the ethics of the profession. Just as doctors and lawyers must respect information about their patients and clients as privileged, so must the survey interviewer.

The only time you can reveal the reason for your call or that you are calling from St. Jude Children's Research Hospital is when you are confident you have reached the participant or participant's personal voicemail, even if you have reached the correct number and are speaking with a family member or shared voicemail. For this latter situation you may, however, leave a message with someone other than the participant that you are calling from the Long-Term Follow-Up Center. When you reach a generic voicemail, you should only leave your first and last name with a phone number, asking the person to call you back. For example, when you reach an answering machine, you may want to say:

"Hello. My name is Bob Jones, and I am trying to reach Sarah Somebody. If you could, please have her call me at 1-800-775-2167. Thanks so much for your assistance."

The interviewer must often ask questions that one would not think of asking a close friend because they may seem sensitive or "too personal" in nature. For example, you may ask questions such as:

- "What is the total income of your household?"
- "Have you smoked at least 100 cigarettes in your lifetime?"

Protecting privacy is of the utmost importance. You will find that the average person is willing to answer these questions, often offering information s/he would not give to a close friend or relative. It is essential to collect the most accurate data possible, so you want respondents to give you truthful answers. The best way to ensure truthful answers is for you to guarantee that the information participants provide will be kept completely confidential. Your protection of all information about respondents gained during the conduct of research is essential. This includes ALL information, including private data such as name, date of birth, and address, responses to the interview itself, or extraneous observations of the respondent's home, family, or activities.

As you now know, gaining someone's trust by assuring confidentiality will improve the quality of the information you gather. However, violating a respondent's confidentiality has serious consequences. Violating confidentiality would cause you to lose your job and may even lead to criminal charges being brought against you in a court of law.

Be Careful What You Say

You may be thinking that you would never violate a respondent's confidentiality, even if you had the chance. But consider what happened to Joyce:

> **Joyce:** "...and so they talked me into bringing cupcakes and brownies for the bake sale. Oh! Speaking of school, I think I talked to Mrs. Jenkins on the phone today at work."
>
> **Teresa:** "Our kids' teacher?"
>
> **Joyce:** "Yes, she is part of the Childhood Cancer Survivors Study. You know, we have to ask questions about age, race, marital status and all that. Did you know she was separated? I wonder when that happened."
>
> **Teresa:** "Yeah, I heard that from Bob, who knows her husband. It just happened—he moved out a few weeks ago."
>
> **Joyce:** "Wow, I wonder what's wrong. It couldn't be money trouble; she said her annual household income is over $75,000, and they don't have any kids. But, you never know."

What's wrong with this scenario?

a) It is a violation of Mrs. Jenkins's privacy
b) Joyce and Teresa are gossiping about things that are none of their business
c) Mr. Jenkins didn't really move out

A conversation like this one is clearly a breach of confidentiality. Joyce should have either ended her interview with Mrs. Jenkins as soon as she recognized her voice, or she should have let another interviewer take over the call.

How to Ensure Respondent Confidentiality

In addition to the information provided in the *PHI Concerns Version 4* document at Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools, here are some ways you can guarantee your respondents' confidentiality and help them understand that you won't misuse the information.

1. **Explain that the data you are collecting will be combined with information collected in thousands of interviews.** Individual information is further protected because the data are combined and reports only include aggregate figures. For example, a report might say that 10% of the population has a household income of less than $10,000, not that Mr. Jones earns less than $10,000.
2. **Don't discuss details of your interviews outside of the work environment.** Although discussion of respondent information among CCSS staff is a necessary part of the research process, do not disclose interview information with family, friends, or anyone else not involved with the CCSS.
3. **Store your materials in a locked (or secure) area when you aren't at work.** Don't leave confidential materials on desks or tables overnight at work or at home. ALWAYS LOCK PATIENT INFORMATION UP IN A SECURE LOCATION. DO NOT TAKE ANY PAPERS HOME WITH YOU UNDER ANY CIRCUMSTANCE.
4. **Do not discard anything with the patient's name or information on it.** All documents containing patient information must be properly discarded in the Shred-It containers.

Responsibility #3: Make Quality a Priority

How to Do It

A lot of people are counting on you to do the best job you possibly can. These people include cancer survivors, researchers, health professionals, the media, state and local health departments, and anyone else whose health will benefit from the data you collect. Here are several ways you can be sure that you are making quality a priority in your work:

- Understand the nature and content of the questions so you can be comfortable with the interview process
- Interview the correct respondent
- Conduct interviews as efficiently as you can

Understand the Questions

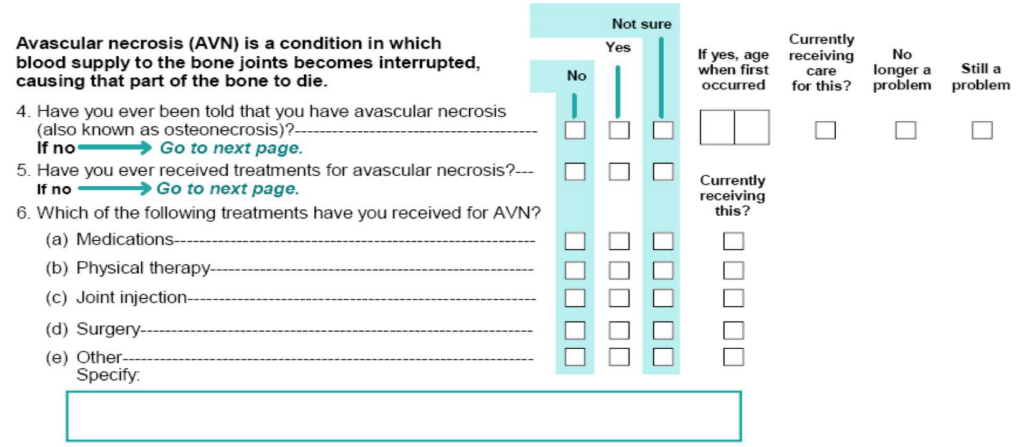
Every two years there are changes and additions to the CCSS questionnaire. Obtain a copy of the questionnaire and read it thoroughly. Then discuss with your supervisor and other interviewers any topics or questions that make you uncomfortable or are unclear. Here are three reasons for discomfort with questions, and what you can do:

1. Unfamiliar terms

If you've never heard terms like “Ataxia Telangiectasia” or "sigmoidoscopy," chances are good that some of your respondents won't know those words either. When they ask you, "what does that mean?" it doesn't inspire much confidence if you say, "I don't know; I'm just an interviewer."

You are not allowed to define terms unless the definitions are standard. Therefore, if a respondent asks you to explain the question, read any explanatory information shown on the questionnaire. If there is no explanatory information, simply say, "Let me repeat the question." If the respondent still can't answer the question, select "Don't know/not sure" as their response. Be sure to document the questions you get from people that you interview and share this information with your supervisor so that any problems can be addressed in future versions of the questionnaire.

Sometimes the questions themselves provide clues to tell you what some words mean. For example, this question provides information on Avascular Necrosis:



2. Sensitive questions

Sometimes respondents believe interviewers are trained healthcare professionals, and they may ask for medical advice. Others may get very emotional describing events of

their lives. For example, questions about recurrence of cancer or HIV/AIDS may be difficult for someone who was recently diagnosed with the illness.

First, emphasize that you are not a healthcare professional and tell the respondent to talk with their doctor. Second, acknowledge that the interview seems difficult for the person and remain as neutral as possible during the interview. Try not to get off the phone, but if the interview becomes too difficult for the participant, offer to continue the interview at another time. It is certainly appropriate to express concern at the end of the interview or at the point of termination, and to apologize for triggering the upset. Lastly, you can refer them to the 1-800 line for further assistance from the study personnel and make your supervisor aware of the situation.

3. Intimidating question wording

Some respondents may view the questions as some kind of test for which their answers are either right or wrong. For example, most women know that they should get regular Pap tests and mammograms, but don't always find the time.

Reassure them this is not a test, and that there aren't any right or wrong answers.

Some respondents, fearful about how the information will be used, may not give you an honest answer. For example, most people know that driving while under the influence of alcohol is illegal, so they might not want to admit to doing it.

Reassure them the information you collect is strictly confidential, and that their answers will be combined with thousands of others.

Properly Record Responses

As with any type of science, some errors are an inevitable part of survey research. However, you can reduce or eliminate error in your data by being careful to choose the correct responses each time you make an entry into the database or on the questionnaire. It is essential that all entries are clear in meaning and that all written work is legible to others. Clear and legible work can be processed and analyzed quickly, while unclear answers may create more work and/or necessitate that you call the patient back to clarify.

Performance Statistics

Interviewer performance statistics are used as tools to monitor and improve data collection techniques. For instance, the number of completed interviews per hour of interviewing time and the number of telephone numbers dialed each hour may be analyzed to determine an appropriate level of productivity, as well as to compare your productivity with others. Don't let it make you nervous that these statistics are being

collected about your work. In fact, expert interviewers say that they began to see big improvements in their performance when they relaxed about the numbers.

Responsibility #4: Maintain a Courteous and Friendly Tone

You will soon learn more about putting "personality" in your voice and how to respond to unkind words. For now, here are a few tips about using your voice to encourage respondents to participate in the survey:

- Practice reading all the questions. If you have questions about how to pronounce unfamiliar terms or how to emphasize particular words, ask your supervisor, a co-worker, or look them up online – there are websites that will actually pronounce the word for you.
- Speak directly into the mouthpiece. Adjust the volume controls as needed.
- Use a low pitch of your voice, and don't raise your voice unnecessarily.
- Speak at a moderate pace, deliberately and distinctly.
- Put a "smile" in your voice.
- Put the respondent at ease by reading the questions in a natural, calm, and friendly manner.
- Don't let your voice trail off at the end of a sentence.

Responsibility #5: Deal Appropriately with Interview Problems

An entire section of this training is devoted to interviewing techniques, which includes dealing with difficult respondents. You will be given a list of statements and questions that are common among people who participate—or refuse to participate—in the survey, along with suggested responses. Here are some basic concepts to keep in mind:

- Be kind, no matter what a respondent says to you.
- Emphasize the respondent's importance to the study.
- Explain the reasons for the study.
- Find a convenient time to conduct the interview.
- Emphasize that the survey is completely confidential.

"It takes a while to get the hang of being a good interviewer. At first it was a bit overwhelming, but you start to figure out why things need to be done a certain way. Then it just comes naturally, and it gets to be really fun and challenging."

-Quote from an Interviewer

The Interviewing Process

In this section, you will learn about the interviewing process, the "nuts and bolts" of what you will be doing as an interviewer. While we make many types of calls and support several studies, the main study you work on is the CCSS. Thus, this section will introduce you to the entire CCSS process, from the time a questionnaire is developed to the time when the data you collect are published. You'll see why it's important to try to contact people at different times of the day and different times of the week. Lastly, you will learn about the measures that are taken to assure the quality of CCSS data.

After completing this section, you will be able to do the following:

1. Understand how data collection fits into the entire CCSS process.
2. Explain why calling occasions are important.
3. List and describe the measures taken to ensure quality and minimize error.

Over fifteen years of experience are incorporated into the CCSS questionnaire and procedures. Understanding the process and why things are done a certain way should help interviewers properly handle any situation.

Although as an interviewer you are mostly involved in the data collection and recruitment aspects of the CCSS, you should be familiar with all the steps in the process. (For information about the recruitment process, refer to the *LTFU Expansion Recruitment and Baseline Interviewer Manual: LTFU Center*.)

Every two years, the content and structure of the questionnaire are determined by the CCSS steering committee and are used without modification. Interviewers have time to get familiar with the new questionnaire before they begin using it for the new interviewing period.

A. Annual questionnaire construction and distribution

1. A CCSS Steering Committee is composed of institutional PIs (Principal Investigators) from across the United States who meet on an annual basis. This group creates and approves the questionnaire that will be used at the upcoming data collection time point.
2. At the point of the questionnaire construction, any ancillary studies are put into place and the procedures for these studies are established.
3. Lastly, any additional telephone scripts to be used will also be developed at this time.

B. Questionnaire piloting and sample selection

Prior to a questionnaire being administered by trained interviewers, the questionnaire is put through a number of different pilot tests.

1. First, the Survey Data Center staff review the document for obvious errors.
2. The survey is administered to staff within the Epidemiology department to test flow and skip patterns.
3. The survey is administered to cancer survivors who are not eligible for the study being conducted.
4. Some ancillary studies require a sub-sample of the study population. These samples are predetermined.

C. Data scanning and verifying procedures

Surveys completed by mail are treated differently than those completed online (either with or without an interviewer). The completed questionnaires are scanned and verified by study staff at regular intervals.

This involves an automated system for data entry requiring the staff member processing these questionnaires to stop at any text and hand enter what a participant hand wrote.

Once the data have all been scanned and verified, data checks are performed. Then the data are given to the data manager for data entry into the main study database. Additionally, staff members processing the incoming mail hand enter the date the survey was received, updated contact information provided by the participant, and any other relevant pieces of data that need to go into the Coordinating Center's databases. Surveys completed online are checked for data errors; however these checks occur towards the end of data collection. Data collected on the online version of the survey are collected and stored immediately in a program called DatStat. As with the paper surveys there is a process for entering updated contact information into the Coordinating Center's databases. It is very important that contact information is updated – a long-term follow-up study is only as successful as its participation rate. If we can't find people, they can't participate!

Now that you know a little more about the entire CCSS process and how you fit into the big picture, let's take a look at some of the specific things that will concern you as an interviewer.

Interviewing Procedures

The paper questionnaire was designed to be mailed and completed at the individual's home. Keep this in mind when interviewing eligible respondents over the telephone. Eligible respondents will either be cases/siblings over age 18 or parents of children less

than 18. The questionnaire was sent to the last known address (some of these addresses are the parents' address).

Regardless of whether a study subject has or has not received the questionnaire, ask if they would like to complete it over the phone with you. While this is the ultimate goal, this will not happen most of the time. If the participant does not want to complete the interview over the phone at that moment, there are a few options you may give them – in this order.

1. Offer them the possibility of scheduling an appointment at their convenience.
2. Ask if they would like a link to the survey to complete the survey online at their convenience (you must obtain a valid email address). **NOTE: Not all study participants are eligible to complete the survey online. Deceased and Spanish surveys must be completed with an interviewer via telephone. Dana Farber participants can only complete the *baseline* survey with an interviewer or on paper.**
3. Let them know they can return the booklet by mail (or online if they still have the letter with the instructions for accessing the website).
4. Offer to send them another survey through the mail (verify correct address).

If a study subject has a questionnaire and agrees to return it via mail or online, they will be called back in a couple of weeks if it is not returned since they last spoke with someone. If the questionnaire is resent and the booklet is not received in the study office within two weeks of the resend date, the subject will be re-contacted to determine the status of the questionnaire.

If a study subject refuses a telephone interview and fails to return a booklet after 20 cumulative calls *to each of their phone numbers* in a two month period, they will be considered a non-responder. These are addressed on a case-by-case basis, but generally we will continue to try to gain the completed survey.

An active refusal is one in which the interviewer is told that the subject does not wish to participate at this time. There are two possible outcomes with an active refusal: The participant can refuse the current questionnaire (refused just this time) or s/he can refuse to ever participate in the study at all (refused all else). If the subject indicates s/he no longer wishes to be part of the study, the interviewer will thank them for their participation and file all materials appropriately. On the other hand, if the participant refuses to participate only for the current questionnaire, ask the participant if s/he would like to be contacted in the future for other questionnaires. For example, you may want to say something such as:

> "I understand that you may not be interested in completing this questionnaire. May we keep you on our list for future questionnaires?"

For participants who do not wish to be contacted again in the future, note this on their paperwork and indicate REFUSED ALL FURTHER CONTACT. It is very important to be pleasant and deal with refusal conversations tactfully, make the proper annotations in the call logs or other paperwork, and file the information appropriately. If they refuse all further contact, they can never be contacted again.

If an individual has died, complete the **Expired Participant Information Sheet** with date, location, cause of death, the person providing the information, and a future way to contact him or her (only if they wish it).

Calling Occasions

In order to reach as many potential respondents as possible, the CCSS call center is open 7 days per week during morning and evening hours. This is to maximize reaching participants who may be available at different times and accommodate differences in time zones.

There are a few important things to remember about calling occasions:

1. You may only call a number once every 3 days (up to 20 times in a 60-day period) and leave up to 3 messages within a 60 day period.
2. To be successful in reaching someone, you should call at different times (weekdays, weeknights and weekends).
3. Follow all the steps required for the study on which you are working. These steps will be explained fully in orientation sessions with your supervisor.

Scheduling a Callback

Sometimes a respondent won't have enough time to complete the interview on your first attempt. For these participants, you will need to schedule a time to call the participant at another time and put the appointment on the callback calendar. See the SOP titled **Call Center Appointment Calendar** for details.

An interviewer should attempt to schedule an appointment if the selected person doesn't have time to do the interview. The interviewer should ask about a convenient time to call back and agree on a specific day and time. Appointments are scheduled at the convenience of study participants. The majority of interviews are conducted in the evening or on a weekend day. It is important to consider time zone and other factors (such as catastrophic events like Hurricane Katrina) when preparing to contact individuals around the country and in Canada. It is possible that certain groups of people will not be available and will need to be contacted at a later date. Placing a hold on a specific group of people will be determined in conjunction with the supervisor.

Defining Callbacks

There are 2 types of callbacks: Definite and Indefinite callbacks. *You've reached a willing respondent, but he is extremely busy and can't talk to you at the moment. He suggests that you call him atexactly 4:30 p.m. tomorrow, and he will be able to talk to you for 15 minutes.* This is known as a **definite callback**, and it is very important that the callback be made at exactly 4:30 p.m. the next day.

You've reached a willing respondent, but she's tied up with a project that won't be complete until tomorrow afternoon. She suggests you call anytime after 2 p.m. the next day. This is known as an **indefinite callback** (a.k.a. general callback or a priority call). In this case it is less important to call exactly at 2:00 p.m. If the call is made at 2:10 p.m. the participant probably won't mind.

Bias In Your Tone of Voice

One way your data can be biased is if you ask questions incorrectly. As previously discussed, it is very important to read all the possible responses to each question. If a respondent doesn't hear all the possible answers, you may not get an accurate response. Your tone of voice is also important for getting accurate responses. Respondents should feel there is no wrong answer to your questions. If you sound judgmental or patronizing, respondents may feel uncomfortable telling you the truth. Imagine asking the following core question with a judgmental or patronizing tone:

> "Considering all types of alcoholic beverages, how many times during the past 30 days did you have 5 or more drinks on an occasion?"

If the true answer is more than the respondent feels would be acceptable to you because of your tone of voice, you may receive and record an inaccurate answer.

Interviewer Monitoring

Your supervisor will occasionally listen in on your interviews. This procedure, which is required by CCSS protocol, is called interviewer monitoring and is done from a separate computer terminal. The purpose of interviewer monitoring is to ensure the interviewer is not inadvertently introducing bias into the survey by tone of voice, not reading the question as written, or not completing a question. Having someone listen to the interviews you conduct is a valuable tool for your continued training and for achieving uniform questionnaire administration.

Interviewer monitoring is a two-way street. The supervisor (monitor) learns about potential problems with the survey, and at the same time may be able to teach interviewers a few tricks to help with specific situations. Almost all interviewers have

areas where they excel and areas where they could improve their skills. Monitoring allows the sharing of good techniques across all the interviewers.

While monitoring, supervisors will be paying attention to the following things:

- Questions being asked as written and in the correct order
- Accurate coding of responses
- Professional attitude and a positive voice
- Respondents' reactions

Overview of How to Conduct Interviews

Knowing how to conduct successful telephone interviews doesn't happen overnight. It is something that you will get better and better at doing each time you try. The following section will provide tips and techniques about several aspects of telephone interviewing.

After you finish this section, you should be able to do the following:

- Understand an interviewer's most important tasks
- Select and speak with the correct respondent
- Identify ways to establish rapport with respondents
- Describe the meaning of voice personality and pacing within the context of telephone interviewing technique
- Get more accurate answers using probing techniques

An Interviewer's Most Important Tasks

By now you should be aware of how important the role of an interviewer is to the research process. Just to summarize the previous sections, your top three tasks are to persuade, report, and record.

1. **Persuade** respondents to cooperate in the research study and answer your questions candidly.

   The respondent needs to see the study as being important and worthwhile. All study participants, even those who are least interested, should feel that the survey is important. They must be assured that their cooperation will be meaningful not only to themselves, but also to the study results as a whole.

   The respondent may feel that the interviewer is a salesperson, bill collector, or a government representative auditing her income tax return. The respondent may feel that she does not know enough information, that she will be embarrassed by difficult questions, or by giving wrong answers. Any such perception on the part of the respondent must be neutralized by their interviewer's early remarks. This can be done through convincing statements from the interviewer on the purpose of the study, the anonymous or confidential nature of the interview, and the importance of the study findings. The interviewer's manner, introductory statements, and the success with which the respondent's questions are answered are the elements that will sell both the interviewer and the study to the respondent.

2. **Report** a clear, complete, and unambiguous statement of a person's ideas. This requires the following:

- Putting respondents at ease so that they feel free to say exactly what they think
- Being careful to get respondents' ideas without suggesting answers

Generally, people will feel free to speak their minds if you are interested in what they really think and do not appear shocked, pleased, or upset by anything they have to say. It is important to remember that the intent of the interviews conducted in a survey is to gather information. They are not intended to change or influence the opinions of the respondent. To avoid contaminating the interview with your own ideas, you must use only neutral probes. Examples of neutral probes will be given later in this section.

3. **Record** the respondents' ideas in a form that will give someone else, such as a researcher, a perfectly clear picture of what information was collected during the interview. This means you must be very careful to input the data accurately.

Getting to the Correct Respondent

Before proceeding with an interview, you'll need to determine if the phone number you've reached is for the participant. To do this, verify the participant's date of birth, which is the first question in the online survey. If the telephone number is a business, a pay telephone, or any other nonresidential line, there are specific rules to follow regarding leaving messages (discussed previously in the section *Responsibility #2: Ensure Respondent Confidentiality*). Most of the time, it's easy to know if you've reached a nonresidential number. The person answering may say something like: "Thank you for calling XYZ Company. May I help you?" Sometimes you'll reach a number that is both a business and a residence. For example, if a recorded message says, "Hello, this is XYZ Enterprises and the home of John and Jane," you should consider it a household number.

As you've previously learned, you'll need to speak with the study participant. When you get that person on the line, the interview begins. Also, please note that you may speak to a parent whose child is under 18; or over 18 and unable to complete the questionnaire independently.

Common Questions and Answers

From time to time, respondents may make comments or ask questions about the study. Interviewers are expected to express themselves clearly when requesting participation in the study. The scenarios below show how you could respond to common questions:

Interviewer: "Hello, this is (interviewer name). I am calling regarding the Long Term Follow-Up Study. I am calling to see if you have received the questionnaire that was sent to you on <DATE> Have you received this questionnaire in the mail?"

Respondent: "Yes, but I'm really busy now. How long will this take?"

Interviewer: "The study takes about 45-60 minutes to complete. Our records show that we have not yet received your completed questionnaire. We are very much interested in your answers to this questionnaire. Do you still have a copy of it?"

Respondent: [Interrupting] "Wait, wait a minute. What's this survey about?"

Interviewer: "As researchers, we know that as a survivor of childhood cancer or a similar illness, you may face special health issues during your adult years. Some patients who were treated as children, for example, may have late-occurring health problems related to their cancer treatment. To address these issues, we are doing a research study with cancer survivors like you. Your answers and input are very important."

Respondent: "They are? Why exactly?"

Interviewer: "The survey allows us to find out information related to late effects that you and other cancer survivors may be at risk of developing."

Scenario highlights:

In this scenario, the interviewer handles some of the most common responses you will hear as a CCSS interviewer. She uses several tactics to encourage the respondent to complete the survey:

1. She stresses that she is not selling anything;
2. She points out that the respondent's involvement could have important effects on the health of other cancer survivors.

The interviewer must always be ready to answer the respondent's questions as they arise. You must have ready, convincing responses to questions and statements such as these. Some common questions and responses are listed below.

Why are you interviewing me?
In order to learn more about survivors ofchildhood cancers, leukemia or similar illnesses, investigators from 26 other institutions involved with the Long-Term Follow-Up Study are conducting a study where individuals who survived these conditions are being interviewed.

Who gave you my name?
Participants in this study are either an individual diagnosed with cancer, leukemia, or similar illness, in childhood, or a parent of a child who was diagnosed with cancer, leukemia, or similar illness, and treated at acollaborating institution involved with the

Long-Term Follow-up Study. Physicians at these institutions were contacted about the study and supplied the names ofthe participants.

Why are you doing this study? What is the purpose of this study?
The purpose of this study is to learn more about the health and the lifestyle of individuals who were treated for cancer or a similar illness in childhood.

Who will see the information that I give you? How will the information be used? Will my name be put in a computer file?
All information is kept strictly confidential. Only the study team will see your information. All survey data are kept in a secured access location behind double locked doors. A number is assigned to each person interviewed. Your name is never identified in any report since all the data are presented in aggregate form only. A final result might, for example, be presented in the following form:

- *50% of the children were between the ages of 1 and 2*
- *5% of children have asthma*
- *80% of children have a brother or sister*

Why are you asking me about (child's name) when I have other children?
The study is designed to only include children who were diagnosed with a certain illness. (Child name) was eligible for our study.

I don't want to buy anything.
I'm not selling anything.

I'm just too busy at the moment to do this.
I understand. Why don't we get started with the first few questions, and then we can finish up at another time? That will give you an idea of what the survey is like."

Okay, I'll answer your questions, but I don't give personal information -- like my age -- over the telephone.
You don't have to answer any question if you don't want to. So, I'll begin.

Highlights:

- People often assume you are **trying to sell something** when you call them. The interviewer quickly points out that she is not selling anything, but rather is simply trying to gather information on cancer survivors.

- Probably the most effective technique used in this interview was asking if he could **start the interview** even though the respondent said she didn't have time. Many people who begin the interview (even though they say they have no time)

will finish. And for those who don't finish, they are still much more committed to doing the survey later if they have already started the process.

The respondent states that he is **uncomfortable discussing certain issues**, but the interviewer assures him that she can leave those questions unanswered. Here's a tip: as the interview progresses, respondents often "warm up" to the interview process and will sometimes answer more questions than they originally thought they might.

- The respondent then asks a few technical questions about **how the information will be used and who will see it.** This interviewer explains that the data from the survey will be used by researches to learn more about the health of individuals who were treated for childhood cancer and similar illnesses. The interviewer also emphasizes that the information is confidential. The interviewer could have also addressed any privacy concerns by explaining that all answers from all respondents are combined into one set of answers.

- The respondent does not have to answer any question s/he does not wish to answer. If s/he refuses a question, make a note stating that participant didn't want to answer the question, and mark it with your initials and Interviewer ID number.

At times, you may reach a skeptical respondent. This may be handled as follows:

Interviewer: "Hello, this is **(interviewer name)**. I am calling from the Long Term Follow-Up Study. I am calling to see if you have received the questionnaire that was sent to you on <DATE>. Have you received this questionnaire in the mail?"

Respondent: "Yes, but who are you and why are you calling me?" (hesitantly)

Interviewer: "I'll be happy to give you the name of my supervisor as well as our toll free number and you can call back and verify who we are and what we're doing. If you'd prefer, you can browse our web site; would you like our internet address?"

Respondent: "All right, I believe you. I have some time now if this won't take too long."

Interviewer: "Thank you, it only takes about 45 minutes."

Scenario highlights:

- In this scenario, the interviewer describes several things that a skeptical respondent could do to verify the **legitimacy of the survey**, including calling the

survey unit and checking the CCSS website. Any participant may check the website by going to http://ltfu.stjude.org/ or by going to www.stjude.org/epidemiology and clicking on the Long Term Follow-Up Study link on the left side of the page.

Reading Questions to the Respondent

Think of the CCSS questionnaire as if it were a movie script. Movie actors with a very strict director stick to the script and say their lines exactly as the screenwriter wrote them. The dialogue seems so natural when we see the movie later, it's hard to believe it was scripted and that the actors probably said those exact lines hundreds of times in rehearsal! The reason it seems so natural is because talented actors use **voice personality**, and they take advantage of techniques known as **rapport and pace**. (These techniques will be covered next.) You can use these same techniques to become a talented telephone interviewer.

Adherence to the Questionnaire

As long as you do not provide false information, there will be times when you can "improvise your lines", such as when you are answering common questions about the survey (as in the examples on the previous section). However, when you are reading the actual questions on the questionnaire, **you must use the exact wording provided for each question.** The questionnaire has been carefully prepared, and each question has a specific purpose. Interviewers can't change or substitute any words, because even slight changes in wording can affect the answers given. If questions aren't read exactly as they are written, the integrity of the entire survey could come into question. **You must ask every question on the questionnaire that is appropriate for the respondent.**

In answering one question, a respondent may sometimes answer another question that appears later in the interview. If this happens, you still have to ask the partially answered question. You can show the respondent that you haven't forgotten what was said earlier by saying something like:"I know we touched on this a few minutes ago, but I'm required to ask this next question". **Questions must be read in the exact order in which they appear.** Just as a movie script is structured to make each scene understandable to the audience and to foreshadow important events, the CCSS questions are ordered to achieve a desired effect. A question asked out of order can influence replies to the questions that follow.

With the CCSS questionnaire, **you can't skip questions, even if the answer seems obvious.** The question may be intended to verify information. Also, an answer received in the context of one line of questioning may not be the same as an answer received in another group of questions.

Voice Personality

"Any line can be said a thousand ways." This important acting advice is just as relevant for a CCSS interviewer. Your tone of voice, attentiveness, and receptive manner can make the difference between a completed interview and a hang-up. Interviewers can put respondents at ease by doing the following:

- Reading the questions in a friendly, natural manner
- Speaking at a moderate rate of speed
- Sounding interested

You should strive for a low-pitched voice. This will help you exude a sense of calmness and authority. Elevating the voice tends to result in an irritating, sing-song delivery that seems to increase refusals. Lowering your head can help lower the pitch of your voice.

Don't let your voice trail off at the end of a sentence. Instead, speak clearly and deliberately.

Establishing Rapport

Rapport can be defined as a harmonious relation. To establish rapport, introduce yourself and emphasize that you are calling from the Long-Term Follow-Up Study. If the respondent seems hesitant, you should

1. Assure them their responses are completely anonymous
2. Take time to convince him or her of the importance of the study
3. Project confidence and professionalism.

While you are "in character" as an interviewer, you are to be nonjudgmental, noncommittal, and objective. You should act neutral so that the respondent feels comfortable answering the questions truthfully and completely. The questionnaire is designed to elicit a free flow of ideas and opinions. Respondents need the freedom to say what they feel and think, without being influenced by anything the interviewers might say.

The respondent's impression of you during the introduction and early remarks will determine considerably the rapport that will develop. Obviously, respondents will react more favorably if they believe their association with the interviewer will be pleasant. The interviewer needs to impress upon the respondent that they are someone understanding and accepting, as well as sincere and courteous. Remember that their participation in the study is voluntary. If they do not want to participate, they do not have to, so your dialogue is critical.

Another good way to establish rapport is to use reinforcements. Reinforcements are words you add to keep the conversation going. This can add to the rapport between

you and the respondent. You must be very careful if you use these. They cannot be judgmental (positive or negative). Acceptable reinforcements to use include, "Okay", "Thank you", or repeating their answer choices back to them. Always avoid responses such as:

- "Oh, really?"
- "Wow!"
- "Oh, boy."
- "You've got me beat."
- "Great answer."
- "Congratulations!"
- "Good"
- "That's ok"

Remember, nothing in your words or manner should imply criticism, surprise, approval, or disapproval of either the questions or the answers. Even positive reinforcements can seem judgmental, as you can see from this example:

Interviewer: "Have you smoked 100 cigarettes or more in your life?"

Respondent: "No."

Interviewer: "Good for you!"

Similarly, avoid any response or even a sound that could be mistaken for a judgment call. For example:

Interviewer: "Do you now smoke cigarettes every day, some days, or not at all?"

Respondent: "Every day."

Interviewer: "Hmmm..."

Responses such as these should not be used because they may influence the respondent to answer questions in such a way as to meet the approval of the interviewer rather than in an honest way. If you feel you need to say something, use a nonjudgmental word like "okay." This can be used just to acknowledge you have received the answer and are ready to move on.

Monitoring can also help identify if you are being judgmental with your reinforcements. If you have a chance to listen to other interviewers, note what reinforcements they use and decide if you feel they may imply approval or disapproval of a response.

Occasionally, rapport may be broken during the interview because the respondent feels a question is too personal. Take time to reassure him/her that they may speak freely without fear. This may be done by restating the confidential nature of the questionnaire and the anonymous nature of the study. If a respondent refuses to answer a question after you have assured him/her of confidentiality, do not press him/her. Record what the respondent has said in refusing to answer the question and proceed to the next question. The interviewer should not irritate the respondent and provoke a refusal to complete the interview.

Pacing an Interview

Pace, *the mode or rate of progressing*, can be a powerful tool. In general, you want an even pace throughout the interview. However, sometimes you will need to increase the pace while other times you'll want to decrease it. The overall pace has to match the needs of the respondent. Some respondents, such as those who have difficulty hearing, need you to speak slowly. On the other hand, people in an active urban environment may become bored with a slower pace, and may want you to speak a little faster. You can usually get the sense of pace for the survey with the respondent by the way they speak. If they seem impatient, try to speed it up.

When to go quickly:

There are some places in the survey where you will want to adjust your pace for maximum results. One effective interviewer technique involves reading the introduction section a little quicker. Because this is a common place for respondents to quit or hang up, don't pause for very long at the end of the introduction—read the first question right away.

Only in your brief rapport with the respondent will you get the clues you need to adjust the pace. Never speak so fast that you may be misunderstood. It is better to take your time and have 290 completes in which the questions were clearly understood than 297 completes in which the respondents did not fully understand all the questions because they were read too fast.

When to go slowly:

A mistake made by some interviewers is to speed up at the end of an interview because they are getting tired and no longer have the patience they had in the beginning. Respondents can feel this and often interpret it as a lack of caring. They can feel your restlessness and will often just quit.

There are other times when you may ask the respondent a question for which they need time to formulate an answer. In this case you may need to slow it down to get a good response. Sometimes you simply need to wait for a response from the respondent.

Probing Techniques

Probing—using words and techniques to get more accurate information—is one of the most challenging and important aspects of interviewing. Probes are used in two situations:

1. A respondent's answer is irrelevant.
2. A respondent's answer is unclear.

Here are some examples of responses requiring probing:

Interviewer: "In the past 12 months, has a doctor, nurse, or other health professional given you advice about your weight?"

Irrelevant answer: "My husband is on a diet."

Unclear answer: "People are always telling me I need to gain some weight."

Use only neutral probes

The most important thing to keep in mind when you are probing for answers is to use only neutral probes that don't suggest answers. Repeating the question is one of the best neutral probes and one you'll probably use often. Under the pressure of the interviewing situation, the interviewer may quite unintentionally imply that some answers are more acceptable than others or may hint that a respondent might want to consider what the interviewer wants to hear when giving a response. Do not lead the respondent into an answer. Be sure to read the question only as it appears on the questionnaire. Remember, probing is to motivate the respondent to respond more fully or to focus his/her answer without introducing bias.

Here are some examples of other neutral probes:

- "What's your best guess?"
- "I just need your opinion."
- "If you had to choose, which would you pick?"

Another technique you may use is an expectant pause. The simplest way to convey to the respondent that you know she has begun to answer the question but has more to say is to be silent. Comments such as "uh-huh" or "I see" can be used to convey interest and understanding. These comments indicate that the interviewer has heard what the respondent has stated, that it is interesting, and that more is expected.

A good technique for holding the respondent's interest is to repeat the response after the participant states it. This lets the respondent know you are listening to every word

and, in fact, recording each one. The technique also serves as a probe. The respondent will hear what she has just said, and this may stimulate further thought and lead her/him to amplify or modify his/her statement.

Never "lead" a respondent to a particular answer. This is difficult because it would seem natural to do so in ordinary conversation. Consider this "leading" probe:

> **Interviewer:** "In the last 12 months, how many times did you go to a doctor's office or clinic to get care for yourself? Would you say:"
>
> A. None
> B. Once
> C. Twice
> D. 3 times
> E. 4 times
> F. 5 to 9 times
> G. 10 times or more
>
> **Respondent:** "Oh, gosh, I don't go very often... in last year, just a few times."
>
> **Interviewer:** "So, would you say twice, or three times?"
>
> **Respondent:** (Thinking to herself, "that must mean that 'a few' means only two or three times a year. I know I've gone more than four times, but I said I didn't go that often, and I don't want to sound stupid.") "I guess I'd say three times."

Rather than suggesting an actual number or numbers, the proper probe would be a neutral probe like the ones suggested above: "What's your best guess?" or "Which would you pick?" Do not ask whether a person means "this or that". This suggests only one of two answers, even though there may be many other possibilities which the respondent is thinking about.

Other leading probes to avoid are: "Do you mean _____?" or "Then you feel ____?" Some people tend to say "yes" to any suggestion either because it's easy or because they think it's the "right" answer.

Examples of Probes to Use:

Probes to Clarify

- What do you mean exactly?
- What do you mean by...?
- Could you please explain that a little?
- I don't think I quite understand.

Probes for Specificity

- What in particular do you have in mind?
- Could you be more specific about that?
- Tell me about that. What/Who/How/Why/When...?

Probes for Data Specificity

- Was he in the hospital before he had the surgery on his knee?
- What was the name of that treatment?
- Who were you working for at the time?

Probes for Relevance

- I see. Well, let me ask you again...REPEAT EXACT QUESTION.
- Would you tell me exactly how you mean that?

Probes for Completeness

- What else?
- What else can you think of?
- What other reason/things/examples, etc., can you think of?

How To Get Adequate Answers Through Probing

Here are a few things that will help you master the art of probing:

1. **Do not try to explain the question or define any terms, even when the respondent asks for a definition.** If a respondent does not seem to understand a question, repeat it slowly and clearly. Give the respondent time to think about the question. If you are asked to define a word, only use the definitions in the survey. Do not try to explain a word on your own. If different respondents ask you to define the same term over and over, bring this to the attention of your supervisor.

2. **Don't leave a question until you have an adequate answer, unless you realize the respondent is getting very annoyed.** Sometimes a respondent will give a general answer instead of the specific one you need. Probing can help the respondent give you an adequate answer, as in the following example:

   Interviewer: "How much do you weigh without shoes?"

   Respondent: "I'm not sure."

   Interviewer: "What's your best guess?"

   Respondent: "Somewhere between 180 and 190 pounds."

Interviewer: "What number between 180 and 190 would you like me to record as your weight?"

Respondent: "I guess the last time I checked it was about 187."

3. **Don't accept "I don't know" as an answer without probing at least once.** When you ask a question, people often say "I don't know" just to have time to formulate their ideas. A good probe for this situation would be to say, "Well, what do you think?" or "What is your opinion?" If the question deals with facts, an approximation is better than no answer at all, so you might say, "What's your best guess?" or "Approximately...?" to convey the notion that 100% accuracy is not required. "I don't know" can also mean:

   - The respondent doesn't understand the question and says "I don't know" to avoid saying they do not understand.
   - The respondent may be trying to evade the issue because he/she feels uninformed, or is afraid of giving the wrong answer, or because the question seems too personal.
   - The respondent may not know the answer to a question.

   If the respondent does not have the information requested, this in itself is significant to the study results. It is the interviewer's responsibility, however, to make certain this is the case. An expectant pause, a reassuring remark, repeating the question, a neutral question will encourage the respondent to reply. If the respondent is adamant about not wanting to respond or doesn't know the answer, you can type in "participant doesn't know" or "participant wants to skip question" where there is a text field. Otherwise, it is better to skip a question all together (leave it blank) than to get stuck on a question. (You'll need to make a note of this in the comments section text box at the end of the survey.)

4. **Watch for irrelevant answers.** Some people talk a lot, but not about the topic at hand. Irrelevant answers can be interesting, but interviewers must make sure the respondent deals with the question that was asked. Consider this example:

   Interviewer: "How often do you eat green salad?"

   Respondent: "A lot. I used to hate salads, but I've learned to like them."

   Interviewer: "Well, since you've learned to like them, how often do you eat green salad?"

5. **Watch for vague answers.** Some respondents find it hard to verbalize and may have difficulty expressing their ideas. You can help them say what they mean with probes such as these:

- "Tell me what you have in mind?"
- "Could you be a little more specific?"
- "Can you tell me what you mean by that?"

6. **Watch for ambiguous answers.** Certain terms may mean different things to different people. Always ask yourself whether you're sure what a respondent meant by an answer. You could ask, "What do you have in mind when you say _____?" or "How are you defining the term ____?"

7. **Give the respondent the time they need.** There is great value in silence during a telephone interview. You may find that by keeping quiet and letting the respondent ramble, he or she will be able to think about the question longer and give a more accurate answer. That period of silence may also allow the respondent to expand upon or clarify a previously inadequate answer. Here is an example:

   Interviewer: "About how long has it been since you last smoked cigarettes on a daily basis?"

   Respondent: "Well, let's see...it was my New Year's resolution, but I started smoking again in the spring...[Interviewer is silent] Then I decided to stop again on my son's birthday [silence continues while respondent is searching his memory] I never really did start smoking on a daily basis again after that, and I haven't smoked at all in over a month."

   Interviewer: "Let me repeat the question now that you've had time to think about it. About how long has it been since you last smoked cigarettes on a daily basis?"

   Respondent: "My son's birthday is in July, so it's been four months."

8. **Know when to stop probing.** You should stop probing when:

   - You have obtained the necessary information
   - You have encouraged the respondent to clarify the meaning of his/her own words so that you know exactly what he/she had in mind
   - The respondent becomes irritated or annoyed
   - The respondent has nothing more to say

Refusal Conversation

Regardless of how good you are at interviewing or how well you are trained, there will be times when respondents refuse to complete an interview. Many things can cause an initial refusal, and few of them have to do with you. The best way to keep from being discouraged by refusals is to realize that the rejection is usually an expression of the

respondent's own stress, fear, or resistance and not a negative judgment of your competence.

Don't be afraid to be assertive with hesitant respondents; use all of your powers of persuasion to get the interview. Remember: **now is better than later**. Research has shown the highest completion rates occur at the initial contact and decline with each call thereafter. Unless it is really impossible for the respondent to talk to you when you first call, you should try to convince the person to conduct the interview right then or schedule it for later. Project a confident and reassuring manner while conveying a genuine interest in the respondent.

Ask the participant to consider a hold of 3, 6, or 12 months if they are refusing due to a currently busy schedule or chaotic time in their lives. However, if they reject the hold, remember that refusing is always an option, and accept the refusal graciously. Try to gain a reason for the refusal and thank them for their time.

Recording and Editing Answers

So far, we have talked about how to ask the questions and how to get clear and complete answers. Both of these are very important jobs. Still, if you fail to write down or mark the answer properly, all your previous efforts will have been wasted.

Writing down and marking what the respondent said is called recording. Always have at least two black pens near you. The key to recording is to indicate the response clearly. When you mark an answer, or record a response, be sure that it can be easily recognized by a coder. When you write out an answer, make sure that someone other than you can read the response. If you are recording answers on paper and you mark the wrong answer, draw a line through it, initial it, and circle the correct response. DO NOT EVER ERASE OR USE WHITE OUT. This applies to any documentation you are using as part of the study.

This interview booklet was designed to have the participant complete the majority of the questions on the questionnaire using forms that can be scanned. Be sure all answers are clearly marked and legible. It is also required that address updates and contact information for study participants, siblings, parents and designated contacts be updated – this may be on call logs or appointment forms or on the survey online. Please be extremely careful not to transpose numbers when documenting new addresses, phone numbers, and email addresses. Since the success of the project depends on us being able to contact participants, it is crucial that all information be recorded accurately. Therefore, all new addresses, phone numbers, and email addresses should be read back to the participant to make sure that they are correct.

Summary: Basic Interviewing Rules

Here are the top interviewing rules:

- Always verify that you have dialed the correct telephone number for each contact you make.
- Be sure that you speak to the correct respondent.
- Read all questions verbatim.
- Never explain, interpret, or add to a question.
- Always read all the available answers.
- Read all questions in the exact order in which they appear.
- Do not skip any questions even if you feel you know the answer.
- Never hurry an interview unless the respondent is under time pressure—match your pace to the needs of the respondent.
- Keep an even pace.
- Remain objective—do not indicate surprise, pleasure, or disapproval at any respondent's answers.
- Be prepared to probe when necessary.
- Be courteous and polite, even if the respondent is rude to you.
- Put a "smile" in your voice.
- Don't just schedule a call back; push the respondent to start the interview.

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?

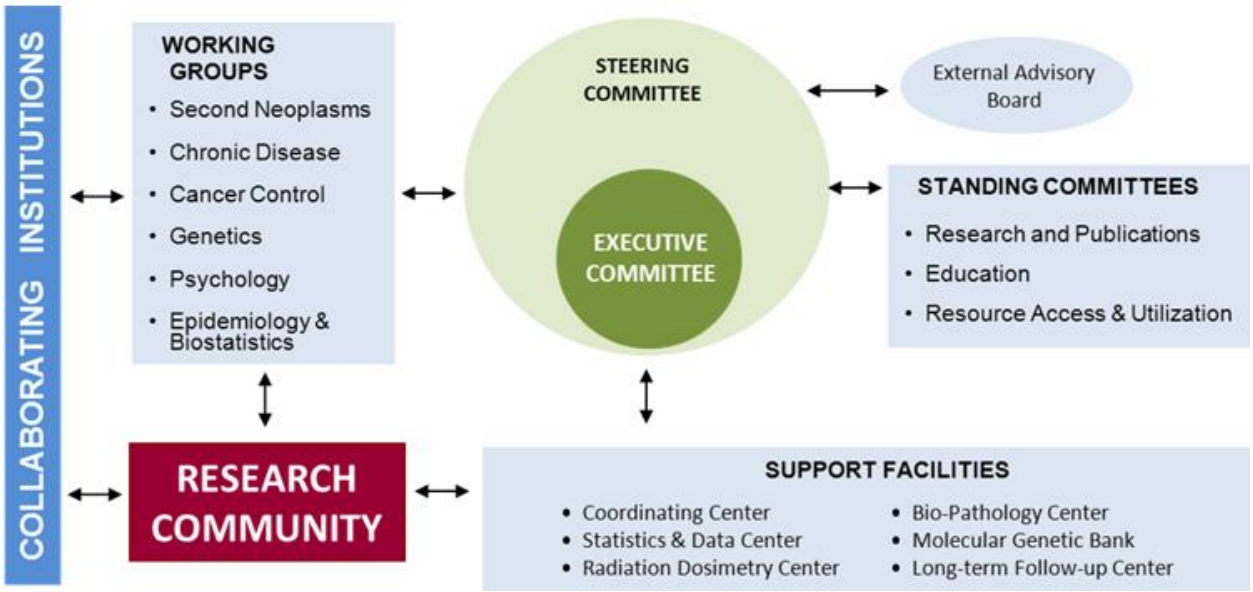
University Of Minnesota	Seattle Children's Hospital	Riley Hospital – Indiana Univ.
Children's Hospital of Colorado	Toronto Hospital for Sick Children	Univ. of Alabama (UAB)/ Children's Hospital of Alabama
Children's Hospital of Pittsburgh	St. Jude Children's Research Hospital	Mott Children's Hospital – 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

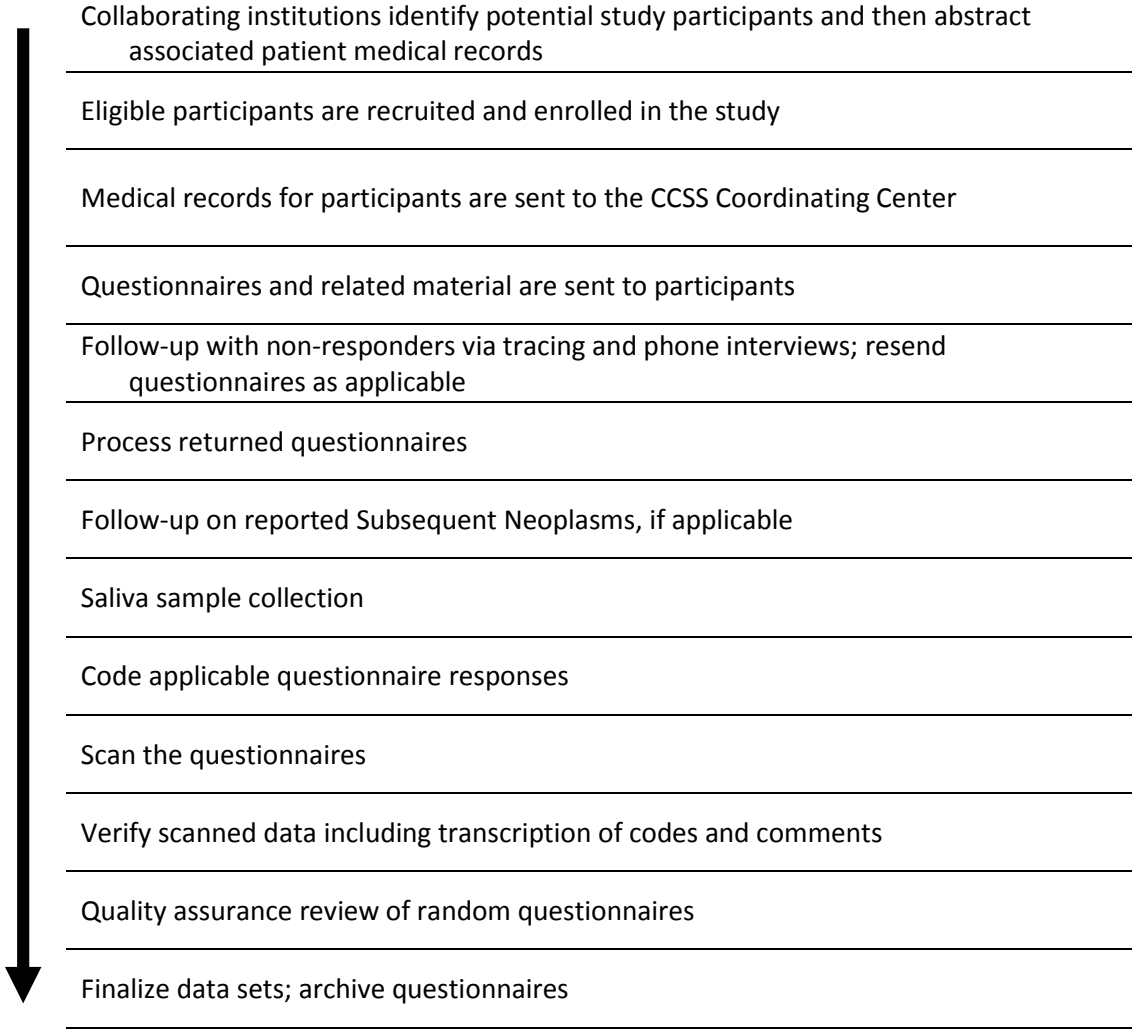
Subsequent Neoplasm Tracking
- Record SN/recurrence data
- Obtain pathology reports from treating hospitals
- Forward pathology reports to CCSS Biopathology lab
- Enter verified SN/recurrence information in MS Access database

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

Printed 12/9/2015 9:21 AM

Current Filename:		CCSS Coordinating Center SOP Manual Introduction ver 2_3.docx	
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

Department of Epidemiology & Cancer Control

Chair, Department of Epidemiology and Cancer Control
Leslie L. Robison, PhD

Departmental Focus

The Department of Epidemiology and Cancer Control is building an internationally recognized program for the conduct of etiology (causes and origins of disease), outcomes and interventional research in childhood cancer and hematologic conditions. The department has significantly increased St. Jude's ability to include preventive medicine in its overall goal to reduce morbidity and mortality from childhood cancer.

The Childhood Cancer Survivorship Study (CCSS), now anchored at St. Jude, is a multi-institutional consortium that markedly expands the scope of survivorship research and complements the work of the After Completion of Therapy (ACT) clinic. CCSS provides the availability of a cohort of approximately 28,000 five-year survivors of pediatric cancer.

The Department of Epidemiology and Cancer Control includes three focused areas of research.

Etiology Research
The emphasis of the Etiology Research program is molecular etiology with investigations focusing on genetic and/or environmental factors in laboratory- and non-laboratory-based research developed through a partnership with the International Outreach Program. The program will also expand secondary malignancies research.

Outcomes Research
The foundation of the Outcomes Research program consists of two remarkable resources; the St. Jude's After Completion of Therapy clinic and the Childhood Cancer Survivor Study. In combination, these two resources represent an unparalleled opportunity to conduct innovative clinical and analytic research into the mechanisms of and risk factors for adverse late events.

Interventional Research
The Interventional Research program will develop interventional protocols in supportive care and behavioral interventions. The proposed St. Jude Consortium for Interventional Research, which will consist of several centers committed to enrolling patients in cancer control protocols developed by St. Jude, will be its foundation.

Leslie L. Robison, PhD

Member, St. Jude Faculty
Epidemiology & Cancer Control Department

Co-Leader, Cancer Prevention and Control Program

Pediatric cancer epidemiology and outcomes

BS - University of California, Los Angeles, California (1976)

MPH - University of Minnesota, Minneapolis, Minnesota (1979)
PhD - University of Minnesota, Minneapolis, Minnesota (1982

Gregory T. Armstrong, MD, MSCE

Associate Member, St. Jude Faculty

Principal Investigator, Childhood Cancer Survivorship Study

Pediatric neuro-oncology and cancer survivorship

BS - Samford University (1995)
MD - University of Alabama School of Medicine (1999)
MS - University of Pennsylvania (Clinical Epidemiology) (2006)

Melissa M. Hudson, MD

Member, St. Jude Faculty

Director, Cancer Survivorship Division
Co-Leader, Cancer Prevention & Control Program

Health outcomes after childhood cancer

BS - Texas A & M University, College Station, Texas (1979)
MD - University of Texas Medical School at Houston (1983)

Aaron McDonald, PhD

Director, Childhood Cancer Survivorship Study

Epidemiology & Cancer Control Department

Late effects in childhood cancer survivors

James Ford, PhD

Clinical Research Scientist II
Childhood Cancer Survivorship Study
Epidemiology & Cancer Control Department

Late effects in childhood cancer survivors

Daniel M. Green, MD

Member, St. Jude Faculty

Adverse cardiac and reproductive effects of therapy

BS - Massachusetts Institute of Technology Cambridge, Massachusetts (1969)
MD - St. Louis University School of Medicine, St. Louis, Missouri (1973)

Kevin R. Krull, PhD

Associate Member, St. Jude Faculty

Neurocognitive outcomes of pediatric cancer

MS - Florida State University, Tallahassee (1986)
PhD - Florida State University, Tallahassee (1991)

Kirsten K. Ness, PT, PhD

Associate Member, St. Jude Faculty

Functional limitations among cancer survivors

BA ge of St. Scholastic (1983)
MA - Augsburg College (1998)
MPH - University of Minnesota (2002)
PhD - University of Minnesota (2004)

Interviewer Training Checklist

Orientation:
____How to clock in and out: TimeKeeper, time clock
____Pay: When received, how to obtain pay stub
____Campus tour
____Location of C-Suite
____Supplies
____St. Jude Today emails
____St. Jude employee bulletin board
____CITI training
____LearnCenter
- ____Mandatory training classes
- ____Telephone Doctor (7 classes on the LearnCenter)
- ____Getting Started With Access 2010
- ____Getting Started With Outlook 2010
- ____Getting Started With Excel 2010
- ____MILLI Training

____Interviewer Training Manual: receive and review
____Read CCSS protocol
____CCSS and LTFU websites, including past newsletters
____DiSC Training
____How to access Barry building for night shifts

Policies and Rules:
____St. Jude: where to find on the Intranet (Policies -> Institutional, Departmental)
- ____Parking (600.200)
- ____Rules of Conduct (600.010)
- ____Attendance and Tardiness (600.000)
- ____Overtime (300.090)
- ____Meals and Rest Periods (300.130)
- ____Internet Use (50.007)
- ____Photo and Video (20.103)
- ____Celebrity Visits (600.300)
- ____Inclement Weather (400.080)
- ____Email Policy (50.011)

____Departmental: in Interviewer orientation binder
- ____Scheduling policy and procedures in Interviewer binder
- ____Personal phone calls: See *Interviewer Rules* document in training binder.
- ____Nothing on top of desk cabinetry
- ____Brilliant Ideas program
- ____Attending workshops, talks, presentations, and seminars
- ____FFQ assistance for St. Jude Life (shadow for FFQ, if opportunity available)

Technical:
____U: drive (interviewer's personal storage), Z: drive (contains network folders), V: drive (contains databases)
____Printers: set default printer, location of printers, difference between printers

____Databases
- ____Trust Center settings
- ____Set up Sharepoint page link (do not use desktop shortcuts for databases)
- ____Purpose of different databases (REG, Recruitment, Expansion Tracking, LTFU Participants, St. Jude Life)

____Intranet (TimeKeeper, TimeOff, Phonebook, St. Jude policies, pay stubs, etc.)
____MS Lync
____MILLI icon

Administrative:
____Edit listing in SJ Phonebook
____How to use the SOP library
____The Call Center appointment calendar: always make/track appointments in CT
____Dry Erase board: completed HIPAAs, permissions, surveys
____File cabinet with blank forms, file folders for completed forms
____Closing monitor duties
____Self scheduling and location of Call Center schedules
____*Expired Participant Information Sheet*

Calls:
____Calling frequency, number of calls allowed, number of voice messages allowed
____Times appropriate to call participants (9am – 9pm in *participant's* time zone)
____Participant confidentiality
____Handling incoming calls
____Types of calls (Recruitment, Baseline survey, ancillary, FU5 survey, etc.)
____Call assignment: where to find them, how to use them

Recruitment:
____Receive and review binder
____Overview: History and purpose
____CCSS Recruitment database and documentation review
____SOPs, scripts
____Shadow experienced interviewers
____Role-play recruitment calls
____Verbal HIPAA procedures and post-HIPAA steps
____Add live Recruitment website link to browser's "favorites" list
____Practice outgoing and incoming calls with interviewer shadow

Baseline Surveys:
____Receive and review binder
____Overview
____CCSS Expansion Tracking database and documentation review
____Review survey with Lead Survey Interviewer (LSI) in detail at least once (Date: _____)
____Review pronunciation of drugs and genetic terms (and any other problem words)
____Shadow experienced interviewers
____Listen to experienced interviewer conduct a baseline survey
____Role-play baseline calls
____Practice baseline survey with experienced SI at least 3 times before making calls
- Date 1: _____ with _____
- Date 2: _____ with _____
- Date 3: _____ with _____

Baseline Surveys (Cont.):
____Importance of accuracy when typing in the survey
____Special considerations: expired surveys
____Perform test survey interview using links and test participant list (Date: _____)
____Add "live" baseline survey links to browser's "favorites" list
____Practice outgoing and incoming calls with interviewer shadow

FU5 Surveys:
____Receive and review binder
____Overview
____CCSS LTFU Participants database and documentation review
____Review survey with Lead Survey Interviewer (LSI) in detail at least once (Date: _____)
____Review pronunciation of drugs and genetic terms (and any other problem words)
____Shadow experienced interviewers
____Listen to experienced interviewer conduct a FU5 survey
____Role-play FU5 survey calls
____Practice FU5 survey at least 3 times before making calls

- Date 1: _____ with _____
- Date 2: _____ with _____
- Date 3: _____ with _____

____Importance of accuracy when typing in the survey
____Special considerations: expired surveys, reconsenting, refusals (FU5 only? All else?)
____Add "live"FU5 survey links to browser's "favorites" list
____Practice outgoing and incoming calls with interviewer shadow

Evaluations:
____Periodic Call Audits by Call Center Coordinator or LSI
____Quality Assurance (QA) of online surveys and other significant events

NOTES:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

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. Once the scheduling period closes, changes can only be made via shift swap with another SI. See below.
   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. (This would create unauthorized overtime.) 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 4 available shift choices on **Sunday**:

Hour Block	Shift Start Time	Shift End Time
4	12:30 PM	4:30 PM
4	1:00 PM	5:00 PM
4	5:00 PM	9:00 PM
8	12:30 PM	9:00 PM

   b. **Monday-Thursday** has 10 shift choices:

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

   c. **Friday and Saturday** has 4 available shifts:

Hour Block	Shift Start Time	Shift End Time
4	10:30 AM	2:30 PM
4	11:00 AM	3:00 PM
4	3:00 PM	7:00 PM
8	10:30 AM	7:00 PM

4. The minimum number of **required monthly weekend hours** varies depending upon the number of hours the SI was hired to work.*
   a. 40-hour positions *require a minimum* of 16 weekend hours per month.
   a. 36-hour positions *require a minimum* of 14 weekend hours per month.
   b. 32-hour positions *require a minimum* of 12 weekend hours per month.
   c. 24-hour positions *require a minimum* of 8 weekend hours per month.
   d. 16-hour positions *require a minimum* of 4 weekend hours per month.

5. The minimum number of required weekday (Monday – Thursday) **evening hours** is 4* per week. Friday, Saturday, and Sunday evening shifts do not count toward the minimum evening hours.

6. Holidays, vacation, and sick days do not nullify the minimum evening and weekend obligations.

7. **Shift Swaps**
   a. If an SI plans to swap scheduled time with someone, these arrangements must be made at least *24 hours* before s/he is scheduled to work. Failure to do this will result in an

occurrence. Please review the St. Jude policy. Essentially, any unscheduled absence is considered an occurrence, including calling in sick.

b. 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.
   vii. If there is an emergency requiring a SI to miss one or more shifts in a timeframe that would make it unreasonable to request the Coordinator's or LSI's permission, he or she can and should make the necessary arrangements with a co-worker to cover the shift, sending an email to the Call Center Coordinator, the LSI team, and all parties involved.

8. **Tardiness or Absence** (This section from the policy refers to **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 a SI does not come to work at all, he or she 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. **Inclement Weather** (The following applies when the Inclement Weather Policy has been activated by St. Jude. Review St. Jude Policy 400.80 for additional information.)
   a. Each SI is expected to come to work unless s/he feels it is unsafe to come in.
   b. If a SI decides it is unsafe to come in, s/he must call or email the Call Center Coordinator and LSI team or risk receiving an occurrence. Vacation time or a Personal Day must be used to be paid for this day. (Sick time is not applicable.)

10. **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.

11. **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 2/18/2015 11:12 AM

[213] Current Filename:		CCSS Call Center Scheduling Policy ver 2_2.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

Interviewer Rules

Confidentiality

Survey staff are not allowed to handle any participant information until they have completed the required education in the protection of human research subjects (mandatory CITI training) and have received permission from the Call Center Coordinator.

Anything with participant personal information that is no longer needed **must** be shredded. Do not place this material in general trash containers or recycle bin.

Anything with confidential participant information needs to be secured prior to leaving the office; do not leave participant lists, folders, etc. on desks or posted on walls at your work station or in the general work area. Filing cabinets must be locked when not in use.

The side door entrance to the survey center needs to be kept locked at all times. Entrance to the survey center is limited. Do not bring children, friends or others into the Call Center unless prior approval has been obtained (see St. Jude's policy 600.010).

Clocking in and out, breaks

The Call Center practices a paid fifteen minute break for a 4 hour shift, and a non-paid 30 minute lunch (off the clock) for every shift of 5 hours or more. Someone must be available to cover the phones during breaks. If you take a break, please coordinate with your colleagues to make sure the Call Center is not left unmanned. Please also ensure your break does not exceed the approved allotted time as this may result in disciplinary action. See the Coordinator or Lead Survey Interviewer (LSI) if you have questions.

Non-productive visiting with co-workers

There are occasions when you will want to visit with a co-worker, such as greetings when they or you begin a shift, you wish to invite a co-worker to take a break with you, or other non-work related interaction. These visits are important to group synergy and teambuilding. They should not, however, interfere with production in the Call Center or generally last longer than two to three minutes. They must be kept at a low volume so as not to disturb others who are working. Extended time spent on non-productive visiting with co-workers wastes NIH grant fund dollars and will result in counseling. Continued violations will result in further disciplinary action.

Personal phone calls, texting or emails during working hours

Personal phone calls are not allowed on St. Jude phone lines (There is a phone in the lobby outside the elevators for personal use.) except under emergency situations. Personal calls and texting on cell phones are permitted outside the Call Center and must be conducted during break periods except in emergencies.

Internet usage

The internet is for St. Jude Children's Research Hospital official business. We strictly follow St. Jude's policy 50.007, Internet Policy. Please see your coordinator or Lead Survey Interviewer if you have questions regarding this policy.

Section 20: Patient Care

Effective Date: 5/7/12

20.103 Guidelines for Photographing, Videotaping and Audiotaping by Patients and Family Members

PURPOSE

The purpose of this policy is to ensure the confidentiality and privacy and maintain the integrity of safe patient care by providing guidelines for photographing, videotaping or audiotaping by patients and family members.

DEFINITIONS

1. Important Events: Stem Cell Infusion, First and Last Day of Chemotherapy, Birthdays or other special patient events (e.g. Halloween or graduation days).

2. Still or Motion Media: Any photography, video recordings, or audio recordings, captured on any device, in any form, including but not limited to traditional cameras, digital cameras, video cameras, iPhones, smart phones, cellular phones, digital audio recorders, web cameras, and other devices.

3. Workforce Members: Employees, trainees, volunteers, or others in the performance of work for St. Jude who are under the direct control of St. Jude, whether or not they are paid by St. Jude.

SCOPE

This Policy applies to all St. Jude patients, former patients and their family members who are on the St. Jude campus and all St. Jude Workforce Members.

POLICY

1. Use of Still or Motion Media by a patient (or former patient) or family member, of any medical care being rendered to the patient is **strictly prohibited**, as it may interfere with the care being rendered. The only permissible exceptions are the Important Events. Further, Workforce Members may not, at the patient's (former patient) or families' request, use any type of Still or Motion Media to record medical care being rendered to the patient.

2. Use of Still or Motion Media by a patient (former patient) or family member in the ICU is **strictly prohibited** under any circumstance. Still photography is not permitted unless permission is given by the ICU attending physician or nurse coordinator.

3. Use of any Still or Motion Media by patients (former patients) or their family members is permitted within the limitations of and in accordance with this Policy. Under any circumstances, should a Workforce Member believes that patient care may be compromised by the use of any Still or Motion Media, the Workforce Member may withdraw this permission and stop the use of any Still or Motion Media.

4. Patients (former patients) or their family members are welcome to take Still or Motion Media of themselves or their children while at St. Jude. However, in order to respect the privacy of other patients (former patients) their family members and Workforce Members, patients (former patients) or their family members are prohibited from using Still or Motion Media of other patients (former patients), their family members or Workforce Members without their permission.

5. Workforce Members reserve the right to refuse to be in any Still or Motion Media.

6. Workforce Members may not participate in videotaped or audio taped interviews, by a patient (former patient) or family member, regarding a patient's (former patient's) care or treatment. Refer requests for videotaping or audiotaping by patients (former patients) or family members to the Communications Department or the Office of Legal Services

7. All unidentified persons using Still or Motion Media should be asked to stop until proper authorization has been verified (call Security if needed).

8. If a patient (former patient) or family member is using Still or Motion Media of other patients (former patients) or their family members or Workforce Members without permission, then refer to the Procedures section of this Policy.

PROCEDURE

1. If a Workforce Member observes a patient (former patient) or family member violating this Policy, then the Workforce Member should request that the patient (former patient) or family member cease the use of Still or Motion Media immediately and should request that the patient (former patient) or family member delete any Still or Motion Media produced.

2. If the patient (or former patient) or family member continues to violate this Policy, a Workforce Member should contact their supervisor. The offender may be asked to leave the St. Jude campus unless and until he or she agrees to comply with this Policy.

3. A Workforce Members should appropriately document (e.g. EERS Reports) any failure(s) to comply with this Policy.

REFERENCES

Institutional Policy 70.132 HIPAA Privacy Administrative Requirements
http://home.web.stjude.org/pp/pdf_files/70_132.pdf

Tennessee State Privacy Laws

SAMPLE FORMS OR OTHER ATTACHMENTS

Not Applicable

APPROVAL PATH/COMMITTEES

Policy Author: Morris Landau, HIPAA Privacy Officer

Policy Owner/Sponsor: Miscellaneous Committee for Clinical Policies

Approval received by the following St. Jude staff, offices and/or committees:

Other Pam Dotson, Janice English, Robin Mobley, John Zacher

Office of the General Counsel (Legal)	Approved.
Chair, St. Jude Standing Committee(s)	Not Applicable.
Chair, Medical Executive Committee (MEC) Subcommittee(s) Miscellaneous Committee for Clinical Policies	Approved.
Chair, Patient Care Committee	Not Applicable.
Chair, MEC	Approved.
Chair, Executive Committee	Not Applicable.

St. Jude Children's Research Hospital

Section 20: Patient Care

Effective Date: 5/7/12

20.103 Guidelines for Photographing, Videotaping and Audiotaping by Patients and Family Members

Original Issue Date: 10/01

Revised/Reviewed Dates: 08/03, 05/05, 11/07, 5/12

Approval:

Director and CEO

Date 5/15/12

Section 30: Research and Academic

Effective Date: 12/19/2012

30.609 Mandatory Human Subject Protections Training

PURPOSE

1. To comply with the Office for Human Research Protections (OHRP) expectation that institutions will ensure that research professionals and others involved in research funded or otherwise supported by the United Stated Department of Health and Human Services will understand and comply with regulations for the protection of human research subjects

2. To comply with National Institutes of Health (NIH) mandate that all investigators submitting applications for NIH funding or receiving new or non-competing awards for projects involving human research subjects complete training on human subject protections.

DEFINITIONS

1. CITI: Collaborative Institutional Training Initiative
2. FDA: Food and Drug Administration
3. HSP: Human Subject Protections
4. ICH: International Conference on Harmonization
5. NIH: National Institutes of Health
6. OCRE: Office of Clinical Research Education
7. OHRP: Office for Human Research Protections
8. PHI: Protected Health Information
9. PI: Principal Investigator

SCOPE

All investigators, faculty, research study personnel and all others who have contact with research subjects, human materials and/ or research - related private health information will be required to complete initial training in human subject protections within 30 days of employment or **before** under-taking any clinical research activity. Individuals responsible for the oversight of clinical research activities are included in this policy.

30.609 Mandatory Human Subject Protections Training

POLICY

1. St Jude Children's Research Hospital (SJCRH) requires that all clinical research professionals or persons having contact with SJCRH research subjects or the subjects' private identifiable health information (PHI) must complete the Collaborative Institutional Training Initiative (CITI) human subject training course. This requirement extends to adjunct faculty who work by contract and actively participate in biomedical or social/behavioral research.

2. Researchers who perform research on human tissue or maintain tissue repositories that include any PHI or other identifiable private information must also complete this training.

3. Training must be completed regardless of the funding source or sponsor of the project.

4. No researcher or staff may become involved in any human subjects' research-related activity without having completed this training.

5. Re-certification is accomplished by completing the basic course at required intervals.

6. The PI is the responsible leader of the team of individuals conducting a study and is responsible for compliance with the ethical and regulatory conduct of the project.

PROCEDURE

1. HSP training and education is a shared responsibility of the Principal Investigator (PI) and the institution per FDA and DHHS regulations and ICH guidance. The PI selects qualified sub-investigators based on training and experience for the conduct of all aspects of the clinical trial and should ensure they are aware of regulatory requirements and acceptable standards for the conduct of clinical trials and the protection of human subjects.

2. The Office Clinical Research Education (OCRE) provides the guidance and training opportunities to meet the HSP training requirements, and tracks and monitors compliance with the policy. OCRE makes the CITI training information available to the appropriate groups of employees, students and trainees (See Attachments) In addition, the office maintains a record of completed training and updates the institutional electronic HSP training database, ensures that the CITI HSP training program continues to satisfy all mandates and that individual HSP re-certification is achieved.

3. Research professionals and others may access detailed CITI registration instructions and the CITI hyperlink on the SJCRH intranet on the Clinical Research Education webpage under "CITI Links and Information".

4. Individual HSP re-certification is required every 3 years for all research professionals and others except Clinical Fellows who must re-certify every two years. This requirement is met by retaking the required basic biomedical or social/behavioral course, as applicable.

5. HSP courses are designated by "Group" and should be selected based on the level and type of involvement with human research volunteers.

6. The PI, the person ultimately responsible for the ethical and regulatory oversight of study conduct, and each of the individual research team members work collaboratively with the OCRE to comply with this policy.

7. The Institution through the Office of Clinical Research Education and in collaboration with administration of the PI's department and clinical trials directors provides guidance or training opportunity for all other staff that meet the criteria for the training requirement.

8. The Office of Clinical Research Education can be contacted 7:30 – 4:00 pm for assistance at 901 – 595 – 4773.

REFERENCES

OHRP Federal Wide Assurance

NIH directive for NIH funding (*Notice OD-00-039, August,* 2000) for new and non-competing awards

FDA 21 CFR 312.53 , 21CFR 312.3 AND 21 CFR 812.3

FDA Guidance: Guidance for Industry: Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects October 2009

FORMS OR OTHER DOCUMENTS

CHART FOR TRAINING REQUIREMENTS
Chart should be accessed through the Clinical Trials Administration Education Office intranet site

APPROVAL PATH/COMMITTEES

Policy Owner: Janie F. Gardner, MS, CCRP, CIM.
Policy Sponsor: Victor Santana, M.D., VP for Clinical Trials Administration

Approval received by the following St. Jude staff, offices and/or committees:

Other	Not Applicable
Office of the General Counsel (Legal)	Not Applicable
Chair, St. Jude Standing Committee(s)	Approved
Senior Program Council	

30.609 Mandatory Human Subject Protections Training

Chair, Medical Executive Committee (MEC) Subcommittee(s)	Not Applicable
Chair, Patient Care Committee	Not Applicable
Chair, MEC	Not Applicable
Chair, Executive Committee	Not Applicable

Original Issue Date:	Revised/Reviewed Dates:
06/09/2008	12/19/2012

Approval:

Signature on File in Administration Office	2/8/13
Director and CEO	Date

Section 300: Administering Wages & Salaries

300.090: Overtime Compensation

Purpose

St. Jude Children's Research Hospital (SJCRH) has established guidelines for payment of overtime premiums to hourly (nonexempt) employees; these guidelines comply with the Fair Labor Standards Act (FLSA) of 1938, as amended. Bargaining unit employees should refer to the bargaining unit agreement.

Policy

1. *Overtime.* Because of the nature of patient care and research at SJCRH, overtime is required, as a condition of employment, when deemed necessary by management. Managers will inform their employees when such a condition exists.
2. Overtime compensation is paid to an hourly (nonexempt) employee who works more hours than specified by SJCRH's primary work schedule: 40-hour work week. An employee who works more than 40 hours in a week shall receive compensation for the excess hours at 1.5 times his or her base hourly pay rate with the extra .5 being paid at the average hourly rate. In a week in which a paid absence occurs, overtime pay will be granted only if the employee actually worked more than 40 hours. The absence will be paid as regular pay but cannot be used toward accumulation of overtime compensation. Employees in job classifications covered under the collective bargaining unit are governed by the terms specified in their union agreement.
3. Employees who have any questions regarding their basic work schedule for overtime purposes should consult their immediate supervisor.
4. *Exempt (salaried Employees).* In accordance with U.S. Department of Labor guidelines, certain job classifications are exempt from overtime regulations and thus not eligible for overtime compensation. St. Jude does not offer a formal "Comp Time" program for exempt (salaried) employees. However, supervisors have discretion to occasionally alter normal work schedules to accommodate exceptional work loads and/or special events.

Definition

Paid absence time – Any hours compensated when an employee has not actually worked – (e.g., vacation, sick, personal, call back, etc.).

ORIGINAL ISSUE DATE:	REVISED DATES:
01/88	11/91, 01/93, 08/00, 04/05, 08/07, 10/09, 2/10

APPROVAL:

Signature on file in Human Resources
DIRECTOR and CEO

DATE

Section 300: Administering Wages & Salaries

300.130: Meal and Rest Periods

Purpose

St. Jude Children's Research Hospital (SJCRH) has established policies regarding the time and duration of meal and rest periods in compliance with the Fair Labor Standards Act (FLSA) of 1938, as amended, Tenn. Code §50-2-103(D) and other applicable laws and regulations. Bargaining unit employees should refer to the bargaining agreement for information about rest periods and breaks.

Policy

1. *Meal Break*
   a. All employees scheduled to work more than 5 hours will take a 30 minute unpaid meal break. Unpaid meal breaks longer than 30 minutes must be approved, in advance, by employee's supervisor.
   b. The meal break is unpaid and is not included in the calculation of hours worked. Non-exempt (hourly) employees are free to leave his/her work area and will not conduct work activity during this break.
   c. Employees leaving the SJCRH campus during their meal period must notify their immediate supervisor. In addition, non-exempt (hourly) employees must clock out when they leave, and clock in upon their return.
   d. Non-exempt (hourly) employees may not work through a lunch period without prior approval from their supervisor. Such events should occur rarely.
   e. Any meal break lasting less than 20 minutes will be compensated as hours worked, for non-exempt (hourly) employees.
   f. Meals breaks should not be taken at the beginning or end of a shift.
2. *Rest Periods* and *Breaks*
   a. Supervisors may authorize 15-minute paid rest periods during an employee's shift.
   b. Paid rest periods should not be taken immediately before or after the unpaid lunch period to provide a longer meal break or at the beginning or end of a shift.
3. *Rest Periods and Breaks for Nursing Mothers*
   a. Nursing mothers are allowed reasonable break times to express breast milk for her child for one year after the child's birth each time such employee has need to express milk. The frequency of breaks varies depending on such factors as the age of the child. The younger the child the more breaks a nursing mother may need.
   b. Nursing mothers should give their immediate supervisor notice of their intent to take break time to express breast milk.

Procedures:

Time clock procedures for non-exempt (hourly) employees.

a. A 30-minute meal break will be automatically deducted from any continuous working period of five and one-half (5½) hours or more per shift.
b. When taking a meal period that is different from the standard 30-minute period, the employee should utilize the time clock so that the time will be accurately reflected on the timesheet. If the employee does not clock out, the supervisor should designate the correct lunch period on the time sheet. Supervisors must approve any meal breaks different than the standard 30-minute period.
c. If an employee works through their scheduled meal break, "no lunch" must be written on the time sheet or the employee may utilize the "no lunch" key on time clock system. Supervisors must approve any employee working through his/her meal break.
d. When a double or triple shift is worked, an additional thirty (30)-minute lunch break will be provided and deducted for each shift worked. (See policy 300.120 Shift Differential).

Section 300: Administering Wages & Salaries

300.130: Meal and Rest Periods

Definitions:
NA

References:
NA

ORIGINAL ISSUE DATE:	REVISED DATES:
11/91	08/00, 4/11, 1/15

APPROVAL:

Signature on file in HR_____ _____

Senior Vice President and Chief Support Operations Officer DATE

Section 400: Time Away From Work

400.080: Inclement Weather

Purpose

The purpose of this policy is to facilitate continuity of St. Jude Children's Research Hospital (SJCRH) operations, to ensure the safety of our employees, and to avoid placing hardships on other employees by unplanned absences or tardiness during periods of extreme weather.

Policy

Because of the nature of the work performed at SJCRH, the institution operates seven days a week, twenty-four hours a day. During severe weather, employees are expected to make reasonable efforts to arrive at work safely and in a reasonable time. However, employees are urged to use reasonable judgment in deciding whether they can safely commute to work. Each employee is responsible for contacting his or her supervisor to determine whether he or she is required to report to work or to notify the supervisor if he or she cannot report to work. Employees who fail to call in or report to work are subject to the terms of Policy 600.000: Absenteeism and Tardiness.

In the event of an absence because of inclement weather, vacation time or a personal day must be used to render the absence paid. Use of sick time is subject to Policy 400.040: Paid Sick Leave.

Procedures for Essential Personnel

1. To ensure the availability and safety of essential personnel, St. Jude will provide overnight accommodations on or near the campus, a stipend for meals, and transportation to and from the lodging facility.
    a. Essential personnel are defined as those required to safely provide patient care or support services.
    b. The management of the following departments determines essential personnel: Anesthesiology, ARC, Environmental Services, Facilities Operations and Maintenance, Food Services, HIMS, Information Sciences, Nursing, Pathology, Patient Business Services, Pharmacy, Radiological Sciences, Respiratory Therapy and any other department deemed essential to safety and security.
2. Responsibilities
    a. Human Resources
        i. Work with administration to determine the need to implement the Inclement Weather Policy.
        ii. Notify departments about implementation and procedures to obtain lodging and meal vouchers.
        iii. Work with Public Relations to communicate pertinent information.
        iv. Assist Financial Services with reconciliation for billing.
    b. Domiciliary Services
        i. Reserve the rooms.
        ii. Assign and communicate lodging locations.
        iii. Serve as primary liaison with off campus lodging facilities.
        iv. Communicate pertinent information to Human Resources and Financial Services to assist with billing.
    c. Department Management
        i. Designate a primary contact during inclement weather coordination.
        ii. Determine need for and contact essential personnel.
        iii. Complete the “Employee Lodging Request for Inclement Weather Form” and submit to Domiciliary Services to coordinate lodging for their essential personnel.

iv. Distribute lodging cards and food vouchers* to essential personnel requiring lodging.
v. Assist or direct employees to contact Security or off-campus lodging facility for transportation.

d. Security
   i. Provide transportation to and from lodging facilities during normal shuttle hours.
   ii. Provide transportation after normal shuttle hours when hotel shuttle is unavailable.
   iii. Assist Nursing Coordinator during emergencies involving inclement weather coordination.

e. Financial Services
   i. Request folios from hotel at month end.
   ii. Reconcile all invoices and billing.
   iii. Charge costs back to department through journal entry.

Definitions:
Essential personnel - Those required to safely provide patient care or support services.

*Food vouchers are distributed to employees staying at the Grizzlies House. Employees staying at hotels will receive their food vouchers at hotel check in.

ORIGINAL ISSUE DATE:	REVISED DATES:
01/88	11/91, 08/97, 08/00, 2/07, 03/08, 6/10

APPROVAL:

Signature on file in Human Resources _____
DIRECTOR and CEO DATE

400.080: Inclement Weather

St. Jude Children's Research Hospital
Employee Lodging Request for Inclement Weather

Department Name:

				Dates Approved for Lodging	
	Employee First Name	**Employee Last Name**	**Cost Center***	**Start**	**End**
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					

Fax Completed Form to Domiciliary Services: (901) 595-8250

* Lodging will be charged to the Cost Center provided

Last updated: 5/25/2010

Department Emergency Contact for dates listed above:

Name - Printed

Work Telephone

Title/Position

Cell Phone/Blackberrry

Email address

Typed/Printed Name - Designated Department Approver

Signature - Designated Department Approver

Date

St. Jude Children's Research Hospital
ALSAC • Danny Thomas, Founder

Section 50: Management of Information

Effective Date: 01/14/15

50.007 Internet Policy

PURPOSE

This policy establishes rules governing use of the Internet utilized by SI. Jude Children's Research Hospital (SJCRH) employees, volunteers and other workforce members. The Internet is a powerful communications tool and a valuable source of information. Every individual who uses SJCRH Internet resources is expected to conduct themselves honestly and appropriately, and to respect the copyrights, software licensing rules, property rights, privacy and prerogatives of others, just as they would in any other business dealings. It should be understood that all institutional policies apply to an individual's conduct on the Internet, especially (but not exclusively) those that deal with intellectual property protection, HIPAA Privacy and Security Rules, misuse of institutional resources, sexual harassment, and Information Security. Information offered through the Internet by an individual identified with the institutional should be in "good taste" and accurate, and personal opinions of the user should be clearly labeled as such. The overall purpose of this policy is to ensure that all individuals use SJCRH Internet resources in a productive, ethical and lawful manner while recognizing the rights of academic freedom, freedom of speech, privacy and confidentiality.

DEFINITIONS

N/A

SCOPE

1. This policy applies to any Internet resource or site that is:

    A. Accessed on or from SJCRH premises

    B. Accessed using SJCRH computer equipment or other electronic communication devices

    C. Accessed outside SJCRH premises by an employee, volunteer, or workforce member that represents himself or herself as a SJCRH employee or an agent of SJCRH in any way or leads others to reasonably believe that he or she represents or performs any function on behalf of SJCRH.

POLICY

1. Employees, volunteers, and workforce members are strictly prohibited from using SJCRH provided Internet services in connection with any of the following activities:

    A. Engaging in illegal, fraudulent, or malicious conduct

B. Disclosing Electronic Protected Information, defined in policy 50.012, unless doing so is allowable in order to perform a job function

C. Sending, accessing, or storing offensive, obscene, or defamatory material

D. Displaying, archiving, storing, distributing, editing or recording any kind of sexually explicit image or document

E. Annoying or harassing other individuals

F. Sending uninvited communications of a personal nature;

G. Monitoring or intercepting the files or electronic communications of employees or third parties

H. Obtaining unauthorized access to any computer system

I. Using another individual's identity, password or other access privileges without explicit authorization

J. Attempting to test, circumvent, or defeat security or monitoring systems of SJCRH or any other organization without the prior authorization of the Information Security Office

2. Internet resources are provided by SJCRH for business use. Limited or incidental use of Internet services for personal, non-business purposes is acceptable. However personal use must be infrequent and must not:

   A. Involve any prohibited activity (See Section 1)

   B. Interfere with the productivity of the employee or his/her coworkers

   C. Consume system resources or storage capacity on an ongoing basis

   D. Involve large file transfers or otherwise deplete system resources available for business purposes

   E. Share confidential or proprietary information about SJCRH patient care, research, or business without appropriate approval

   F. Violate patient privacy or confidentiality

3. Any use of social media sites should be in compliance with institutional policy 10.126 – Social Media.

4. SJCRH currently has software and systems in place that can monitor and record all Internet usage. These systems are capable of recording, for each and every user, each World Wide Web site visit and each transfer in and out of our internal networks. Monitoring of SJCRH Internet activity and analysis of usage patterns will be conducted on an ongoing basis. In the event there is a reasonable belief that that this or any other SJCRH policy has been violated, SJCRH reserves the right to inspect any and all files stored within the institutional networks to assure compliance with this policy. SJCRH has the right to request and must be permitted access

to any employee's personal web site, social network site, or online presence if there is reasonable belief that this policy or other relevant policies are being violated. Employees violating this policy are subject to discipline, up to and including termination of employment.

5. Employees using any SJCRH computer system for defamatory, illegal, or fraudulent purposes also are subject to civil liability and criminal prosecution.

PROCEDURE

N/A

REFERENCES

Institutional Policy 50.012 - Definition of Electronic Protected Information

Institutional Policy 10.126 - Social Media

Policy 600.010 Rules of Conduct

HIPAA Privacy Rule

HIPAA Security Rule

Tennessee Security Breach Notification Law

SAMPLE FORMS OR OTHER ATTACHMENTS

N/A

APPROVAL PATH/COMMITTEES

Policy Author: Brian Elrod
Policy Owner/Sponsor: Brian Elrod

Approval received by the following St. Jude staff, offices and/or committees:

Other	N/A
Office of the General Counsel (Legal)	N/A

Section 50: Management of Information

Effective Date: 01/14/15

50.007 Internet Policy

Chair, St. Jude Standing Committee(s)	N/A
Chair, Medical Executive Committee (MEC) Subcommittee(s)	N/A
Chair, Patient Care Committee	N/A
Chair, MEC	N/A
Chair, Executive Committee	N/A

Original Issue Date:	Revised/Reviewed Dates:
02/99	11/03, 05/05, 01/07, 01/11, 01/15

Approval:

Signature on File in Administration Office	1/14/15
EVP, Chief Administrative Officer	Date

50.011 Email Policy

Purpose

The Email system is provided to employees to assist them in the performance of their job responsibilities. Email allows employees to communicate with each other internally and with third parties outside the institution via the Internet. The purpose of this policy is to establish guidelines for the use of Email to ensure this use is appropriate, lawful and consistent with the mission of the institution.

Policy

1. Permitted Uses

The Email system shall be used by St. Jude employees and other persons granted access to the system to assist them in the performance of their job responsibilities. Occasional personal Email use is permitted so long as the personal use does not interfere with the employee's job performance or violates this policy.

2. Prohibited Uses

The Email system may not be used to:
(A) make any inappropriate or discriminatory statements based on race, gender, religion, national origin, sexual preference, disability or veteran status;
(B) harass or intimidate another person;
(C) interfere with another person's ability to perform their job;
(D) access, read, copy, store or forward inappropriate or sexually explicit messages or materials;
(E) use, copy or distribute documents in violation of U.S. copyright laws;
(F) fabricate and send an Email so it appears to be from another person;
(G) obtain access to the files or Emails of others without proper authorization;
(H) breach any information security systems;
(I) send non-requested communications such as "chain letters," "prayer wheels" solicitations for goods or services or Emails that ask the recipient to forward the message to others;
(J) broadcast / circulate personal information, such as items for sale, giveaways, promotional activities, personal announcements, etc. (exception – St. Jude Bulletin Board),
(K) For personal use if such use interferes with the person's job performance; or
(L) For any purpose that may constitute a violation of applicable laws or regulations.

Use of Email in violation of this policy may result in disciplinary action up to and including termination of employment.

Procedure

3. Confidentiality

All electronic protected information, or EPI as defined in policy 50.012, financial, research or other proprietary information of St. Jude should be treated as strictly confidential and its transmission by Email should be protected to the same extent as other forms of confidential communication. Confidential information contained in an Email should only be sent to authorized individuals inside and outside the institution on a "need to know" basis. Extra caution should be taken when addressing Emails to ensure messages are not inadvertently sent to the wrong individual inside and outside St.

Jude. The Information Security Office will monitor external Email for EPI, determine when a user should employ other methods to transmit the information, and assist the user in doing so. Monitoring and controlling EPI being sent via Email will address SJCRH compliance with state and federal laws. The Information Security Office recommends the secure file transfer solution (FTA) be used when feasible to send EPI to external individuals.

While every reasonable measure is taken by St. Jude to protect the security of its internal information systems, the Email system does not provide a totally secure means for communicating privileged, sensitive or confidential information. Because of the ease with which recipients can forward Emails and the possibility of unauthorized system access, extreme caution should be exercised in using Email to communicate confidential or sensitive matters, particularly those involving patients or employees.

Email windows should not be left open on an unattended computer screen. Individuals should exit the Email program or use the lock computer function before leaving his or her PC area. Computer passwords (as well as other system passwords) should be routinely changed in compliance with the St. Jude Confidentiality and Security Policy. Sharing of computer passwords is strictly prohibited.

4. Privacy

St. Jude shall use all reasonable means to protect the privacy of Email information sent and received both internally and externally to the patient /parent / legal guardian. Internal Email is an essential form of internal communication among and between St. Jude healthcare providers and support personnel and is used to facilitate the healthcare process. Whenever appropriate, the patient's identity should be disguised by use of the patient's initials or medical record number in lieu of their full name. Employees should be aware that Email communications are both difficult to delete from the Email system and may be subject to discovery in a lawsuit. Additionally, the informality of Email may lead employees to be more casual than they would otherwise be when documenting communications. Employees should take care to ensure that the tone and content of their communications in an Email is appropriate. St. Jude will use all reasonable means to protect the privacy of External Email information sent and received from the patient / parent / legal guardian (see "Confidentiality"). The following steps are necessary for Privacy of patient Email and should be followed by required St. Jude personnel:

- Prior to utilizing Email communication, patients / parents / legal guardians should complete and sign the "General Consent for Routine Medical Diagnosis and Treatment and Release of Information" form.

- All Emails from or to a patient /parent / legal guardian concerning diagnosis or treatment should be printed out and made a part of the patient's medical record.

- Emails may be forwarded internally as necessary for diagnosis, treatment, reimbursement and other healthcare operations. Employees should not however, forward Emails to third parties without the patient / parent / legal guardian's prior written consent, except as authorized or required by law.

- Although employees should try to read and respond promptly to an Email from a patient/ parent / legal guardian, St. Jude cannot guarantee that any particular Email will be read and responded to within any particular period of time. Patients / parents / legal guardians should be instructed not to use Email for medical emergencies or other time sensitive matters.

- Employees, patients / parents / legal guardians should be instructed not to use Email for communicating sensitive medical or personal information such as information regarding HIV/AIDS, mental health, development disability or substance abuse.

5. Smart Phones, PDA's, and Personal Email Devices

The following safeguards are required to receive, store, and transmit SJCRH Email on a smart phone, PDA, or any other personal Email device:

- A password must be used to secure the device
- Encryption must be used to secure the device
- If the device is lost it must be reported to the Information Security Office as soon as possible
- The technology employed to send and receive the Email must be supported by SJCRH
- SJCRH reserves the right to destroy all data on the device via a remote wipe function
- All non-SJCRH owned devices used to access Email must be authorized for use by submission and approval of the Personal Email Device Form

6. Distribution Lists

Email Distribution Lists are maintained for specific departments and designated key communication groups defined by senior management. Distribution Lists should be periodically reviewed and updated to ensure recipients are appropriate. A global list (encompassing all Email users) is used for communications critical to the entire organization. Use of the "Everyone" group list is limited to authorized users in Administration, Human Resources, Security and others designated by senior management. Unless approved in advance by senior management, the global distribution of Email is strictly prohibited. Personal distribution lists can be built and maintained by individuals or within a department or functional area.

7. Copyrighted Information

Use of Email to transmit copyrighted information, including software, research data, manuscripts, music, video files and graphics without the consent of the copyright holder is strictly prohibited.

8. Email Etiquette

Emails, like other St. Jude communications, should be used in a courteous, professional and businesslike form.

9. Email Disclaimers

Personal Email disclaimers are not permitted except with the prior approval of the General Counsel or his or her designee. A link to an officially approved Email disclaimer is automatically appended to all outgoing SJCRH Emails (http://www.stjude.org/emaildisclaimer).

10. Email Signatures

Email signatures represent St. Jude and should reflect a professional image of the organization. Email

signatures may only include information related to the employee's position and contact information. Messages or quotes of a political, religious or personal nature may not be included, nor images, fancy fonts or colors. The following guidelines should be used to create an Email signature:

1. Standard fonts include Arial, Calibri, Courier, Times New Roman, or Verdana.
2. Black or blue font may be used.
3. Images, including any embedded background images, may not be used.
4. The recommended layout for an Email signature is:
    a. Name, Degrees, Credentials (if appropriate)
    b. Title
    c. Department/Division
    d. St. Jude Children's Research Hospital
    e. 262 Danny Thomas Place, Mail Stop _____
    f. Memphis, TN 38105
    g. St. Jude Email address (optional)
    h. St. Jude phone number
    i. St. Jude cell phone, pager or blackberry number (optional)
    j. Fax number (optional)
    k. www.stjude.org

11. Mailing lists, List Servers or Discussion Groups

Subscription to mailing lists, bulletin boards, chat groups, commercial on-line services and other information services is permitted so long as they are directly related to the employee's job responsibilities. To prevent unnecessary traffic on the Email system, subscriptions to non-job related services are not permitted.

12. Personal Email Accounts

It is acceptable to use a personal Email account from the SJCRH network to send and receive non-business or personal Email. It is not acceptable to forward SJCRH business Email containing EPI to a personal account.

13. Storing and Deleting Emails

St. Jude strongly discourages the electronic storage of large numbers of Emails due to storage space limitations on the network server and personal hard drives, and to avoid reduced system performance levels. Employees are urged to promptly delete any Email that no longer requires action or is not necessary to an ongoing project and to periodically audit stored Emails and delete those that are no longer needed. To control the volume of stored Emails, Outlook accounts, including mailboxes, will be limited to a specific amount of space for each user. The Email system backup is stored to tape and will be retained for a designated period, and then automatically purged.

14. System Protection

St. Jude maintains several programs to protect the Email system against viruses, worms, other potentially harmful executable code, non-business items that use excessive system resource, and unsolicited commercial Email (Spam). These protective measures are necessary but may result in some false positives. Assistance with these will be coordinated through the Information Security Office.

15. System Monitoring

St. Jude maintains the Email system for use by its employees in the performance of their job responsibilities. All equipment, programs, networks, servers, etc. associated with the Email system are the exclusive property of St. Jude. St. Jude has an affirmative duty to protect the integrity and security of all confidential patient and institutional proprietary information transmitted, received or stored on the system. St. Jude must also take reasonable measures to ensure that the Email system is not used in a discriminatory or illegal manner, or in such a way as to negatively reflect on the reputation of the institution.

St. Jude, through its Information Security Office under the direct supervision of the Information Security Officer maintains a specialized Email monitoring program designed to identify, segregate and document institutional Email activity that may violate this policy. St. Jude has the right to review, inspect and copy all Emails located on the network or on an individual computer to ensure compliance with this policy. No employee should have an expectation of privacy relative to his or her use of the St. Jude Email system.

In the event there is reasonable belief that this Email Policy has been violated, Information Security personnel will notify the Information Security Officer and the Human Resources Employee Relations Manager and provide a confidential report, as requested, to permit a full investigation of the matter. If the employee's use of the Email system is found to be in violation of this Policy, the employee's supervisor or Chair will be notified. The Information Security Officer will also notify senior management if necessary. Employees violating this policy are subject to discipline, up to and including termination of employment. All investigations will be handled in a confidential and professional manner.

16. Other Access

On occasion, Email system support personnel may, during the performance of their duties, inadvertently see the contents of a particular Email. There may also be circumstances where it will be necessary for systems personnel to view a particular Email in order to forward or dispose of undeliverable mail. This exception does not exempt the employee from the prohibition against disclosure of personal or confidential information, except to the extent that the disclosure represents a good faith attempt to send otherwise undeliverable mail to an intended recipient. This forwarded mail should be accompanied by notification to the recipient that the Email was inspected for such purposes. Except as provided herein, any intentional, unauthorized viewing or disclosure of any Emails by these personnel is strictly prohibited and will subject the employee to discipline up to and including termination.

References

HIPAA Security Rule
Policy 50.012 Definition of EPI

Section 50: Management of Information

EFFECTIVE DATE: 05/15/08

50.011 Email Policy

ORIGINAL ISSUE DATE:	REVISED DATES:
03/98	06/03, 03/04; 05/05, 01/07, 05/08, 12/08

APPROVAL:

DIRECTOR DATE 12/08

Section 600: Daily Work Practices

600.000: Attendance and Tardiness

Purpose

St. Jude Children's Research Hospital (SJCRH) values the contributions of its employees and expects that they will report to work on time and as scheduled. Because employees are vital to the operations of St. Jude, adherence to the work schedule is a condition of employment. Unscheduled absences, late arrivals, and early departures must be kept to a minimum.

Policy

1. Work schedules are established by the management of each department. Planned absences must be approved by your supervisor twenty-four (24) hours in advance.
2. *Reporting procedures.* Employees are expected to be ready to work at their work station at their scheduled start time. SJCRH recognizes that an occasional unscheduled absence or tardiness may occur. If an unplanned absence or tardiness is unavoidable, the employee must notify his or her immediate supervisor or designee as specified by department management. A call from a spouse, friend, or relative on the employee's behalf is unacceptable unless the employee is physically unable to call. A message left with a non-supervisory employee is not sufficient. The reason for the absence and the anticipated date and time of return must be reported to the immediate supervisor.
3. *Scheduling Absences.* Scheduled absences must be approved in advance by the immediate supervisor. The immediate supervisor has the right to request that employee's plan partial-day absences first thing in the morning or late in the afternoon, as so not to disrupt the work flow. The supervisor also has the right to request the employee to take the entire day off for scheduled or unscheduled absences.
4. *Pattern of absenteeism, tardiness, or both.* An employee may be subject to accelerated progressive discipline if a pattern of absenteeism or tardiness is identified. A pattern may be shown where an employee incurs frequent absences on a Monday, Friday, before or after holidays or paydays. An employee receiving more than one (1) written warning, final written warning or suspension within a rolling twenty-four (24) month period may be subject to immediate suspension or termination.
5. *Failure to clock in or out.* Non-exempt (hourly) employees are required to clock in upon reporting to work, and out at the end of the shift or when leaving the campus for non-work related reasons. A pattern of failure to clock in or out, or falsification of time records may result in disciplinary action up to and including termination of employment.
6. Absences due to an *approved* Family Medical Leave (FMLA) do not count as occurrences. (See definition of exceptions).
7. *Three days "no call, no show."* Three (3) consecutive days of absence without authorization or notification to department management may result in termination of employment and can be considered job abandonment.
8. *Reporting illnesses.* Many St. Jude patients are immunosuppressed, and infections that develop in these patients may be very serious and difficult to treat. Therefore, employees must report any illness that is or may be infectious in nature, to their supervisors and the Occupational Health Nurse. The nursing coordinator will take such reports in lieu of the Occupational Health Nurse after normal working hours, on weekends, or on holidays. If an absence is due to an infectious illness, written notification from a physician must be given to the Occupational Health Nurse for each day of the absence beginning day one. The physician's statement must indicate diagnosis, the period of illness, the date authorized to return to work, and any temporary or permanent restrictions related to work. If an employee is sent home due to a possible infectious illness, the attendance policy will apply.
9. *Absences that exceed three (3) consecutive workdays.* If an absence caused by illness or injury exceeds three (3) consecutive workdays, the employee must, before reporting to the work place, provide the Occupational Health Nurse with a physician's statement indicating diagnosis,

the period of illness, the date authorized to return to work, and any temporary or permanent restrictions related to work. The Occupational Health Nurse will issue a return to work authorization form that the employee must present to his or her immediate supervisor. Second- and third-shift employees are required to obtain a return to work slip during the normal workday before reporting to work. SJCRH has the right to require employees with poor attendance records to provide a physician's certificate justifying absences resulting from illness or injury.

10. *Occurrences of absenteeism or tardiness.* Occurrences of absenteeism or tardiness will be documented on a twelve (12)-month rolling basis as follows:

8th occurrence	Documented Counseling
9th occurrence	Documented Verbal Warning
10th occurrence	Written Warning
11th occurrence	Final Written Warning or Suspension*
12th occurrence	Termination of Employment

* Bargaining unit employees must receive a suspension on the 11th occurrence per the bargaining union contract.

11. *Consecutive days of absence.* Consecutive days of absence are considered one (1) occurrence unless the reason for each day of absence is different, or if the employee fails to notify the immediate supervisor of the absence.
12. *Failure to Return to Work*. Failure to return to work after being released by a physician will be considered job abandonment and may result in disciplinary action up to and including termination of employment.
13. *Leave of Absence.* Employees requiring an absence of more than two (2) weeks must apply for applicable leave of absence. It is the supervisor's responsibility to notify Human Resources if or when an employee is absent for more than two (2) weeks or ten (10) consecutive work days. (See Policies 400.000: FMLA, 400.010: Personal Leave). This does not apply to vacation time that has been scheduled and approved by a supervisor or manager.

Definitions

1. *Occurrence of tardiness.* The failure of an employee to be at the workstation and ready to work at the assigned time regardless of the reason.
2. *Occurrence of absenteeism.* The failure of an employee to report to work or to work the entire shift, as scheduled regardless of the reason. Consecutive days of absence for the same reason are considered one (1) occurrence, unless the employee fails to notify the immediate supervisor of the absence.
3. *Exceptions*. The following occurrences of absenteeism are considered to be outside the scope of this policy and will not result in discipline: holidays, planned vacation, jury duty*, worker's compensation leave*, military duty*, approved leaves of absence*, bereavement leave*, and family and medical leave*.

∗ Certification/proof required.

Section 600: Daily Work Practices

600.000: Attendance and Tardiness

Signature on file in Human Resources
DIRECTOR

_____
DATE

600.010 Professional Conduct On and Off St. Jude Campus

Purpose

St. Jude Children's Research Hospital (St. Jude) has developed guidelines designed to promote a safe and productive work environment for our employees, our patients, and their families. Violation of these guidelines and other similar misconduct will result in corrective disciplinary action.

Policy

1. All St. Jude employees, vendors, contractors and other individuals on campus for work-related reasons are expected to act in a respectful and professional manner in order to provide a positive and productive work environment for all employees, patients and families.
2. Misconduct or violations of St. Jude guidelines, policies and procedures by employees will result in corrective disciplinary action up to and including termination of employment.
3. The following list includes examples of reasons for disciplinary action. **St. Jude** reserve**s** the right to deal with individual circumstances and determine when the disciplinary process should begin. This is not intended to be an exhaustive list, and employees may be subject to discipline for reasons not set forth in this list.
    a. Unsatisfactory behavior or work performance
    b. Leaving work area or St. Jude premises during work time without authorization and/or failure to clock out
    c. Excessive or a pattern of tardiness or absenteeism
    d. Excessive adjustments to timesheets for failure to clock in and out
    e. Sharing of computer security password or breach of computer security through unauthorized access
    f. Unauthorized use of the name, property, or records of St. Jude
    g. Failure to comply, support and enforce all policies of St. Jude, including campus traffic control and parking policies
    h. Malicious mischief
    i. Failure to disclose a conflict of interest or failure to eliminate a conflict of interest when so directed
    j. Gambling on premises
    k. Inappropriate or unauthorized use of St. Jude letterhead
    l. Inappropriate use of St. Jude Internet, e-mail, mobile devices, electronic files, or equipment that is the property of St. Jude
    m. Violation of the harassment policy
    n. Violation of the Solicitation, Internet & E-Mail policies
    o. Smoking in unauthorized areas
    p. Unproductive use of work time
    q. Working unauthorized overtime
    r. Unauthorized family or friends in the work area
    s. Failure to submit to a drug or alcohol test requested by Human Resources or their designee

4. Conduct outside the workplace, which brings discredit to St. Jude may give rise to disciplinary action. In arriving at a decision for proper action, the following may be considered: seriousness of the violation, past record of the employee and the circumstances

surrounding the matter.

5. Some violations are so severe in nature and gravity that they may be cause for immediate termination of employment. The following list includes examples of reasons for immediate discharge. St. Jude reserves the right to deal with individual circumstances and determine the appropriate corrective action or level in the disciplinary process on a case-by-case basis. This is not intended to be an exhaustive list, and employees may be subject to immediate termination of employment for reasons not set forth in the list below.Failure to successfully complete the introductory period.

a. Failure to successfully complete the introductory period
b. Gross neglect of duties, including failure to provide patient care, patient abandonment, or job abandonment
c. Unauthorized sleeping on the job during work hours
d. Unauthorized possession or use of drugs or alcohol on St. Jude time or premises, or reporting for work under the influence of alcohol, prescription drugs, narcotics, or illegal drugs
e. Illegal possession, sale, distribution, or consumption of drugs or intoxicants
f. Receipt of three (3) written warnings, suspensions, or both during a 12-month period, regardless of the reason(s)
g. Divulging or releasing confidential or unauthorized official information
h. Falsification of records, including employment-related applications, time and attendance records, health records and forms, credentials or licensure, research data, and patient records
i. Unauthorized possession of firearms or weapons of any kind on St. Jude premises or at St. Jude-sponsored events
j. Insubordination or refusal to follow work instructions
k. Damaging, defacing, mishandling or unauthorized use or removal of St. Jude property;
l. Failure to cooperate or comply with a request in an investigation, including security investigations
m. Fighting, verbal or physical threats or threatening statements, gestures or physical contact;
n. Violation of safety and security regulations
o. Abusive, inappropriate, discourteous language or behavior toward a patient, parent, supervisor, coworker, vendor, visitor, or other person having business with St. Jude including the use of profanity and other harassing statements
p. Use of any device that records, transmits or captures vocal or images without a person's knowledge or permission
q. Three consecutive days of absence without authorization or notification
r. Conviction of a felony or failure to disclose a felony or any charge that involves minor children; prescription drugs, narcotics, or illegal drugs
s. Failure to return to work after the expiration of an approved leave or release from physician
t. Conduct that brings discredit to St. Jude
u. Theft or attempted theft from St. Jude , a coworker, a patient, parent or other persons having business with St. Jude
v. Misappropriation of funds
w. , Expiration of required licensure, certification, registration or work authorization
x. Diversion of Drugs

y. Lack of grant funding
z. Unlawful retaliation
aa. Failure to comply with the Privacy or Security policies or procedures or with the HIPAA Privacy Rule and/or the HIPAA Security Rule, as amended

Procedure

See Policy 600.020: Disciplinary Process.

Definitions

References

ORIGINAL ISSUE DATE: 01/88	REVISED/REVIEWED DATES: 07/89, 11/91, 01/94, 08/97, 08/00, 09/03, 01/04, 4/11, 07/14, 01/15
APPROVAL: Signature on file Senior Vice President and Chief Support Operations Officer	Date

Section 600: Daily Work Practices

600.200 Parking and Traffic Control on Campus

Purpose

St. Jude Children's Research Hospital has established policies and procedures for the issuance and use of parking hang tags; identifying authorized parking spaces; and controlling the movement of vehicles on campus to ensure the safety of drivers and pedestrians.

Policy

1. Parking hangtags and temporary parking permits are required for entering and parking on the St. Jude campus.
   a. Hangtags are issued by Security.
   b. Hangtags must be affixed to the rear view mirror and must be clearly visible and readable.
   c. Lost or stolen hang tags or temporary permits must be reported to Security immediately.
   d. Vehicles may park in areas designated for their parking category only.
2. All vehicles without a parking hangtag must obtain a temporary permit to enter the campus.
   a. To receive a temporary parking permit, the driver must provide a valid driver's license or other approved form of identification, the purpose of the visit and the name of the person to be visited.
   b. Temporary permits must be prominently displayed on the driver's side dashboard.
3. Talking or texting on cellular phones and other wireless communication devices while operating a vehicle on campus is strictly prohibited.
4. Drivers are required to comply with all parking regulations.
   a. Reserved spaces may be used by the designated individuals only.
   b. Vehicles may park only in areas lined as parking spaces.
   c. Parking along curbs, unless clearly marked as a parking space, is strictly prohibited.
   d. No vehicles are allowed on grass, lawns or fields without authorization.
   e. Drivers must comply with all traffic control devices such as stop, yield and speed limit signs.
5. Any vehicle parked on campus for a period of 72 hours or more without prior approval from Security is considered abandoned and may be towed at the owner's expense.
6. Handicap parking permits may be obtained from your local County Clerk's office.
   a. Cars not displaying an official permit may be towed at the driver's expense or may be issued a citation by Security or the Memphis Police Department.
   b. Handicap parking permits are intended for use by the handicapped driver or passenger only.
   c. Employees with short-term disability needs may obtain temporary handicap parking by submitting a request to Occupational Health.
      i. The request must be accompanied by documentation from the employee's physician explaining the reason for the request.
      ii. Short-term disability parking will be approved for a maximum of 30 calendar days.

   Please note that permits granted by this institution are solely for the purposes of meeting the needs of the employee but do not, however, meet the guidelines for the Shelby County, Tennessee, Code of Ordinances, which require a county-issued temporary disability placard. It is also important to note that St. Jude will not be responsible for any personal outcome in the event that Law Enforcement Officials enforce the Shelby County, Tennessee, Code of Ordinance by issuing citations. Official placards may be obtained from the Shelby County Clerk's Office.
7. Motorcycles, bicycles, utility, and golf carts may be driven only on the streets and driveways of the campus and are prohibited from sidewalks, lawns and from the inside of buildings. Such vehicles must abide by all traffic regulations. Bicycles left on campus for more than 30 days are considered abandoned and may be disposed of by Security.

8. Drivers are required to yield to pedestrians in the crosswalk. Pedestrians are expected to take appropriate precautions before entering crosswalks.
9. St. Jude security personnel are authorized to enforce compliance with all parking procedures and traffic control regulations. Employees and visitors must comply with all appropriate directions issued by security personnel.
10. Any employee in violation of the parking procedures and or traffic control regulations is subject to disciplinary action up to and including termination of employment.

Procedures:

1. Issuance of hang tags and temporary permits:
   a. A *Hang Tag Application Form* must be submitted to Security in order to receive a hang tag. Forms are available on the St. Jude Intranet and at the Security Control Room.
   b. Employees, contract management, volunteers, and consulting physicians will receive a color-coded plastic hang tag with no expiration date.
   c. Individuals not on payroll will receive a paper color-coded hang tag that expires annually.
   d. Patients / parents will be a issued paper, color coded hang tag with an expiration date by the security officer assigned to the PCC Lobby.
   e. All other campus visitors will be issued temporary parking permits by the security officers at the entrance gates to the campus.
2. Enforcement and Reporting
   a. Enforcement activities will include routine patrol and observation of campus roadways and parking areas. Security personnel may set up checkpoints on campus to assess and enforce compliance with parking and traffic control policies,
   b. Security personnel or the Memphis Police Department may issue a citation, immobilize a vehicle or tow a vehicle.
   c. Documentation of violations will be forwarded to the employee's supervisor and a member of Employee Relations in Human Resources for appropriate action.
   d. Employees observing parking or traffic control violations should contact the Security Department. Security personnel are responsible for investigating complaints received.

Reference:

1. Policy 10.118, Institutional Wireless Technologies Equipment and Service
2. Electromagnetic Interference Policy – General Safety Manual
3. HR policy 600-010, Rules of Conduct

ORIGINAL ISSUE DATE:	REVISED DATES:
01/88	11/91, 12/94, 08/95, 08/00, 05/01, 09/04, 01/05, 09/09, 7/13

APPROVAL:

Signature on file in Human Resources
DIRECTOR and CEO

DATE

Section 600: Daily Work Practices

600.300 Celebrity Visits: Guidelines for Employees

Purpose

The purpose of this policy is to ensure that visits to St. Jude Children's Research Hospital by celebrities and public figures are managed with professionalism consistent with St. Jude standards and with respect for the time and privacy of both visitors and patients.

Background

St. Jude is fortunate to have the support of many well–known national figures from the fields of entertainment, sports and politics, who choose to visit St. Jude when their schedules allow. Our guests come to visit with our patients and their parents/families, and to learn about the lifesaving work of St. Jude. Because they are here for a limited amount of time, employees are expected to comply with the following guidelines.

Policy

1. Employees are expected to remain respectful and appreciative of celebrity visitors, but also unobtrusive as our guests proceed along their structured tours.

2. Filming, photographing or audiotaping visiting celebrities by employees on St. Jude property is prohibited; this includes cell phone photos and video.

3. Employees should not approach celebrities for autographs or make other personal requests of our guests.

4. Employees are expected to continue their regular work and to remain in their work areas during celebrity visits.

5. Failure to comply with this policy may result in disciplinary action up to and including termination of employment.

ORIGINAL ISSUE DATE:	REVISED DATES:
3/08	8/12

APPROVAL:

_____ _____

DIRECTOR and CEO DATE

Fair Labor Standards Act (FLSA)

Purpose

- Discuss St. Jude's policies and procedures related to FLSA guidelines.
- Discuss timekeeping policy changes for 2010.
- **Note:** The content of this presentation only applies to non-exempt (hourly) employees.

What is FLSA?

- Governed by the Department of Labor Wage and Hour Division.
- Primarily focuses on minimum wage, overtime, record keeping and exemption compliance.
- Salaried employees, with certain duties, are exempt from overtime regulations and record keeping provisions.

Areas of Focus

- Defining work time
  - Working from home
    - Checking emails
    - Phone calls
  - Working off the clock
- Lunch and break periods
  - 30 minute auto-deduct lunch system
  - Call back from lunch
- Confirming/reporting accurate time records

Defining Work Time

- The term "work" is very broad and generally includes all time that you are either:
  - Required to be on duty
  - Required to be at the workplace
  - Required to be at a certain location
  - Allowed or permitted to work
- Work can occur even when a manager has not asked you to work.
- Working at home, on vacation, or away from the worksite may be considered work time.

Defining Work Time

- Off the clock work would occur if you perform work but do not report the time on your time sheet even if overtime occurs.
  - i.e. Finishing up a project after you have already punched out for the day.
  - i.e. Checking emails, opening mail, etc. prior to clocking in before your scheduled shift
- You are **strictly prohibited** from working off the clock whether it be voluntary (your choice) or involuntary (manager choice).

Defining Work Time

Working from Home…

- It is understood that there may *occasional* times when you need to check e-mail or answer a work phone call outside of regularly scheduled work hours.
- The time spent doing this should be minimal, if it becomes frequent or lengthy, then you should be compensated for this time as time worked.
- Such work should be approved in advance by your supervisor.

Lunch and Break Periods

- St. Jude provides breaks for the health and well-being of its employees.
- According to St. Jude policy, employees who are scheduled to work longer than 5 hours are required to take an *uninterrupted* 30 minute meal break.
- You may not work through your lunch break unless authorized to do so - such events should rarely occur. If this happens, you should identify "no lunch" on the time system on the final out punch of the day. This will ensure you are paid for the lunch break.
- If you are called back from lunch early and your lunch break has lasted less than 20 minutes, the 20 minutes will be compensated as time worked. In such case, the "No Lunch" code will need to be entered on the last out punch of the day to override the 30 minute auto deduction.
- If you leave campus for lunch, you must clock out using the automated time keeping system and clock in upon return to campus.

Confirming Time Records

- You should proactively confirm your time record prior to the end of each bi-weekly pay period.
- If you notice a discrepancy on your time report, contact your manager and request the change to your time record (in writing).
- Changes should be made in the current pay period for the time in which you are reporting.

NOTE: Policy Change for 2010

- As of January 1, 2010 - Vacation and Sick time will be available for use in increments of less than one hour for non – exempt employees.

- Personal days will still need to be used in one day increments.

QUESTIONS?

- If you have a specific question, please contact your direct supervisor after this presentation.

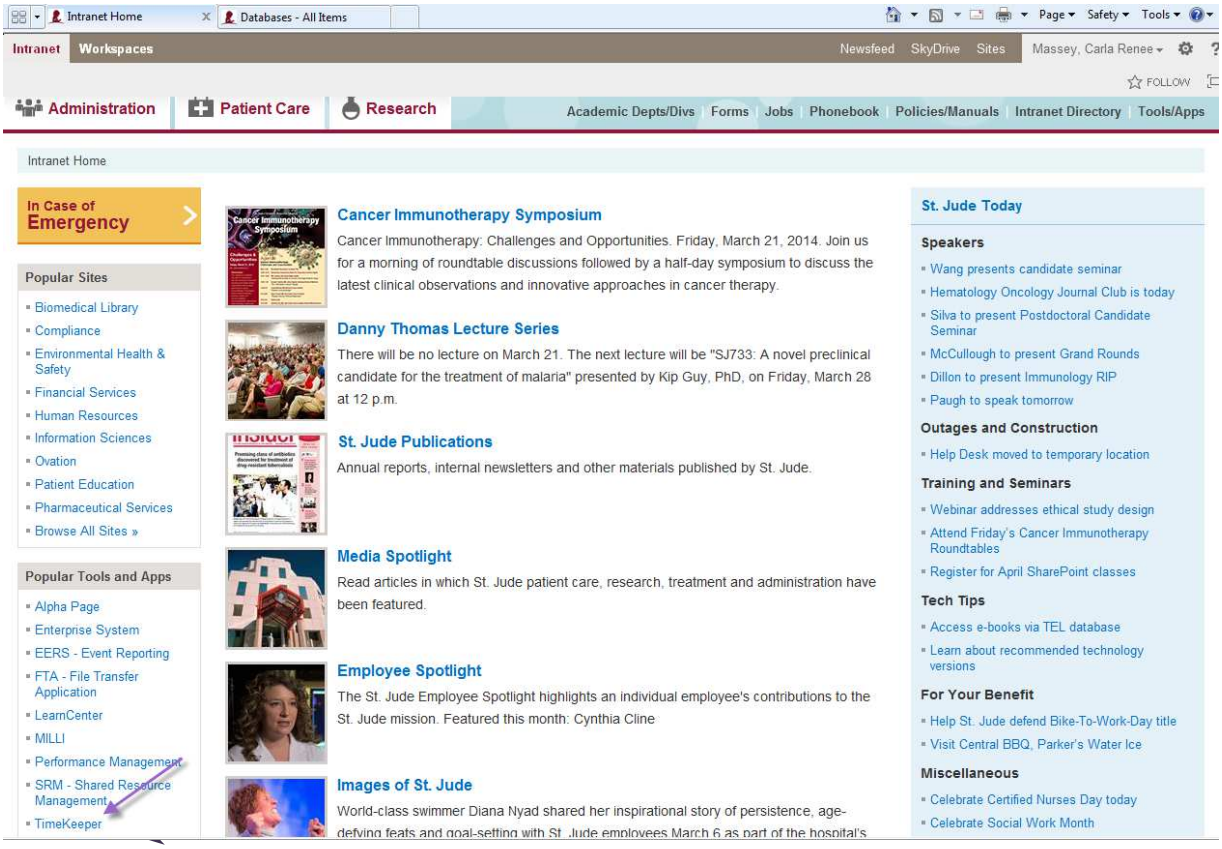
- St. Jude policies and procedures related to timekeeping can be located on the Human Resources homepage on the St. Jude Intranet.

The St. Jude Intranet

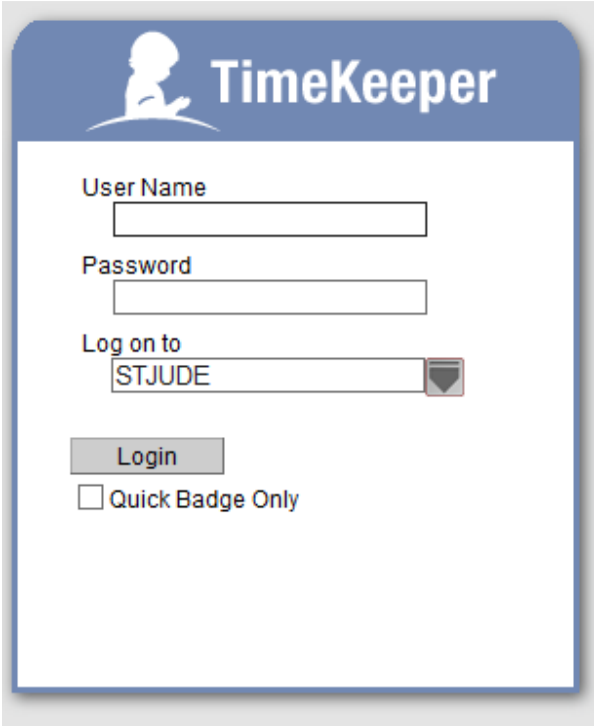
The St. Jude intranet is your source for multiple valuable internal tools, applications, and websites. A few of these will be discussed, below, but feel free to browse the site to explore what is available. The web address is below and is the default homepage for all computers at St. Jude. Thus, when you open Internet Explorer, this is the page you will be directed to. (NOTE: Do not set your homepage to a different website. Your homepage should always be the St. Jude intranet page.)

The TimeKeeper time-clocking system, LearnCenter, and Enterprise System will be discussed below.

The Time Clock:

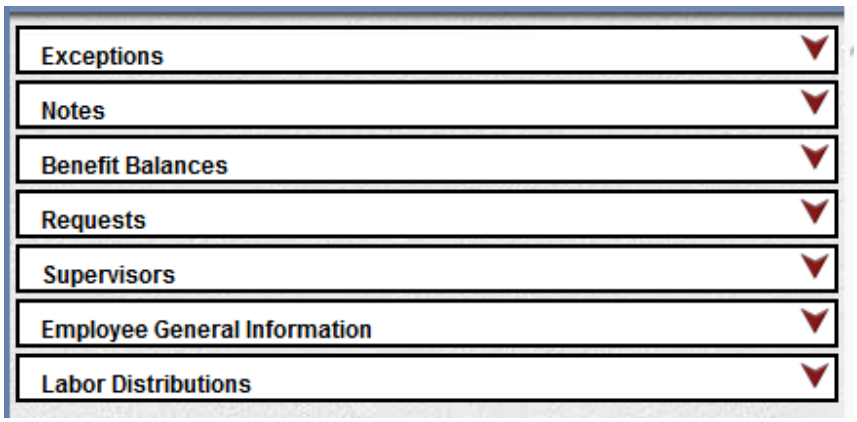


In addition to clocking in and out downstairs in the lobby, you can also use TimeKeeper to clock in and out at your desk. TimeKeeper also allows you to keep track of your benefits and pay period reports. Your User Name and Password are identical to the ones used to access the St. Jude network.

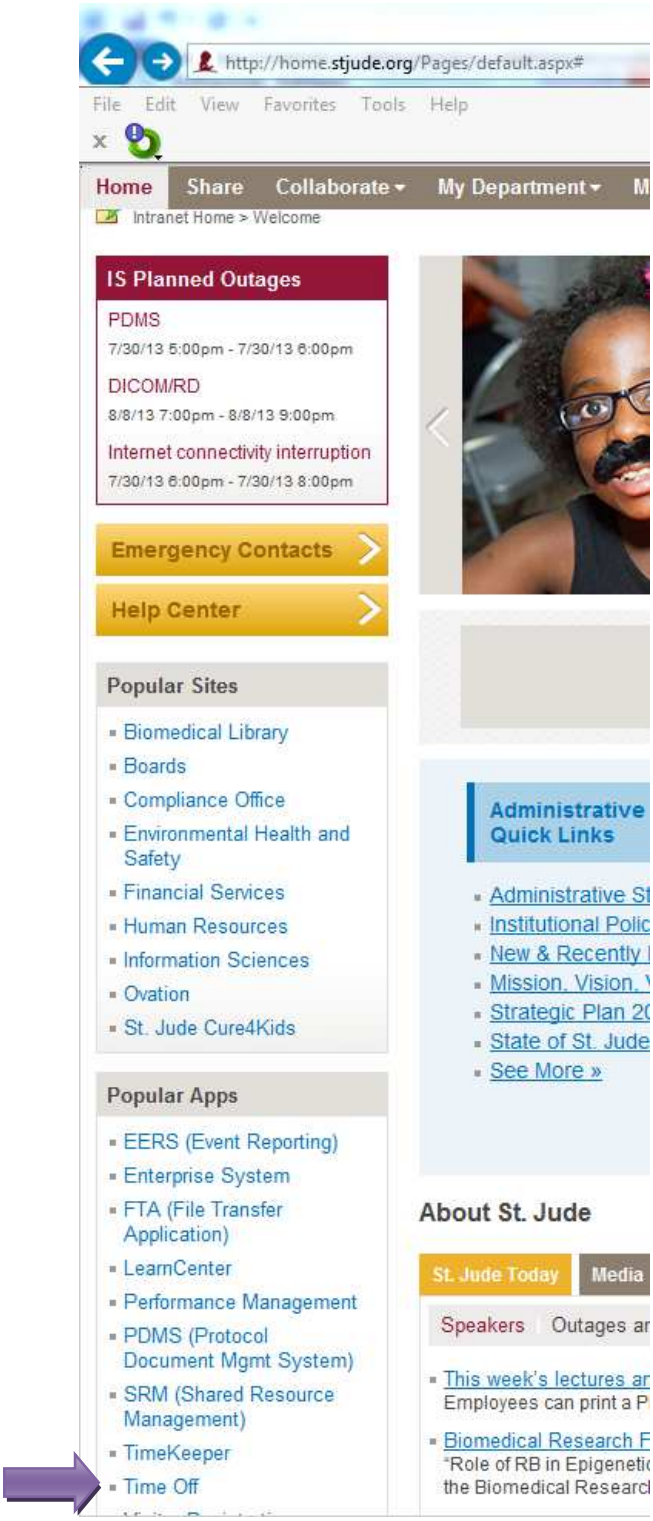


Keep in mind that if you work more than 5 hours, the timekeeping system will automatically deduct 30 minutes for lunch. You are required to take a lunch when working an 8-hour shift unless you have received approval from the Call Center Coordinator. If you are approved to work through lunch, ensure you specify "no lunch" in your clock times. If you leave the St. Jude campus during your lunch period, you are required to clock out and back in for lunch rather than allowing the timekeeping system to do the automatic 30-minute deduction. Use the "no lunch" feature in this case as well. Please obtain approval from the Call Center Coordinator for these circumstances.

TimeKeeper also provides the following options after logging in:

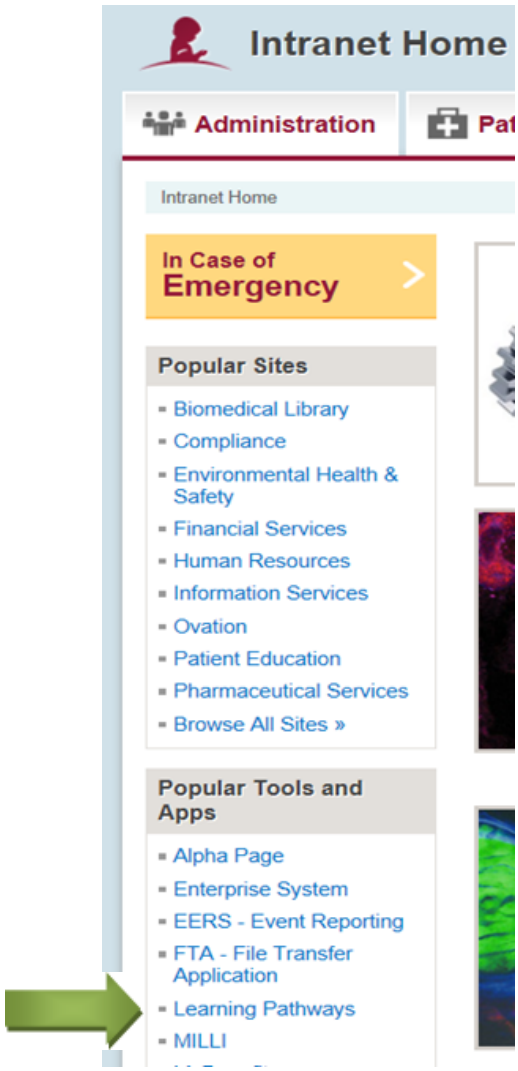


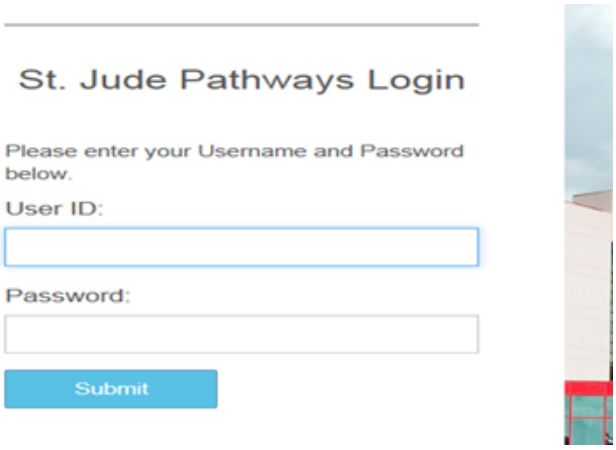
When requesting time off, please enter your request into the TimeOff system. TimeOff will automatically import any approved time off into TimeKeeper for you. See the section of this binder titled *TimeOff for Employees* for further information.



The Learn Center:

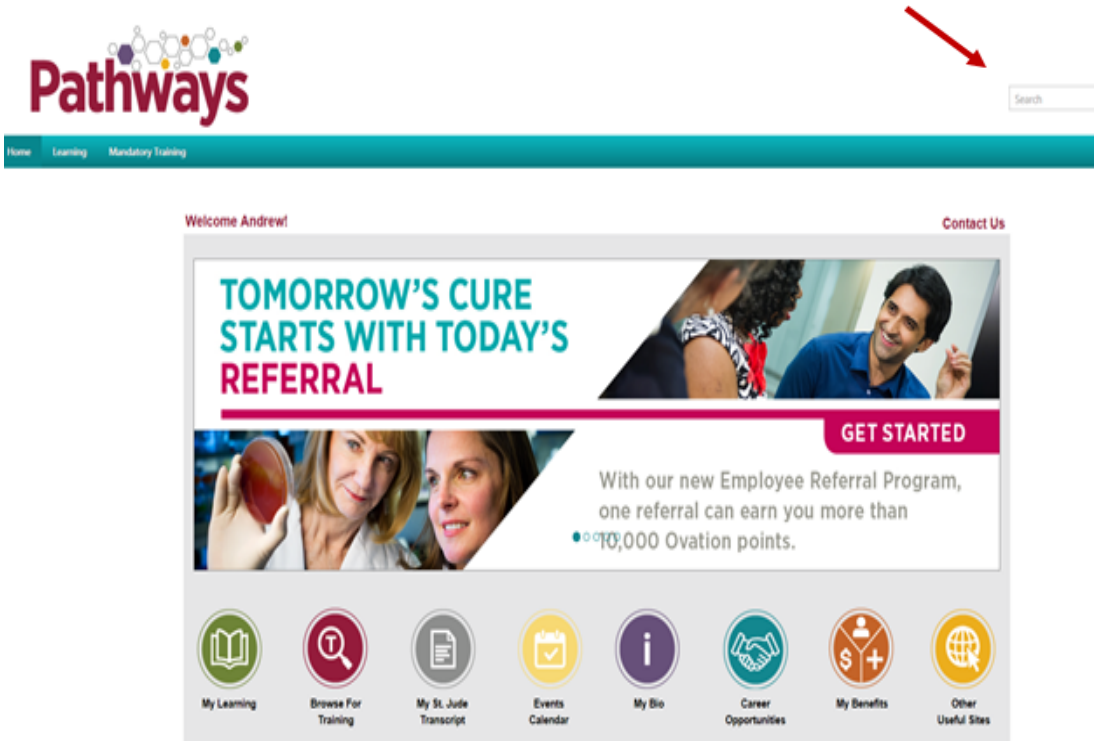
Most required training, such as the Telephone Doctor and End-of-Year Annual Mandatory Training classes, is found here. This site also hosts classes to help you improve skills in a variety of areas. All new interviewers are required to take *Getting Started With Access 2010*. Any other courses that you would like to take need to be approved by the Call Center Coordinator.





STEP 1. ENTER YOUR USERNAME (same as St. Jude network username)
STEP 2. PASSWORD (same as St. Jude network password)

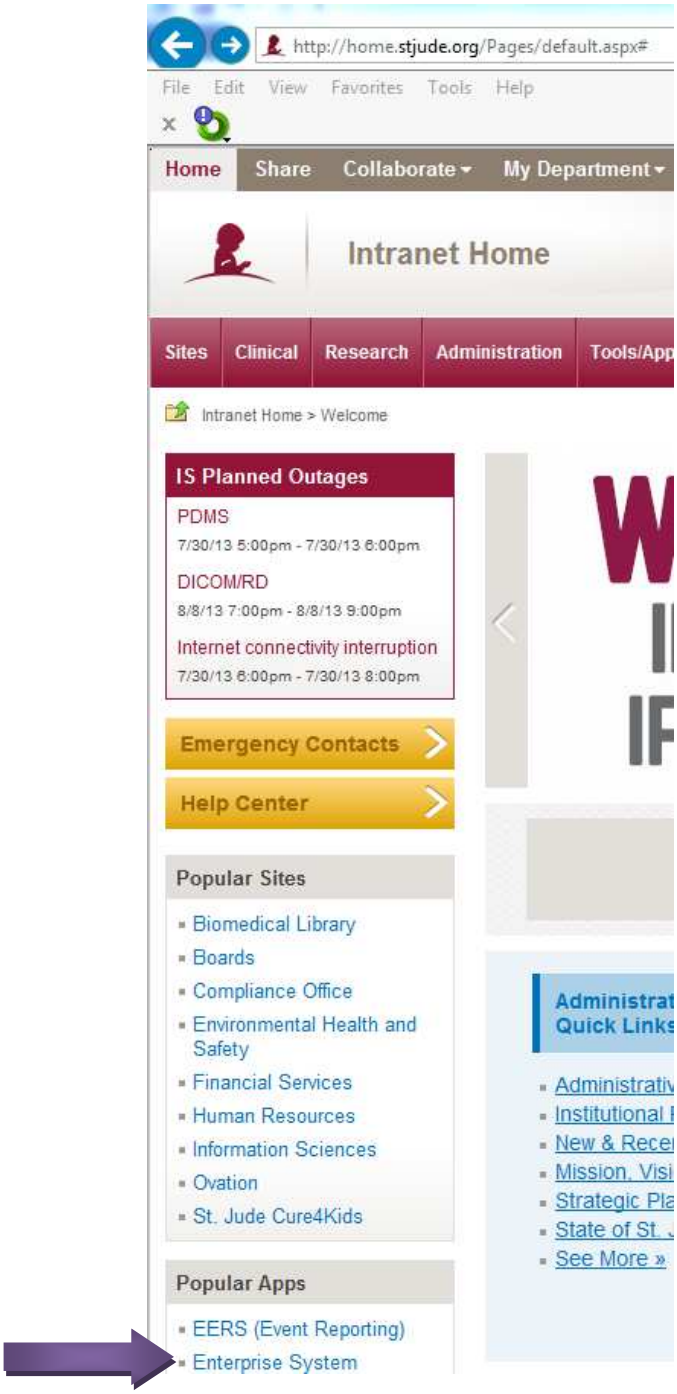
Upon logging into the LearnCenter, the following displays:



Use the Search feature to locate the class you need.

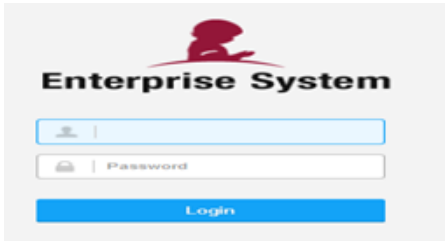
The Enterprise System

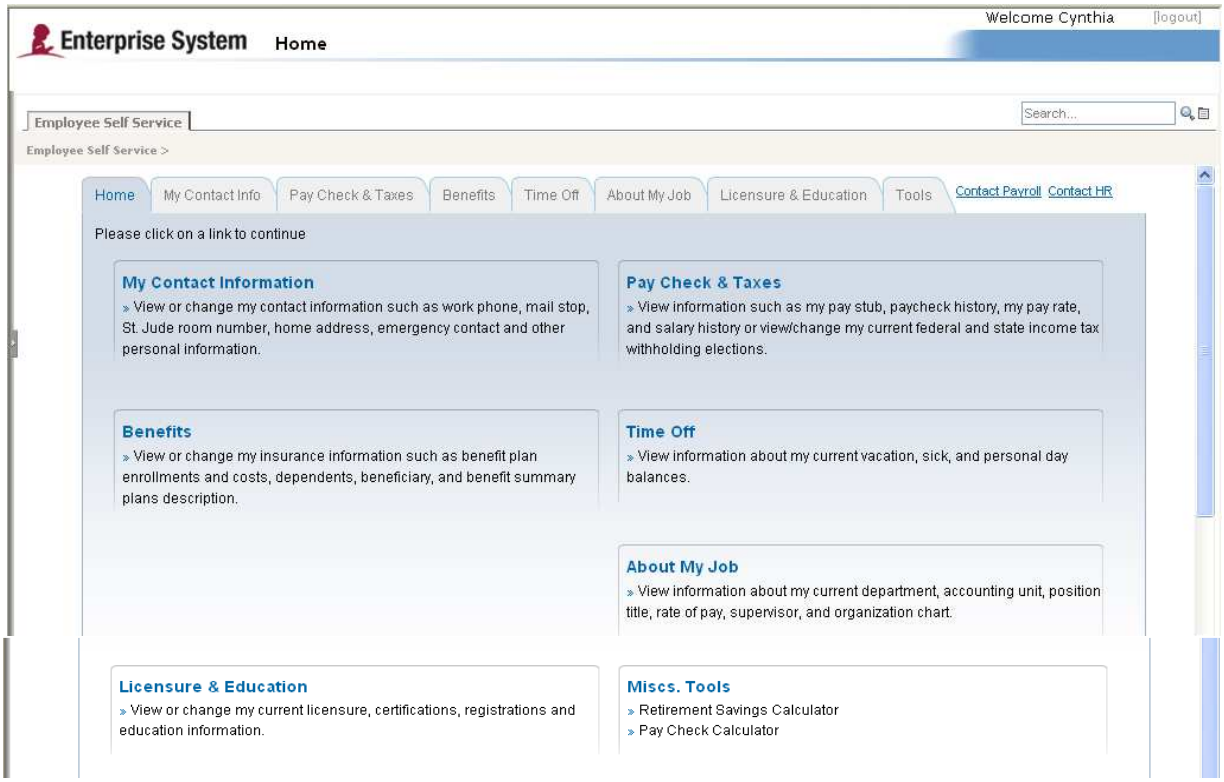
The Enterprise System is another network place that allows you to look up your available vacation and sick time balances as well as view and print previous and current pay stubs. You can also edit your contact information, tax withholdings, and more.



Your Enterprise System username and password are the same as your St. Jude Network username and password.

Upon logging in, the following options are displayed:





Feel free to browse the Enterprise System to learn what is available to you.

This document highlights only a few of the tools available to you on the St. Jude intranet page. Please see the Call Center Coordinator or a Lead Survey Interviewer for questions or concerns. Welcome aboard!

TimeOff *for* Employees

SIMPLIFYING THE TIME OFF REQUEST PROCESS

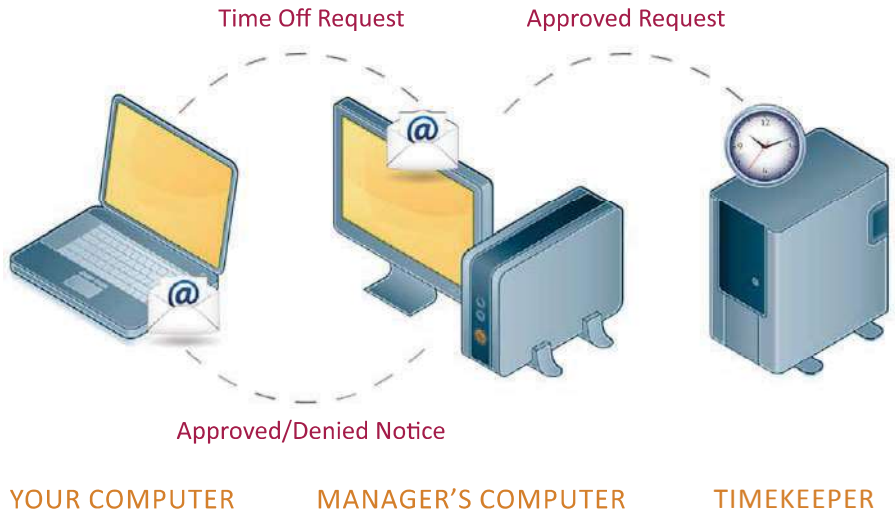
WHAT IS THE TIMEOFF APPLICATION?

TimeOff is a web-based application that simplifies the time off request process. It assists you and your manager in submitting, approving, tracking, and reporting time off requests.

HOW DOES IT WORK?

After submitting a time off request, your manager receives an email notification alerting them of your request. Your manager will access the TimeOff application to approve or deny the request. You then receive an email notification alerting you of your manager's response. The TimeOff application will automatically send approved time off requests to TimeKeeper. See Diagram 1 below.

DIAGRAM 1: TIMEOFF REQUEST PROCESS



WHAT ELSE CAN I DO WITH TIMEOFF?

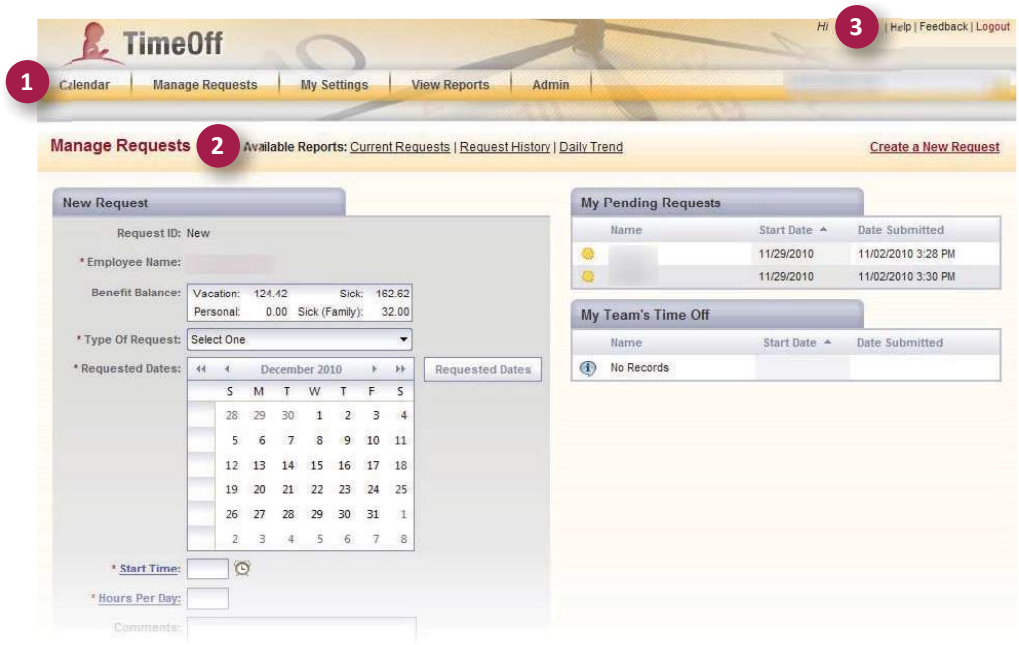
In addition to simplifying the time off request process, the TimeOff application tracks your requests. Having your requests tracked, allows you to modify pending or upcoming requests, view archived requests, view when your co-workers plan to be off, and generate time off event reports.

ACCESSING TIMEOFF

To access the time off application, visit http://app1.web.stjude.org/timeoff or click the TimeOff link in the Popular Apps list at the bottom-left of the St. Jude Intranet home page. If desired, bookmark the link or add it as a favorite site.

Information Services
St. Jude Children's Research Hospital

NAVIGATING TIMEOFF

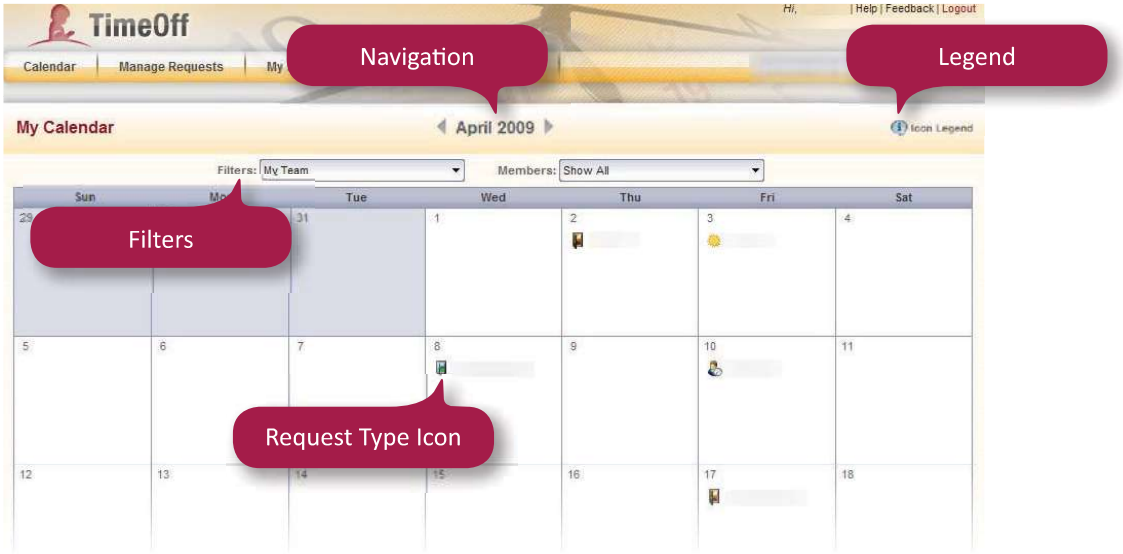


1	Calendar	Click the Calendar link to access My Calendar.
	Manage Requests	Click the Manage Requests link to open the New Request form. Use this form to submit time off requests to your supervisor.
	My Settings	Click the My Settings link to adjust your TimeOff application preferences.
	View Reports	Hover over this link to view and select a report.
2	Available Reports	Lists the reports available within the application. Click the report type to run that report.
3	Help	Click the Help link to access the help/training materials for using the TimeOff application.
	Feedback	The Feedback link opens a new email addressed to the TimeOff Administrator. Use this link to provide comments, etc.
	Logout	When you are done using the application, click the Logout link. This logs you off of the TimeOff application preventing others from coming behind you and accessing the application using your account.

USING THE CALENDAR

Use My Calendar *(Figure 1)* to view your personal time off requests as well as your co-workers' requests in a monthly view. The purpose of the Calendar is to provide you, your manager, and your co-workers with an overall view of who is out and when. Having this information available helps to better manage project deadlines and ensure daily work responsibilities are met.

FIGURE 1: MY CALENDAR



Filters

By default, the Calendar displays the current month along with your team's requests. However, you can change whose requests you see by filtering the calendar view. Use the Filters drop-down menu to view time off requested by your teammates, entire department or a group of selected departmental co-workers included in a custom filter *(see Using My Settings for more information about creating custom filters)*. Narrow your filter using the Members drop-down menu.

Color Coding and Indicators

When viewing the calendar, you will see to the left of each name an icon that indicates the time off event type. You will see specific icons representing the type of event for yourself and a generic out of office icon for vacation, sick and various other leave requests for others on your calendar view. For a description of each icon, hover your mouse over the Legend icon located at the top right of the calendar. The calendar also indicates pay days, St. Jude Holidays, current date, and prior or upcoming month. Pay days and St. Jude Holidays appear on the date they occur. Yellow shading indicates the current date. Grey shading indicates the prior or upcoming month.

Quick Comment View

You may quickly view your personal comments entered for a request by hovering your mouse over the request type icon. Only you and your immediate manager can view these comments.

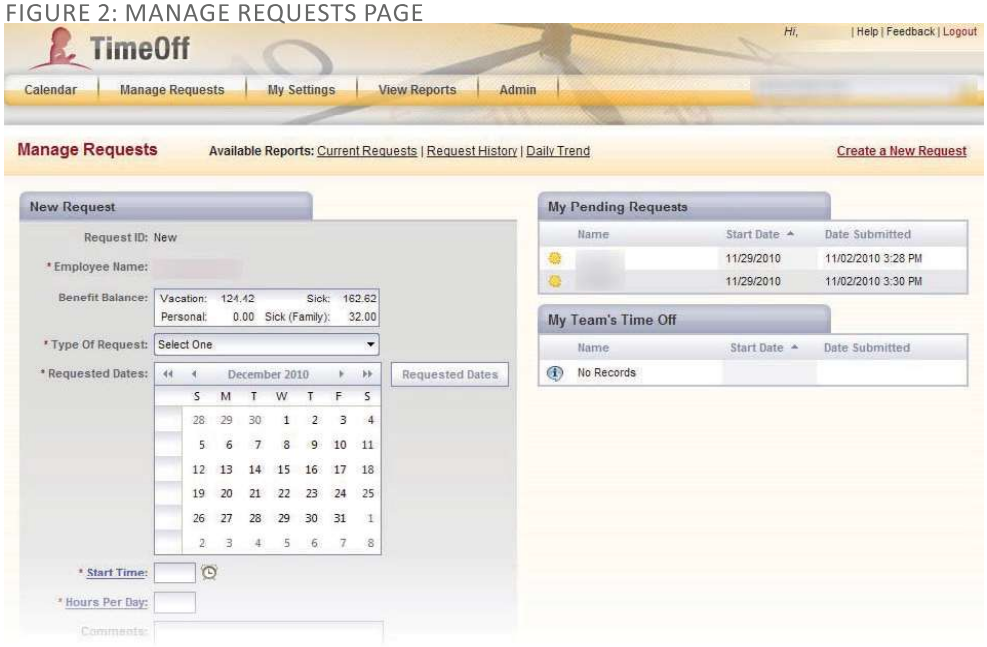
Month/Year Navigation

At any time, you can navigate to another month and/or year. Click the forward and back arrows to move to the next or previous month. Click the month or year text to select a different month and/or year to view.

SUBMITTING A REQUEST

Submitting a request is as easy as accessing the TimeOff Manage Requests page, filling in the required fields, and clicking the Submit button. As you submit a request, reference your available Benefit Balance, My Pending requests, and the My Team's Time Off list. All of which are provided to you in a two column layout *(Figure 2)*.

FIGURE 2: MANAGE REQUESTS PAGE



New Request Form and Benefit Balance

Use the New Request Form to enter the details of your time off request. Included at the top of the form is your Benefit Balance for reference.

My Pending Requests and My Team's Time Off

Pending Requests are any requests still waiting on your manager's approval. They remain in the Pending Requests list until your manager approves or declines your request. The My Team's Time Off lists your team members who are off on or during the dates of your request. This list appears to the right of your request after selecting the Type of Request and the Requested Dates. It lists the team members' names, dates off, and time off event type. Click Name, Start Date, or Date Submitted to sort the list by that field.

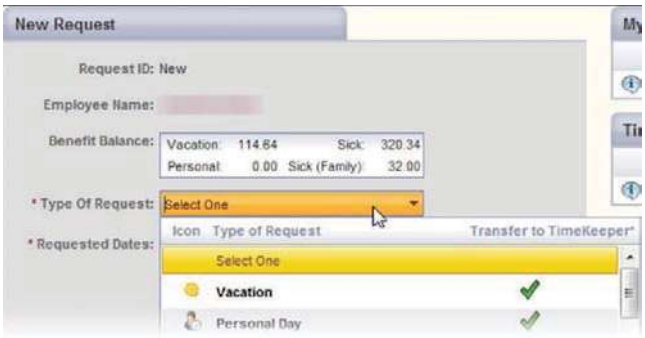
Request Submission Deadline

You have until 11:59 p.m. on the Saturday a pay period closes to submit and/or edit requests.

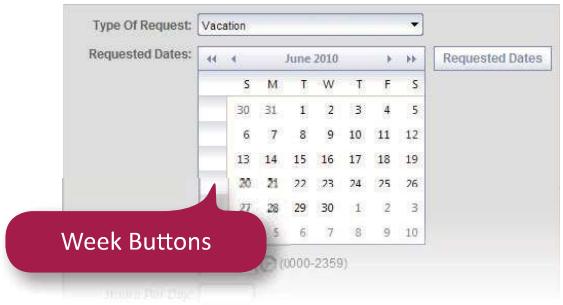
Submitting a Request: Step-by-Step

To submit a request, follow these steps:

1. Access the TimeOff application (http://app1.web.stjude.org/timeoff).
2. The TimeOff application site opens. Click the **Manage Request** link.
3. Complete the **New Request** form as needed.
   a. Select the request type from the **Type of Request** drop-down menu.
   Note: Request types with a checkmark automatically transfer to TimeKeeper. Also, when requesting Sick (Family) or Bereavement the Family Member drop-down menu appears. Select the relationship of the family member for whom you are requesting time off.



   b. Add day(s) to **Requested Dates** list - Click the date(s) to add an individual day or the "Week" button to add all the days for that week. Days crossed out by "X"'s cannot be requested as they occur in a past pay period.
   Note the "date" and "week" buttons are toggle buttons. To remove a date or dates from the Requested Dates list, simply click the appropriate button.



   c. Enter **Start Time** – Click the Clock button to the right of the **Start Time** field.
   Note, when entering an In Late or Leave Early request, the Start Time field adjusts to Arrival Time or Departure Time.

   d. Enter **Hours Per Day** - Enter the number of hours you will be away from work. For example, if you work eight hours per day, enter 8 for any vacation or sick day requests. For leave early or arrive late requests, enter the number of hours you will miss for that work day.

   e. Enter any desired comments about your request in the **Comment** box for your manager to review.

   f. Enter an **In My Absence** message in the provided text box.
   Note: The In My Absence Message is displayed when fellow departmental employees hover over your time off request on the calendar. It provides direction as to whom they should contact, etc. during your absence. By default, this field includes an example. Use this as a guide to create your own message.

   g. If desired, select the **Export To Calendar** checkbox. Select this option if you want to export the details of your request to your Outlook calendar.

4. Click the **Submit** button to submit the request to your manager.
5. A request submitted successfully notice appears. Click the **OK** button.

If you chose to export your time off request to your email calendar, additional options appear allowing you to adjust the calendar event before saving to your calendar.

a. Adjust the event as desired. You may make the following changes:

- **Event Title** - Title displayed for the calendar item.
- **Start Time** - Time the event begins on your calendar.
- **End Time** - Time the event ends on your calendar.

  Note: When requesting time off for a full workday, you will need to adjust the end time or set your Lunch break option in My Settings (see the Using My Settings section of this guide).

- **Show As** - How your time appears to others looking for a time to meet with you, etc.
- **Set Reminder** - Number of minutes or hours prior to the event you wish to receive a pop-up reminder.

b. Then, click the **Save** button.

VIEWING, MODIFYING, OR DELETING CURRENT REQUESTS

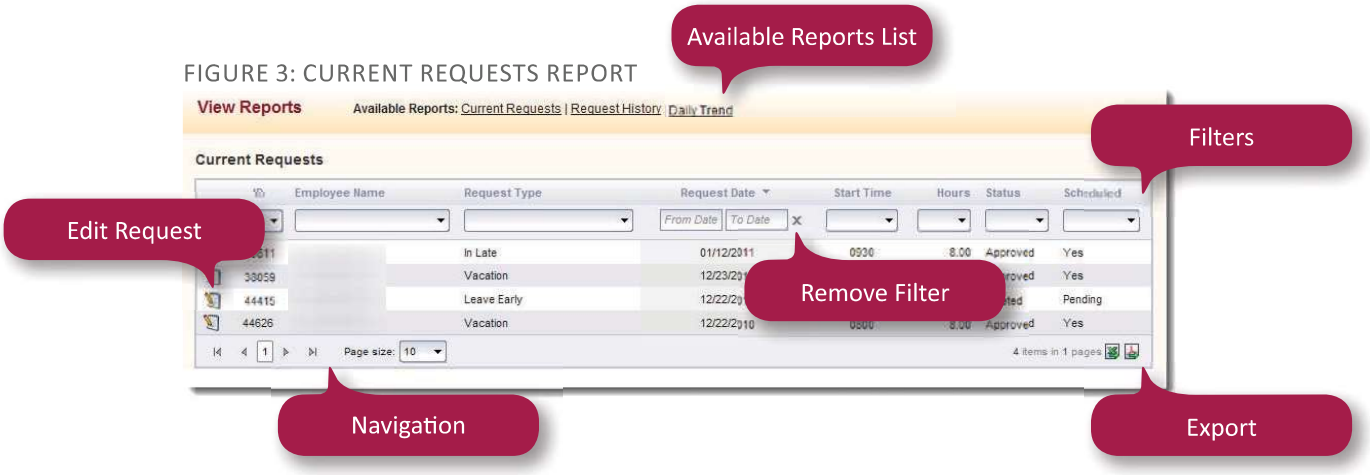
Current requests are any time off occurrences that occur during the current or future pay periods. You can view, modify, or delete these requests by accessing the Current Requests report *(Figure 3)*. When viewing requests, you may filter the report to view the time off occurrences which meet a desired criterion.

Requests may be filtered by:

- Request Type - enter filter criteria to view only sick time occurrences, vacation requests, etc.
- Request Start Date - enter filter criteria to view your previous time off requests based on a fixed time duration.
- Date Submitted - enter filter criteria to view requests submitted during a fixed time duration.
- Days - enter filter criteria to view requests made for a specific number of days.
- Hours - enter filter criteria to view requests made for a specific number of hours.
- Status - enter filter criteria to view requests by status (pending, approved, denied, etc.).
- Scheduled - filter your criteria to view scheduled or unscheduled time off occurrences.

You may also export resulting report as an Excel spreadsheet or PDF file. Current requests can be modified or deleted up until the pay period ends during which it occurs. Once the pay period ends, the request is archived.

FIGURE 3: CURRENT REQUESTS REPORT



Viewing a Request: Step-by-Step

To modify a request, follow these steps:

1. Access the TimeOff application (http://app1.web.stjude.org/timeoff).
2. The TimeOff application site opens. From the **View Reports** sub-menu, choose **Current Requests**.
3. The **Current Request** report appears listing all requests that occur during the current or future pay periods. If desired add one or more filters - The report reloads to display the filtered report.
   Note: To remove a filter, click the "X" to the right of the filter criteria. If you applied more than one filter, you must remove the filter for each criterion.

Modifying a Request: Step-by-Step

To modify a request, follow these steps:

1. Access the TimeOff application (http://app1.web.stjude.org/timeoff).
2. The TimeOff application site opens. From the **View Reports** sub-menu, choose **Current Requests**.
3. The **Current Requests** report appears. Locate the request to edit by navigating or filtering the requests.
4. Click the **Edit** button *(see image below)* to the left of the request.

5. The selected request opens in the **Edit Request Details** form. Edit as needed.
6. Then, click the **Update** button.

Deleting a Request: Step-by-Step

To delete a request, follow these steps:

1. Access the TimeOff application (http://app1.web.stjude.org/timeoff).
2. The TimeOff application site opens. From the **View Reports** sub-menu, choose **Current Requests**.
3. The **Current Requests** report appears. Locate the request to delete by navigating or filtering the requests.
4. The selected request opens in the **Edit Request Details** form. Click the **Delete** button.
   Note: Deleting a pending request generates an email notification to your manager. Your manager may also delete a pending request you submit. If so, you will receive an email notification of the deletion.

VIEWING ARCHIVED REQUESTS

The TimeOff application provides two additional types of reports to help you and your manager track your archived time off requests - Request History and Daily Trend.

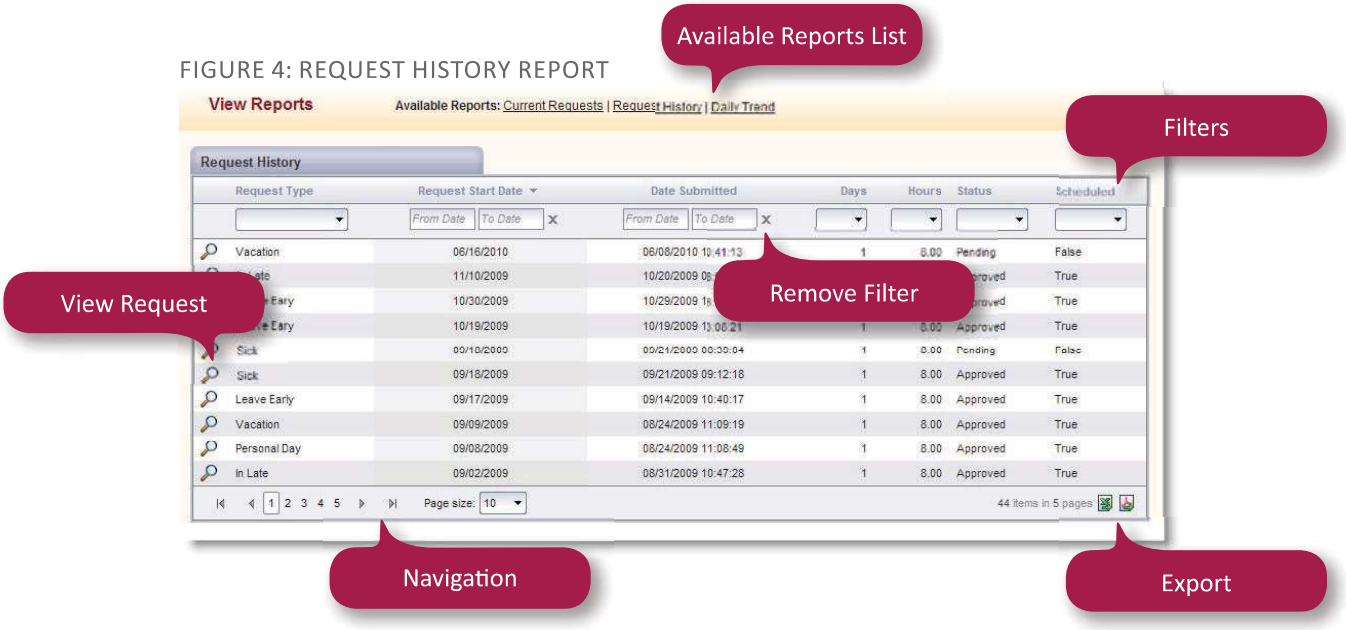
Request History

The Request History report *(Figure 4)* lists all your time off requests *(i.e., vacation, sick, leave early, jury duty, etc.)*. You may view all requests or filter the report to view requests meeting a desired criteria. Filter requests by:

- Request Type - enter filter criteria to view only sick time occurrences, vacation requests, etc.
- Request Start Date - enter filter criteria to view your previous time off requests based on a fixed time duration.
- Date Submitted - enter filter criteria to view requests submitted during a fixed time duration.
- Days - enter filter criteria to view requests made for a specific number of days.
- Hours - enter filter criteria to view requests made for a specific number of hours.
- Status - enter filter criteria to view requests by status (pending, approved, denied, etc.).
- Scheduled - filter your criteria to view scheduled or unscheduled time off occurrences.

You may also export resulting report as an Excel spreadsheet or PDF file.

FIGURE 4: REQUEST HISTORY REPORT



Generating a Request History Report: Step-by-Step

To generate a report, follow these steps:

1. Access the TimeOff application (http://app1.web.stjude.org/timeoff).
2. The TimeOff application site opens. From the **View Reports** sub-menu, choose **Request History**.
3. The **Request History** report appears. If desired add one or more filters - The report reloads to display the filtered report. *Note: To remove a filter, click the "X" to the right of the filter criteria. If you applied more than one filter, you must remove the filter for each criterion.*
4. View an individual request and/or export the report results.

Daily Trend

The Daily Trend report *(Figure 5)* displays a line chart detailing trends in your time off *(i.e., displays the pattern of your time off requests on a daily basis)*. With the Daily Trend report, you can identify patterns in your time off event requests. You may view your daily trend by all requests or filter the report to view requests meeting a desired criteria.

Filter requests by:

- Date Range (From/To) - enter filter criteria to view your previous time off requests based on a fixed time duration.
- Request Type - enter filter criteria to view only sick time occurrences, vacation requests, etc.
- Scheduled - enter filter criteria to view scheduled or unscheduled time off occurrences.

FIGURE 5: DAILY TREND REPORT

Generating a Daily Trend Report: Step-by-Step

To generate a report, follow these steps:

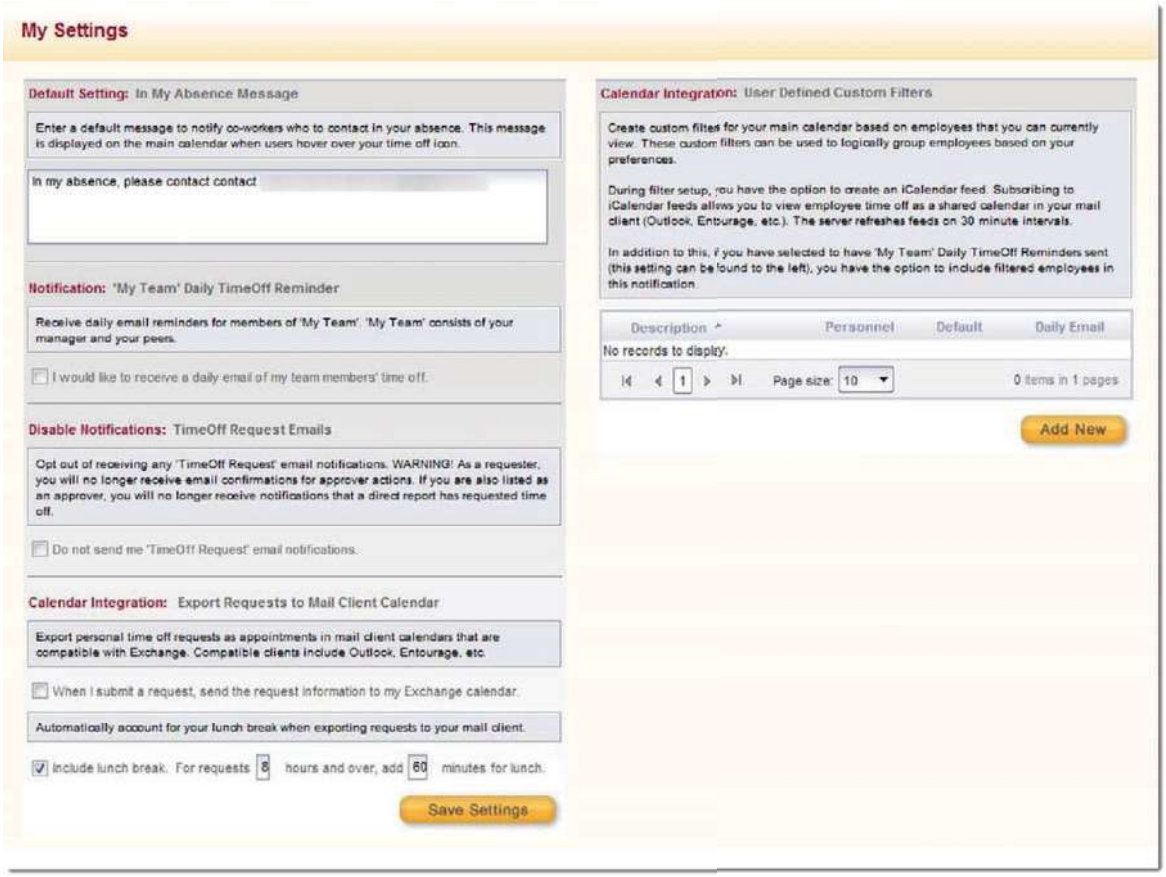
1. Access the TimeOff application (http://app1.web.stjude.org/timeoff).
2. The TimeOff application site opens. From the **View Reports** sub-menu, choose **Daily Trend**.
3. The **Daily Trend** line chart appears detailing total requests by day of week. If desired add one or more filters - The Daily Trend report reloads to display the filtered report.
   Note: To remove a filter, click the "X" to the right of the filter criteria. If you applied more than one filter, you must remove the filter for each criterion.

USING MY SETTINGS

My Settings *(Figure 6)* allows you to customize your experience with using the TimeOff application. You may adjust these settings at any time. Current customizations include:

- In My Absence Message - Enter a default In My Absence Message - the In My Absence Message is displayed when fellow departmental employees hover over your time off request on the Calendar. It provides direction as to whom they should contact, etc. during your absence. What you enter here is automatically entered in the In My Absence Message text box on the New Request form. This keeps you from entering a message each time you request time off.
- 'My Team' Daily Time Off Reminder - Receive a daily email listing your manager, team member or other peers' time off for that day.
- Export Requests to Mail Client - Automatically send time off request information to your Outlook calendar. Set your lunch break settings to automatically include lunch in requests exported to your Outlook calendar.
- Custom Filters/ Group Calendar (iCalendar Feed) - Create a custom calendar filter to display time off on My Calendar for a desired group of employees within your department(s). By default, you can filter My Calendar by team members and department. With custom filters, you can create a calendar view of people from your department(s) that may not be on your team, but you work with them on a regular basis. Examples include: project members, lab members and cross-functional teams. When creating custom filters you have the option to create an iCalendar feed with the members of your custom filter. An iCalendar feed allows you to view time off requests as a shared calendar within Outlook. In addition, you can select to include the custom filter members in the 'My Team' daily time off reminder email.

FIGURE 6: MY SETTINGS



Customizing My Settings: Step-by-Step

To customize your TimeOff application settings, follow these steps:

1. Access the TimeOff application (http://app1.web.stjude.org/timeoff).
2. The TimeOff application site opens. Click the **My Settings** link from the main menu.
3. The **My Settings** page appears. Do one or more of the following:
   - *Enter a default In My Absence Message*, enter desired message in the **In My Absence Message** text box.
   - *To turn on the daily email notification of team member's time off*, click the checkbox for "**I would like to receive a daily email of my team member's time off**".
   - *To send request information automatically to your Outlook calendar,* click the checkbox for "**When I submit a request, send my request information to my Outlook calendar**".
4. Click the **Save Settings** button.

Creating a Custom Filter/iCalendar Feed: Step-by-Step

To create a custom filter and iCalendar feed, follow these steps:

1. From the **TimeOff My Settings** page, click the **Add New** button.

2. The **Create New Custom Filter** window appears. Enter a description for the view in the **Filter Description** field.
3. Use one or more of the following methods to add employees to the filter:
   - **Add Individual Employees**: In the **Add Employees** field, enter the name of an employee to add to the filter. After locating the employee, click their name within the resulting search list.
   - **Add all Employees within a Department**: From the **Add Department** drop-down menu, select the name of the department to include within the filter.

4. Once the employee list is complete, select your desired view options. You may select one or more of the following options:
   - **Default Filter** - Select this option to make the custom filter the default view when accessing My Calendar.
   - **Include in Daily Email** - Select this option to include the employees within the custom filter in your 'My Team' Daily Email reminder.
   - **Create iCalendar Feed** - Select this option to create an iCalendar feed of the custom filter.

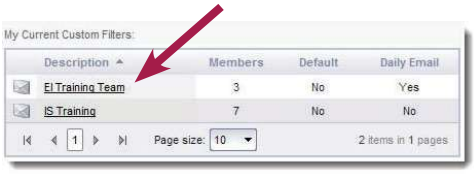
5. If you chose to create an iCalendar feed, you must then determine how to handle each employee's lunch break each employee's lunch break and/or lunch breaks for a department as a whole. To automatically adjust time off events to include lunch, select the **Include lunch break** checkbox. Then, use the hours and minutes fields to set how TimeOff should handle those requests. For example, if an employee's work schedule is from 8-5 p.m., when they request an 8 hour vacation day, the resulting calendar item displays as 8-4p.m. TimeOff does not automatically include lunch because employees may take a 30 minute or one hour lunch break. For this employee example, enter 8 in the hours field and 60 in the minutes field.

6. Click the **Save** button.
7. A notification appears to let you know the custom filter was created successfully. Click the **OK** button.
8. Your custom view is now available as a custom filter on **My Calendar**. To use your custom filter, choose the created filter from the **My Calendar Filters** drop-down menu.
9. If you selected to create an iCalendar feed the TimeOff system generates an email to your Outlook Inbox. Follow the instructions provided in the email to subscribe to the feed. After subscribing, the calendar appears in your email calendar list. You may use the overlay feature to compare the TimeOff group calendar with any of your other calendars for scheduling purposes.

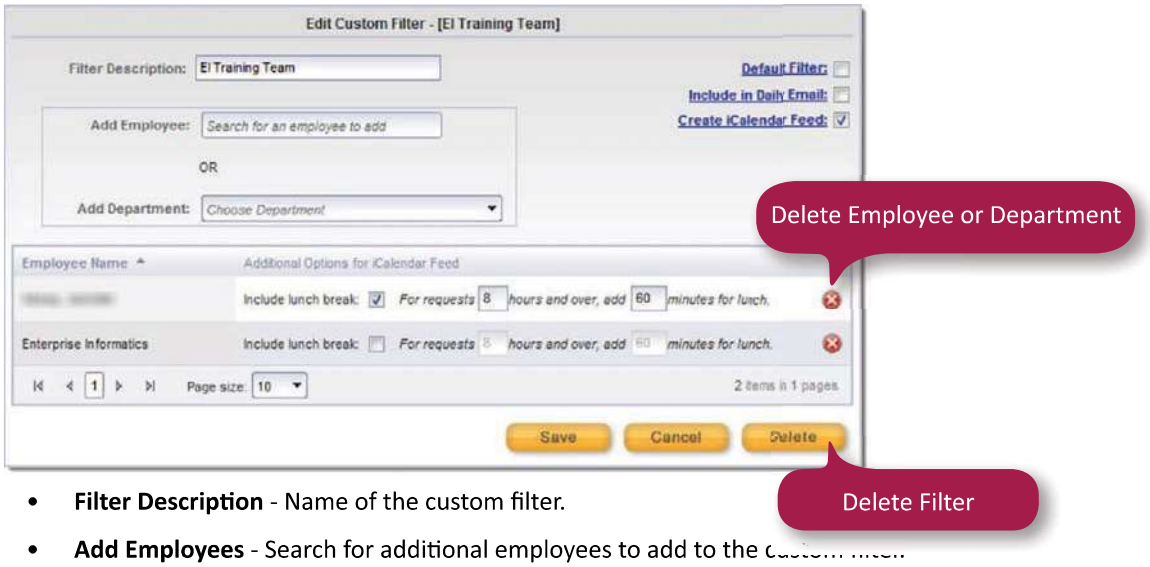
Editing or Deleting a Custom Filter: Step-by-Step

To edit or delete a custom filter, follow these steps:

1. From the TimeOff **My Settings** page, click the filter description link for the filter to edit.



2. The **Edit Custom Filter** window appears. From this window you may make the following adjustments:



- **Filter Description** - Name of the custom filter.
- **Add Employees** - Search for additional employees to add to the custom filter.
- **Delete Employees** - Remove employees from the custom filter.
- **Additional Options for iCalendar Feed** - Change the lunch break settings for an individual employee.
- **Select/Deselect View Options** - Choose to make the filter the default calendar view, include custom filter members in daily time off email reminder and/or create an iCalendar feed.
- **Delete Filter** - Delete the custom filter.

3. After making your desired adjustments, click the **Save** button.
4. A notification appears to let you know the custom filter updated/deleted successfully. Click the **OK** button.

Re-send iCalendar Feed Subscription Email: Step-by-Step

If you lose access to your iCalendar feed in Outlook, you will need to re-send the feed subscription email. To re-send the subscription email, follow these steps:

1. From the TimeOff **My Settings** page, click the re-send button *(envelope icon)* to the left of the desired custom filter.

2. A notification appears to let you know an email was sent to your Outlook Inbox. Click the **OK** button.
3. Follow the instructions provided in the email to reestablish your subscription to your custom iCalendar feed.

CITI Training Instructions

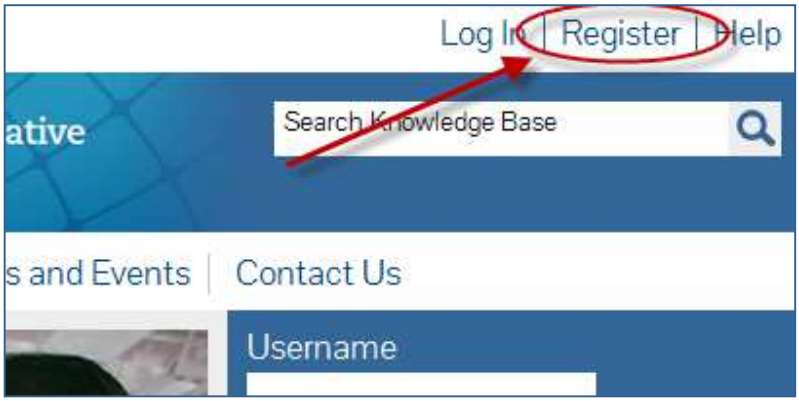
The Collaborative Institutional Training Initiative (CITI Program), founded in 2000 and based at the University of Miami, is a provider of research education content. The CITI Program's mission is to provide educational content that promotes the quality of and public trust in the research enterprise.

All Survey Interviewers (SIs) will complete CITI training upon hire. To being your CITI training, go to the following website: www.citiprogram.org.

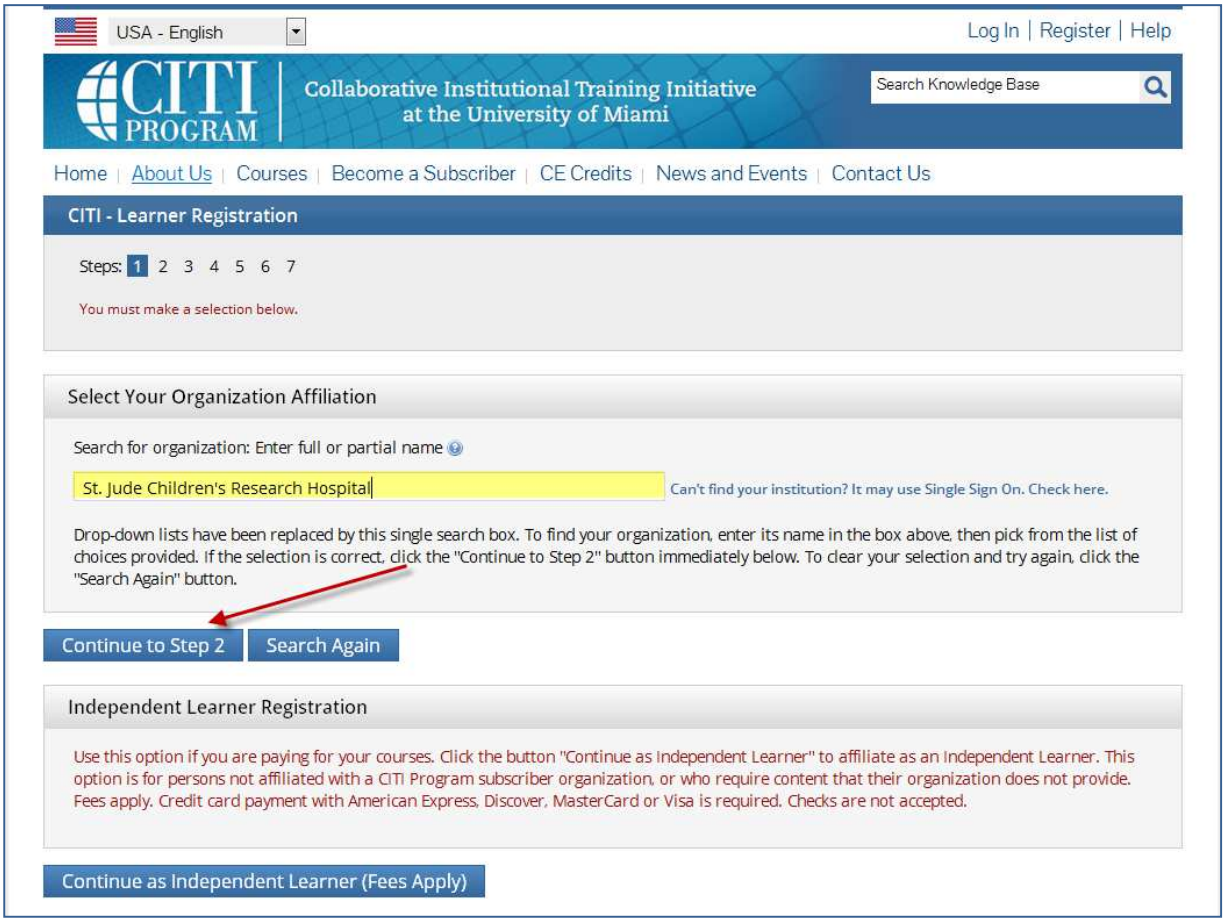
Begin by registering for the training. Follow the steps listed below to ensure all the required registration questions are answered and the appropriate modules are completed. Items that need to be filled out are highlighted in yellow. Selections that must be made have a red arrow ( ) pointing to them.

Screen 1:

Click on **Register**. At the first registration screen, search for St. Jude Children's Research Hospital in the organization list by typing the hospital's name and making the appropriate selection.

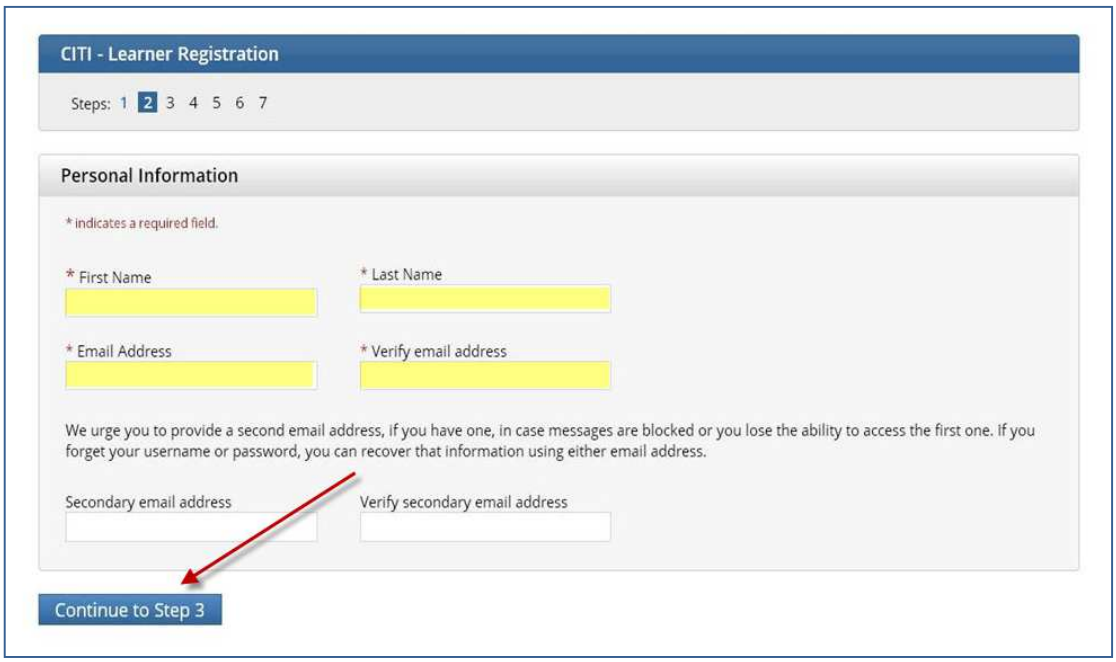


Once the organization has been selected, click on the **Continue to Step 2** button.



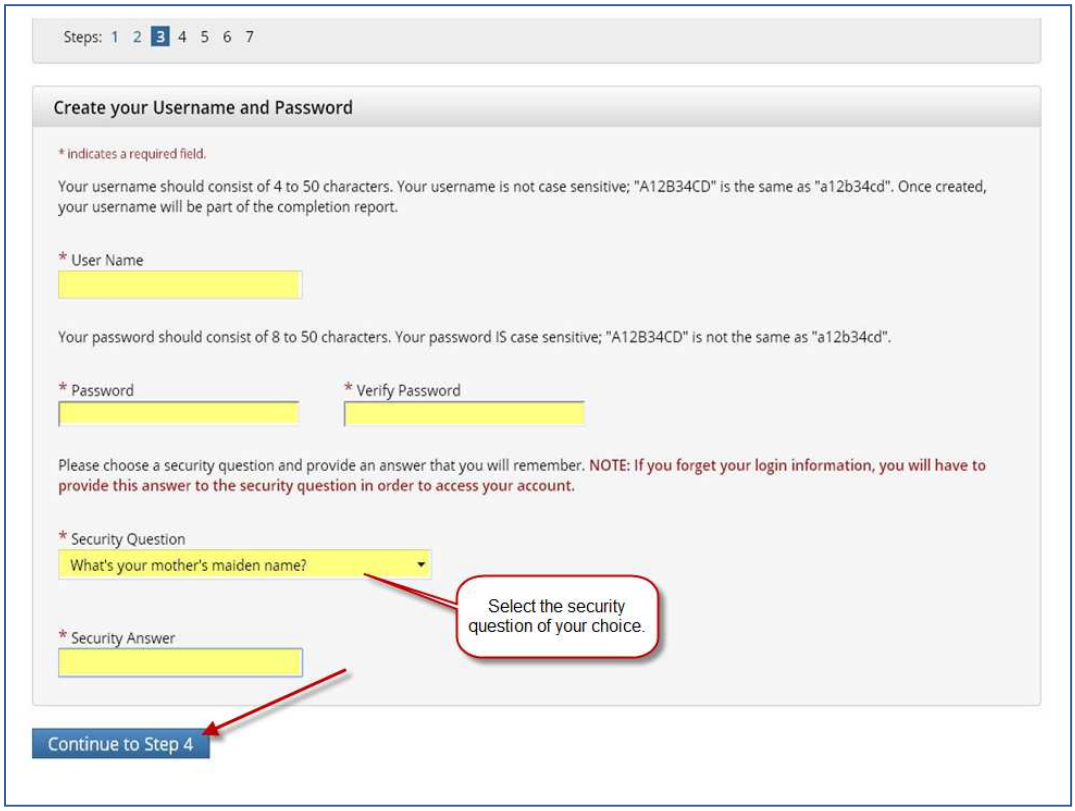
Screen 2:

At the second registration screen, enter your name and St. Jude email address. Upon completion, click on the **Continue to Step 3** button.



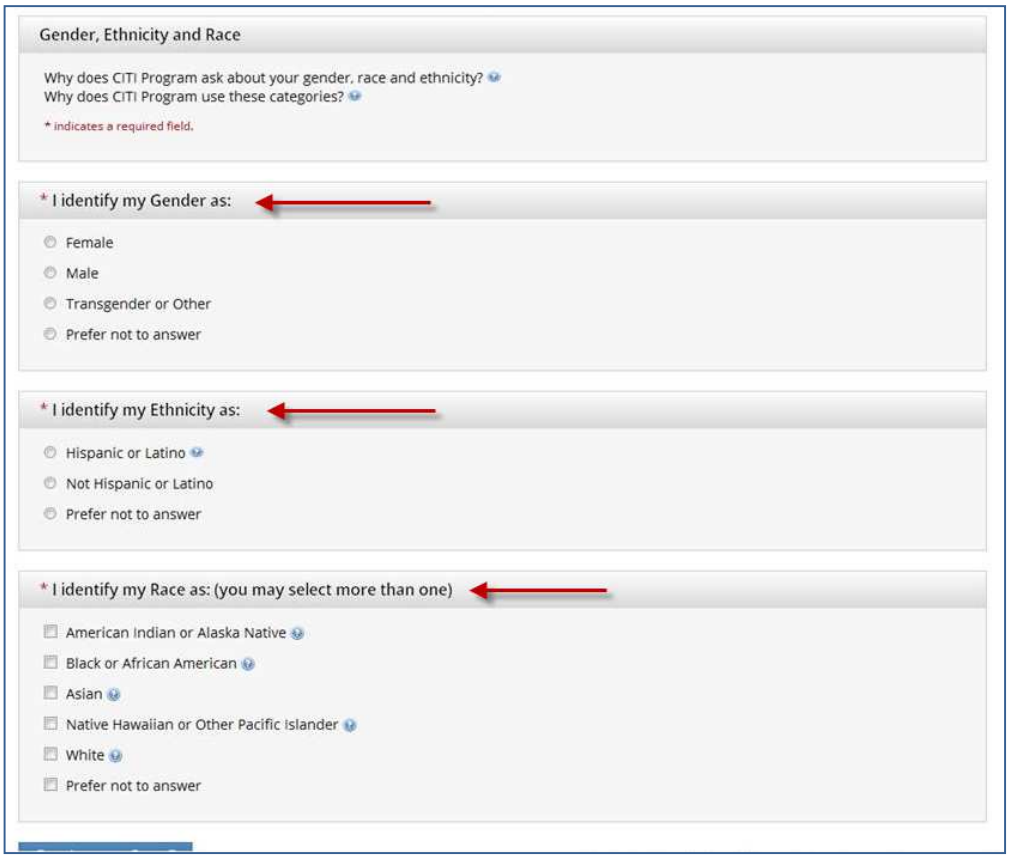
Screen 3:

At the next registration screen, select the username and password of your choice. These credentials do not have to match your St. Jude login information. Select the security question of your choice, enter the answer, and then click on the **Continue to Step 4** button.



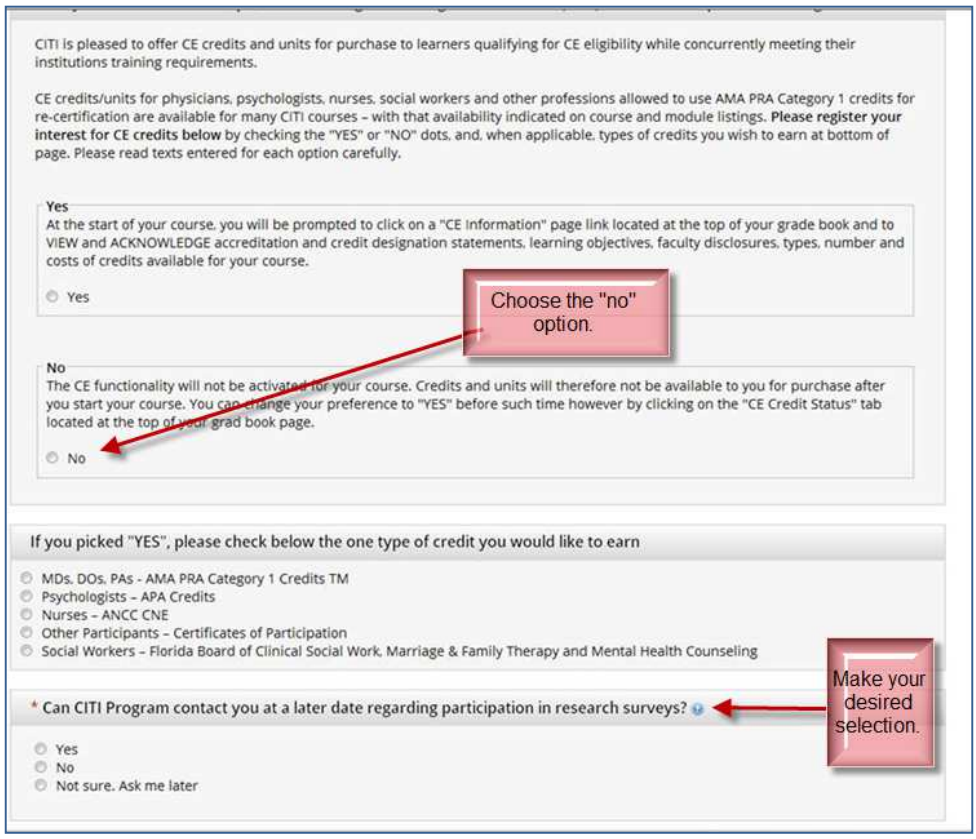
Screen 4:

Complete the Gender, Ethnicity, and Race screen, noting that there is a "Prefer not to answer" option at each question, then click on the **Continue to Step 5** button.



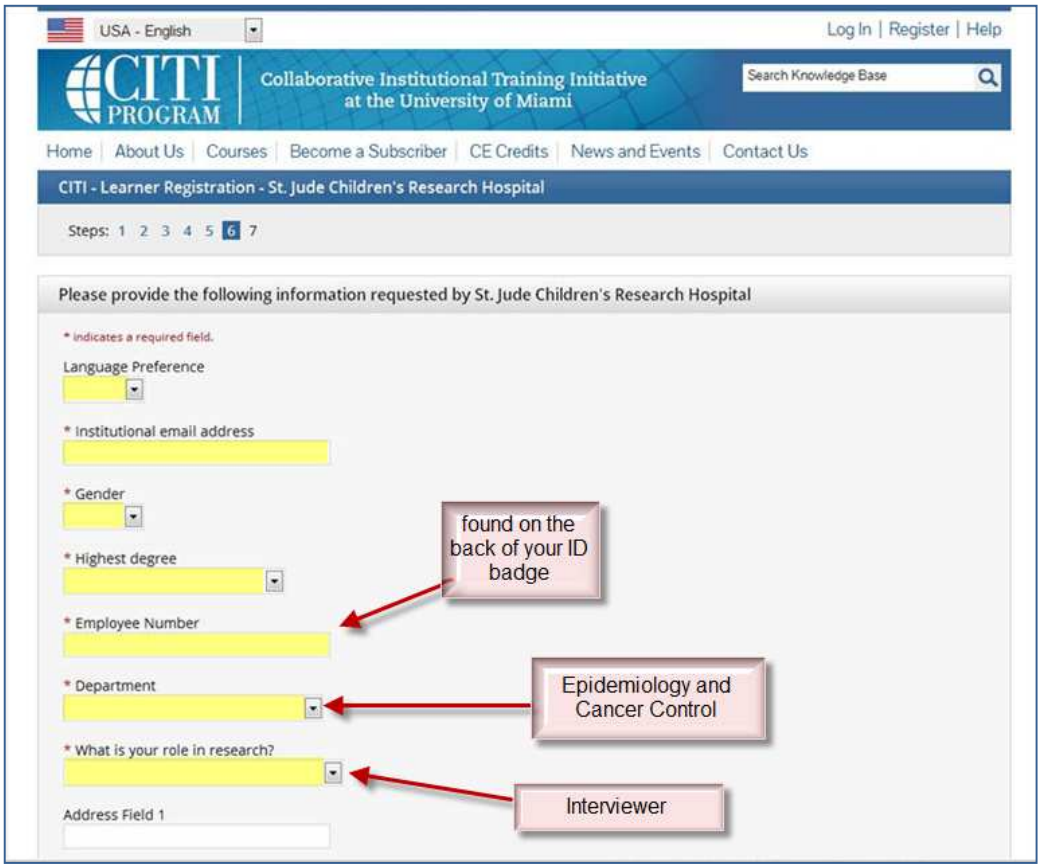
Screen 5:

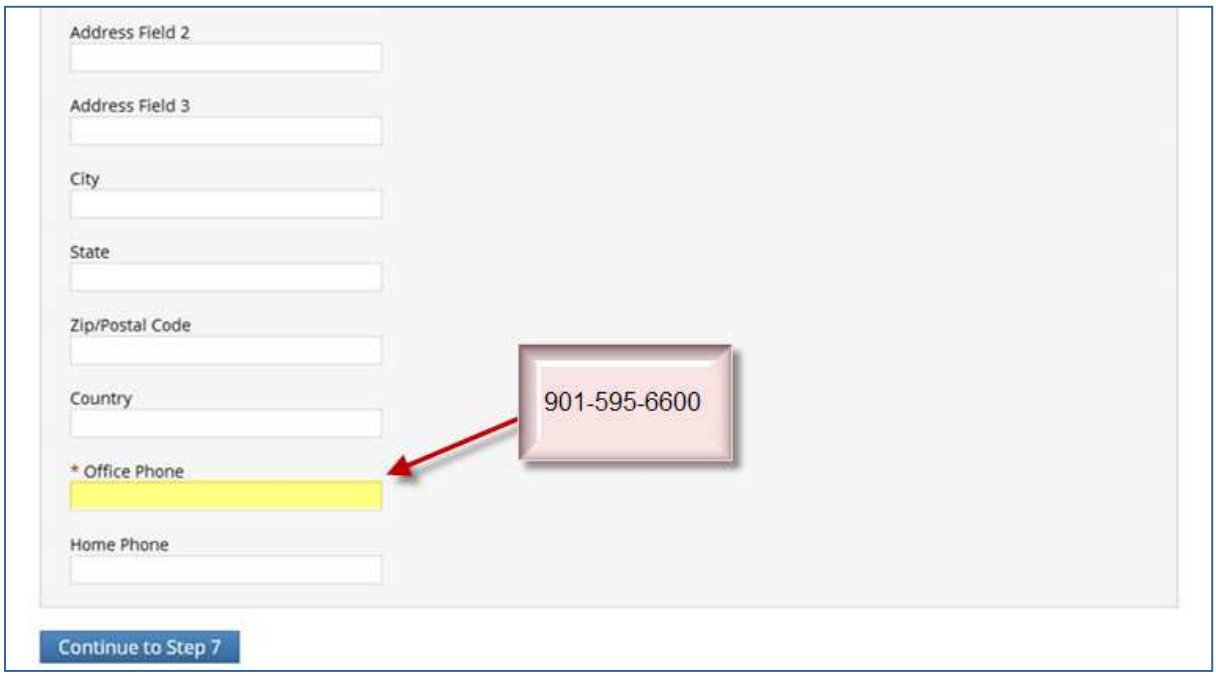
On the fifth registration screen, indicate that Continuing Education (CE) credits do not need to be activated for your course, and then indicate whether or not CITI Program may contact you at a later date regarding participation in research surveys. After making these two selections, click the **Continue to Step 6** button.



Screen 6:

On screen 6, populate the indicated fields. Note that your employee number is located on the back of your ID badge under the bar code. When everything is entered, click the **Continue to Step 7** button.

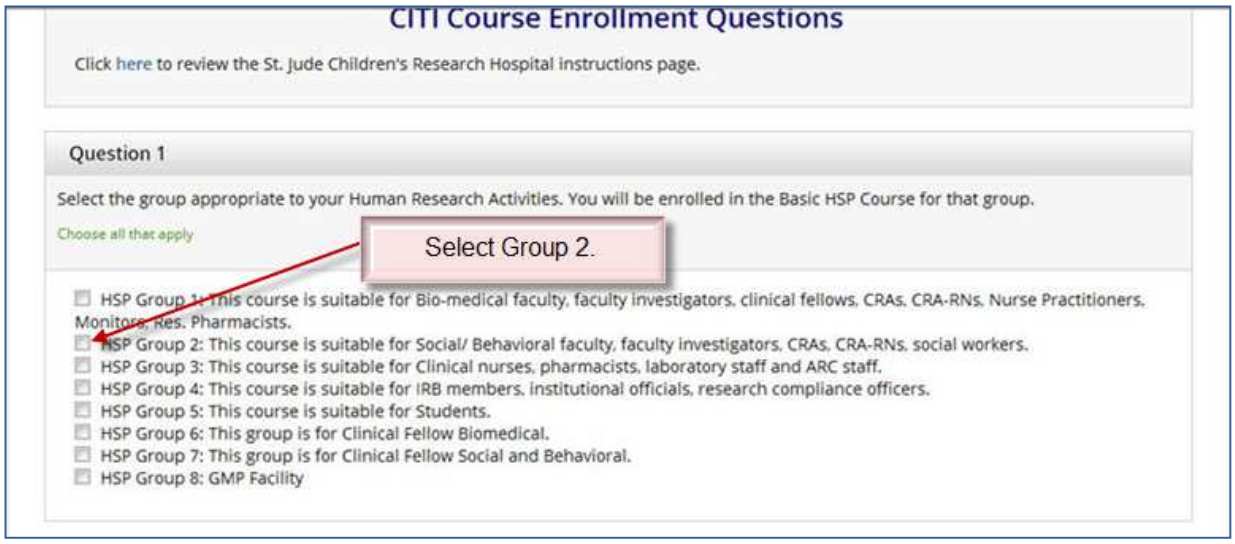




Screen 7:

On the final registration screen, scroll down to Question 1, and select group 2 (suitable for Social/Behavioral faculty, faculty investigators, CRAs, CRA-RNs, social workers.

Do not answer questions 2 – 4. Instead, scroll to the bottom of the screen and click the **Complete Registration** button.



Once you have gotten to this point, you are registered and ready to begin the modules.

Your cumulative score must be at least 85%, so you don't have to get 100% for every module. You can retake the quizzes as many times as needed.

While the program will not allow you to skip ahead, you can move backwards. Each time you finish a module, the next one will have a hyperlink.

When you have completed all the modules, there will be a screen to print your records. Please do this and bring the results to the Call Center Coordinator or a member of the LSI team.

Introduction and Overview

The Childhood Cancer Survivor Study (CCSS) is a collaborative, multi-institutional study funded as a resource by the National Cancer Institute and composed of individuals who survived five or more years after treatment for cancer, leukemia, tumor, or similar illness diagnosed during childhood or adolescence.

The Childhood Cancer Survivor Study (CCSS) was created to 1) take advantage of the opportunity to gain new knowledge about the long-term effects of cancer and therapy, knowledge that can be used to help design treatment protocols and intervention strategies that will increase survival and minimize harmful health effects, and 2) fulfill the obligation to educate survivors about the potential impacts of cancer diagnosis and treatment on their health, and to provide follow-up care, for example, by creating and implementing programs for the prevention and early detection of late effects.

The CCSS is known in the survivor community as the Long-Term Follow-Up Study. The project, initiated in 1993, is a retrospectively ascertained cohort of over 20,000 childhood cancer survivors diagnosed between 1970 and 1986. It also includes approximately 4,000 siblings of survivors who serve as the comparison group for the study. Since its origination, the cohort has been expanded by another 14,000 potential participants diagnosed from 1987 through 1999. The expanded cohort will also add another 2,000 – 4,000 siblings of expanded cohort survivors.

The CCSS cohort has been assembled through the efforts of 27 participating centers in the United States and Canada. It is coordinated through St. Jude Children's Research Hospital in Memphis, Tennessee. Other core facilities include the Statistical Center, located at the Fred Hutchinson Cancer Research Center (Seattle); the Biopathology Center (Columbus); and the Radiation Physics Center at MD Anderson Cancer Center (Houston).

For more information about CCSS, visit: http://ltfu.stjude.org/childhood-cancer-survivor-study

Terms and Definitions

Ancillary Study:	one of several studies with a specific focus that is separate from the main LTFU Study and uses the LTFU cohort and data
Case:	survivor of childhood cancer, leukemia, tumor, or similar illness
CCRP:	Certified Clinical Research Professional (certified by SoCRA)
CCSS:	Childhood Cancer Survivor Study (synonymous with LTFU Study; used by the scientific community within the study)
CCSSID:	a specific unique number assigned to each individual survivor who is a participant or potential participant (See the SOP titled **Decoding CCSSID** for full details.)
Clinical Research:	research involving human subjects
Control Group:	human subjects who are not treated with the investigational aspect of a study and are used as a comparison with the treatment intervention group
CRA:	Clinical Research Associate
Database:	MS Access forms for a given study that display information stored on tables, relative to each individual participant or potential participant
DatStat:	the software that houses our online study questionnaires
Forms:	a physical paper form, a digital MS Word form, or an MS Access form which displays information from the MS Access tables
HIPAA:	Health Insurance Portability and Accountability Act
Informed Consent:	the process by which a subject voluntarily confirms willingness to participate in a study
IRB:	Institutional Review Board
LAR:	Legally Authorized Representative - may be a parent or other person responsible for a minor or physically/mentally disabled patient
LSI:	Lead Survey Interviewer

LTFU:	Long Term Follow-Up, the common name of the CCSS used by and in conversation with participants
Participant:	a human subject that has enrolled in a research study
PHI:	Protected Health Information
PI:	Principal Investigator (the lead scientist for a study or project)
Proxy:	the party, usually a parent, who participates in the study on behalf of a deceased case or deceased sibling participant or on behalf of a cognitively disabled adult participant
QA:	Quality Assurance - systems and procedures designed to ensure that a study is performed in accordance with Good Clinical Practice (GCP) guidelines and that the data being generated are accurate
SI:	Survey Interviewer
SIBID:	a specific unique number assigned to each individual *sibling* who is a participant or potential participant in the sibling control group (See the SOP titled **Decoding CCSSID** for full details.)
SoCRA:	Society of Clinical Research Associates
SOP:	Standard Operating Procedures - written instructions for the management and conduct of study processes to ensure consistency and efficiency
VH:	verbal HIPAA (gained during Recruitment calls)

Recruitment and **Retention** When planning a study and determining who is to be included in the study, potential participants are invited to enroll. This phase is called *recruitment*. Investigators want people to stay in the study once they are recruited and enrolled and will look at their continued participation, or *retention*, in the study.

What is an epidemiological investigation? The classic definition of *epidemiology* is the study of the distribution and determinants of health-related states and events in populations and the application of this study to control of health problems. The LTFU Study is a large study, or *investigation*, of the distribution and associations of various health-related states found over time among survivors of childhood cancers.

What is a cohort study? A *cohort study* is a study that compares a group of people who share a common characteristic with another group that does not have the characteristic. The common characteristic might be a medical condition, a treatment, or even a behavior (e.g. smoking). The participants in the LTFU Study share a common history of diagnosis and treatment for cancer or a similar illness during childhood or adolescence. For best results, the people in the comparison group should be as similar as possible to the group being studied. In the LTFU, a certain number of participants were randomly chosen, like a flip of a coin, to invite their sibling (full-blooded brother or sister) closest to them in age to be in the control group for the cohort.

What is a sibling comparison group? Some siblings were invited to participate in the LTFU as a *comparison group*, sometimes called a control group. The sibling control group is similar to the LTFU cohort in almost every way except they did not receive treatment for cancer or a similar childhood illness. The health status of siblings and participants are followed over time. If survivors in the LTFU Study have a different health outcome when compared to their brothers and sisters, these results provide strong evidence about how cancer treatments affect long-term health. Siblings in our control group are very important to the success of the study.

What is meant by late effects outcomes? The LTFU Study was designed to obtain health information at regular intervals from a select group of survivors of childhood cancer to determine if there was an increase in health problems later in life associated with certain chemotherapies or radiation treatments they received as treatment for childhood cancer. The general term used for analyzing the development of adverse health problems is "*late effects outcomes*."

What is DNA banking? As part of the LTFU Study, investigators ask participants to store some of their biological material (blood, saliva, buccal cells) for use in genetic studies in the future. Another term for storing the *DNA* is "*banking*" it, putting away for future use.

Standard Procedures Applicable to All Studies

There are many steps to processing calls to participants and potential participants in the Call Center which are standard and generic regardless of the study you may be involved in. All studies and projects require:

1. Working with a list of participants and potential participants
2. Performing pre-call checks to develop a profile on the person you are contacting
3. Adherence to well-developed and IRB-approved scripts
4. Consistent and comprehensive data entry following the call

These steps will always be performed regardless of the study or project a Survey Interviewer may be involved with.

1. Working with a list of participants and potential participants

Every study will begin with a list of people who need to be contacted. These lists may include CCSS ID numbers (or SIBID numbers), first names, last names, date of birth, Social Security number, the CCSS password assigned (for completing surveys online), and/or Roll Over date, etc. These lists are created as Call Assignments in the CCSS SI Assignments database.

2. Performing pre-call checks to develop a profile on the person you are contacting

Because of the unique complexities involved with most research studies supported by the Center, pre-post call checklists have been created to help Survey Interviewers work cases completely without missing important steps. Many people within the department who work outside of the Call Center depend on the information we enter in the databases. Therefore, it is critically important that the data we enter be complete, accurate, clear, concise, and easy to understand. Pre-post call checklists, located in the SOP library, have been designed to help ensure data quality. See the document titled **Using the On-Line Procedure (SOP) Manual** for instructions on using the SOP Library.

In addition to using the checklists, all data entry should be proofread before moving on to the next participant record.

An effective way to use these lists is to print off those that apply to the studies or projects on which you work and post them at your workstation. If you have questions regarding these lists, please contact an LSI or the Call Center Coordinator.

Disclaimer: These check lists are dynamic and fluid documents and need to be looked at carefully for errors or obsolete information. If you should find any errors or obsolete

information in any pre-post call check off list, please notify an LSI or the Call Center Coordinator immediately.

Example: Recruitment Pre-Post Call Check List :

Pre-Post Recruitment Calls — Ver. No. 1.3
2 Pages — Rev. Date: 1/22/2013
Survey Interviewers

Pre-Post Call Checklist - Recruitment (Expansion Cohort) Calls

Background

This procedure lists the key steps that should occur before and after Expansion Cohort Recruitment phone calls. See the procedure called *Expansion Recruitment Process for Interviewers* for more detailed information about making the calls and location of referenced files.

Procedures

BEFORE THE CALL: Review all available data

**If prospective participant is a former Riley Hospital patient (institution 24), then see the procedure called Verbal HIPAA Authorization Process for Riley. Remember to use the special Riley script and form.*

Recruitment Database

- Name
- Birth date (Over 18 = Adult; Under 18 = minor)
- Diagnosis and Diagnosis date
- Date of last phone call
- Address/Phone date and source
- Time zone
- Gender
- Alive or expired (1 = alive; 2 = deceased)
- Review Comments section on Quest, Tracking,
- Outcomes and notes in Call logs
- Review and adhere to IRB approved scripts
- Have website www.longtermfollowup.org open
- Be prepared to gain the Verbal HIPAA and Survey (or appointment)

AFTER THE CALL:

- Enter all data concisely and completely in the *Recruitment Database.*
- If you obtained a verbal HIPAA authorization, create a *Word Participant Call Log (*see the procedure *Using and Creating MS Word Participant Call Logs* for guidance*).* Reminder - no data will be entered in the Participant Call Log until the expansion baseline calls begin.
- Database reminders
  - Update Date last call

3. Adherence to well-developed and IRB-approved scripts

Scripts for making calls to participants and potential participants have been thoughtfully prepared to fulfill the following:

- Maintain compliance with state, federal, institutional, and IRB guidelines
- Protect the right to privacy of human subjects
- Connect with the participant or potential participant
- Build credibility and trust
- Inform
- Aid in decision making

- Gain commitment

Because scientific research is highly regulated, it is critical that the SI adhere strictly to the content of the script. Although there may seem to be redundancies with some of the content, *the SI cannot deviate from, omit from, or in any way alter the scripts*. If you have questions regarding scripts, please see an LSI or the Call Center Coordinator.

Scripts for different studies can usually be found in the training manuals for a given study. Other scripts are located in the Interviewers folder on the Z drive or in the SOP Library. Here are some examples:

Study or Project	File Name	Location
CCSS Expansion Recruitment	17_Expansion recruitment phone scripts 9-14-10 (5)	Z:\...\Interviewers\Training\Intervie wers Binders\LTFU Expansion Recruitment and Baseline Interviewer Manual LTFU Center rev.2015
Expansion Baseline Survey	Expansion Baseline Questionnaire Incentive Script	Z:\...\Interviewers\Expansion Survey Calls\Scripts
Informed Consent for Baseline	Informed Consent with Incentive Expansion Baseline 07312014	Z:\...\Interviewers\Expansion Survey Calls\Scripts
Phone Message Guidance	Phone Message Guidance_Rev 5-30-2014	Z:\...\Interviewers\Calling Tools
Saliva Calls	Saliva Study Call Script ver 1 0	Z:\...\Interviewers\Saliva Study\Scripts
Health eHeart Calls	Health eHeart Study Calls Script_rmdr	Z:\...\Interviewers\Health eHeart Study\Scripts

Other scripts have been developed to assist in helping a potential participant make a decision about whether to participate in a research study. Many times a potential participant has a concern that needs to be addressed before they will make such a decision. If these concerns are not addressed satisfactorily, then the concern becomes a barrier.

Important Note: A decision to refuse participation in a study is always an acceptable option and one we accept graciously. In using the following scripts, the SI is not attempting to coerce participation but is providing information to help the potential participant make a decision.

Barrier	File Name	Location

Potential participant is too busy to participate	Barrier, No Time to Participate.docx	Z:\...\Interviewers\Calling Tools\Overcoming Barriers to Participation Scripts
Survey questionnaire takes too long to complete	Barrier, No Time to Complete Questionnaire.docx	Z:\...\Interviewers\Calling Tools\Overcoming Barriers to Participation Scripts
Ineffective phone messages that do not generate a call-back	Barrier, Leaving Ineffective Messages.docx	Z:\...\Interviewers\Calling Tools\Overcoming Barriers to Participation Scripts
Value of participation not perceived due to good health	Barrier, I'm Doing Fine, Why Do You Need My Information.doc	Z:\...\Interviewers\Calling Tools\Overcoming Barriers to Participation Scripts
Security of privacy and protecting health information	PHI Concerns Version 4.doc	Z:\...\Interviewers\Calling Tools
Difficulty dealing with painful memories	Barrier, I Don't Want to Think About My Cancer.docx	Z:\...\Interviewers\Calling Tools\Overcoming Barriers to Participation Scripts
Siblings do not see the value of participation	Reasons for participating in LTFU.doc	Z:\...\Interviewers\Calling Tools
Participant satisfaction	TIPS FOR OBTAINING MORE PARTICIPANTS.doc	Z:\...\Interviewers\Calling Tools

Participant satisfaction is critical to the success of all research studies. It is important that the SI maintains the highest level of professional courtesy during all call efforts. Friendliness, compassion, humility, graciousness, and an attitude of service will go a long way in making our participants or potential participants proud to be a part of the LTFU Study.

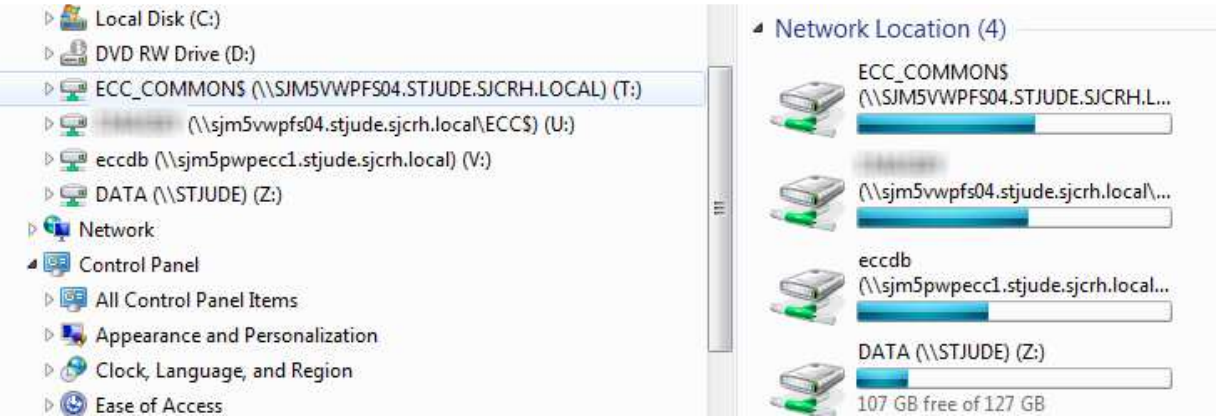
4. Consistent and comprehensive data entry following the call

All participant and potential participant information is stored at the Long-Term Follow-Up Study Coordinating Center at St. Jude Children's Research Hospital in digital form on tables in MS Access. Forms for each aspect of the LTFU Study and ancillary studies have been created in MS Access to display participant information in a user-friendly manner. They are used for processing all aspects of participation and include contact numbers, parent, spouse, or other information; call outcome information; survey and HIPAA form completion information; and other miscellaneous, important information. Every call that is made to a participant will result in some data entry.

Accessing Network Drives, Interviewers Folder

Left-click on the Microsoft Windows "START" button, then choose the option displaying your network username and PC identification number.

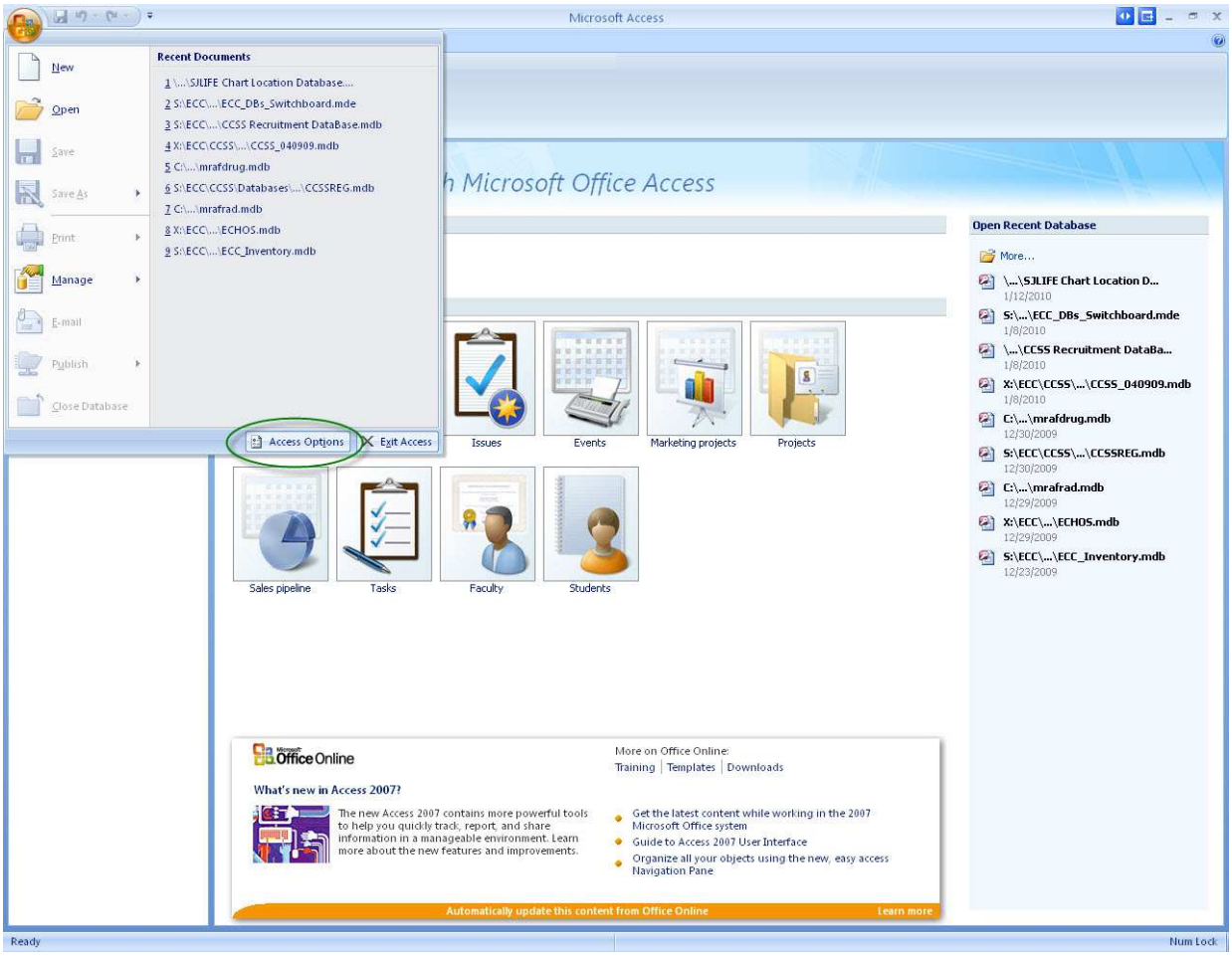
Under Network Locations, you will see multiple drives. Double-click on the drive you need, as indicated below:



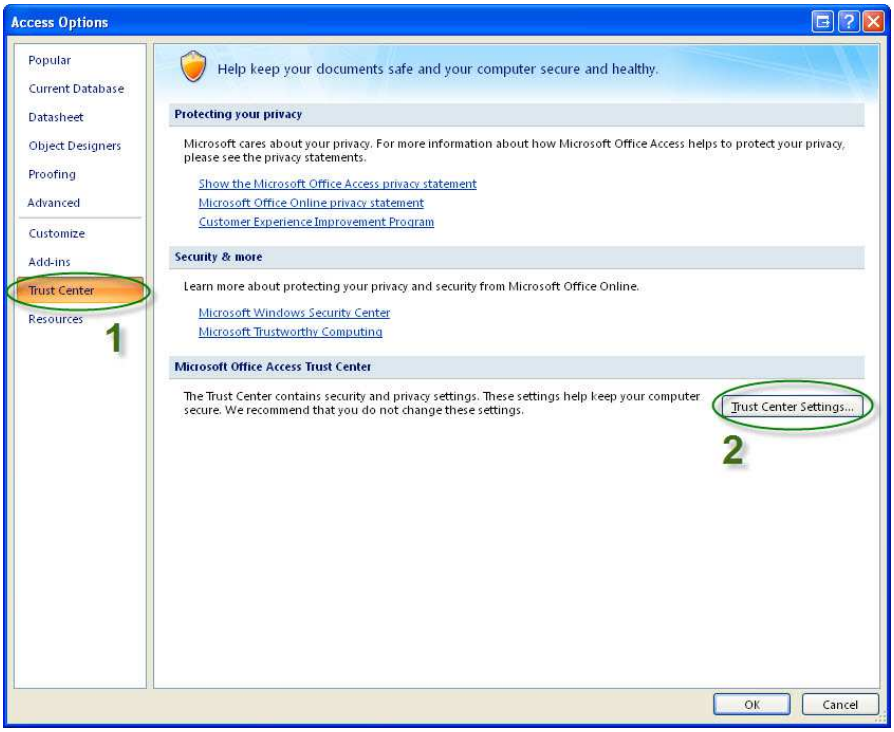
1. The V: drive is where our databases are housed.
2. The U: drive is the network storage available on your local computer and is where you should store all your personal work-related documents to ensure they are properly backed up. Double-click on the U: drive to view your files.
3. The Z: drive is where our shared network folders are located and will be used every day. Double-click on the Z: drive, then SJShare, SJCOMMON, ECC, Interviewers. This brings you to the Interviewers folder, which contains critical documents for daily procedures.

Setting Up Access Trust Centers

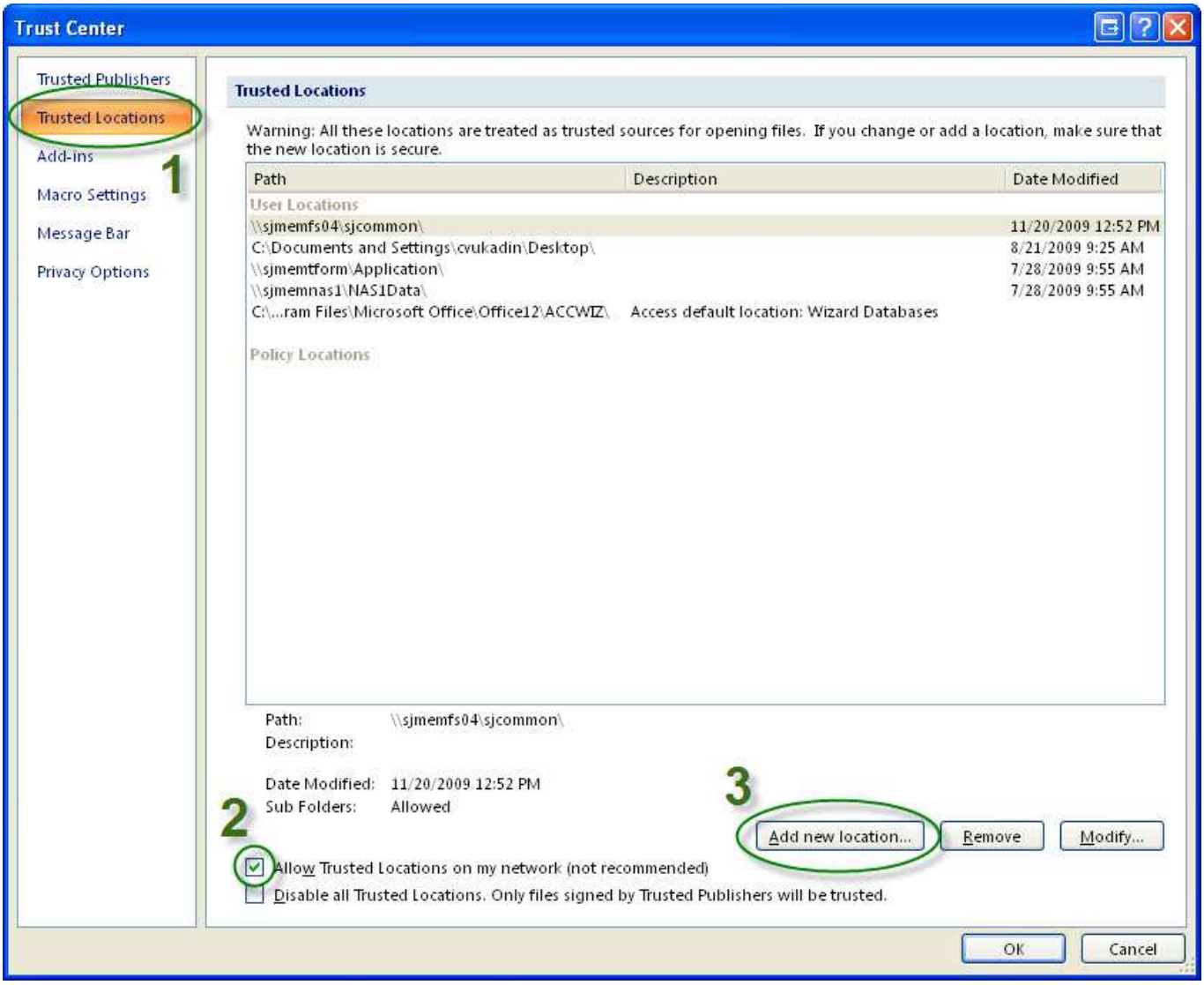
Click the round Start button, top left of Access Window, select Access Options.



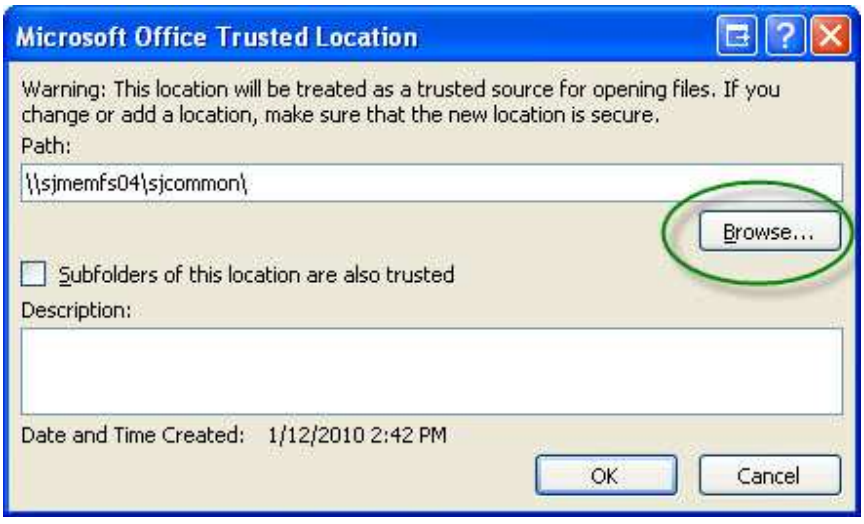
Click Trust Center on left, then Trust Center Settings when it comes up on the right.



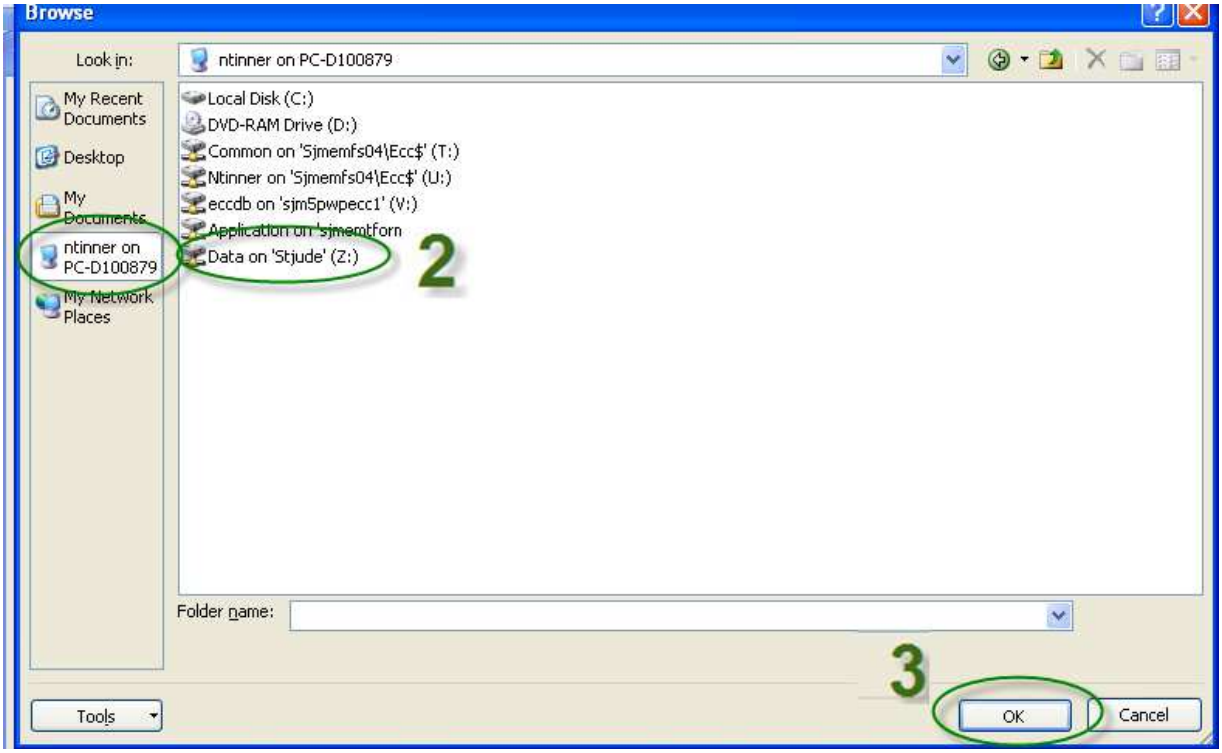
Click Trusted Locations on the left, then when the window below comes up check the Allow Trusted Location on my network, then click Add new location…



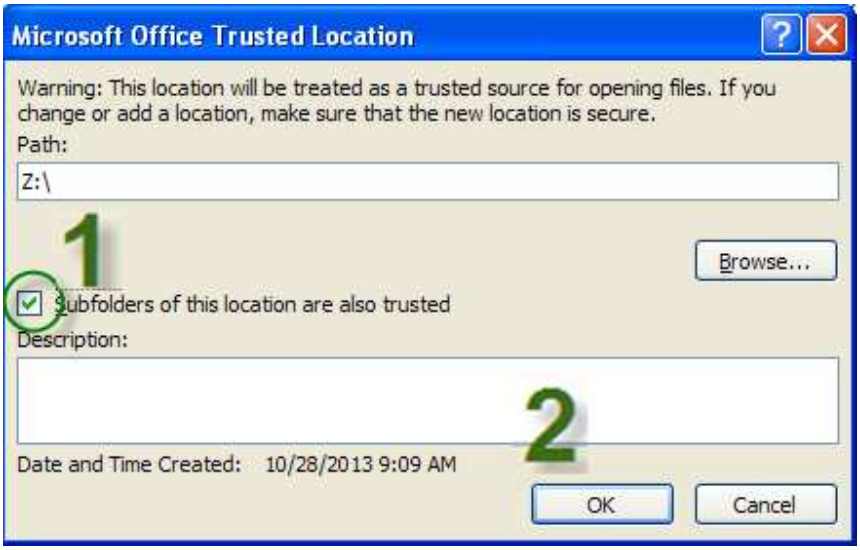
Click Browse



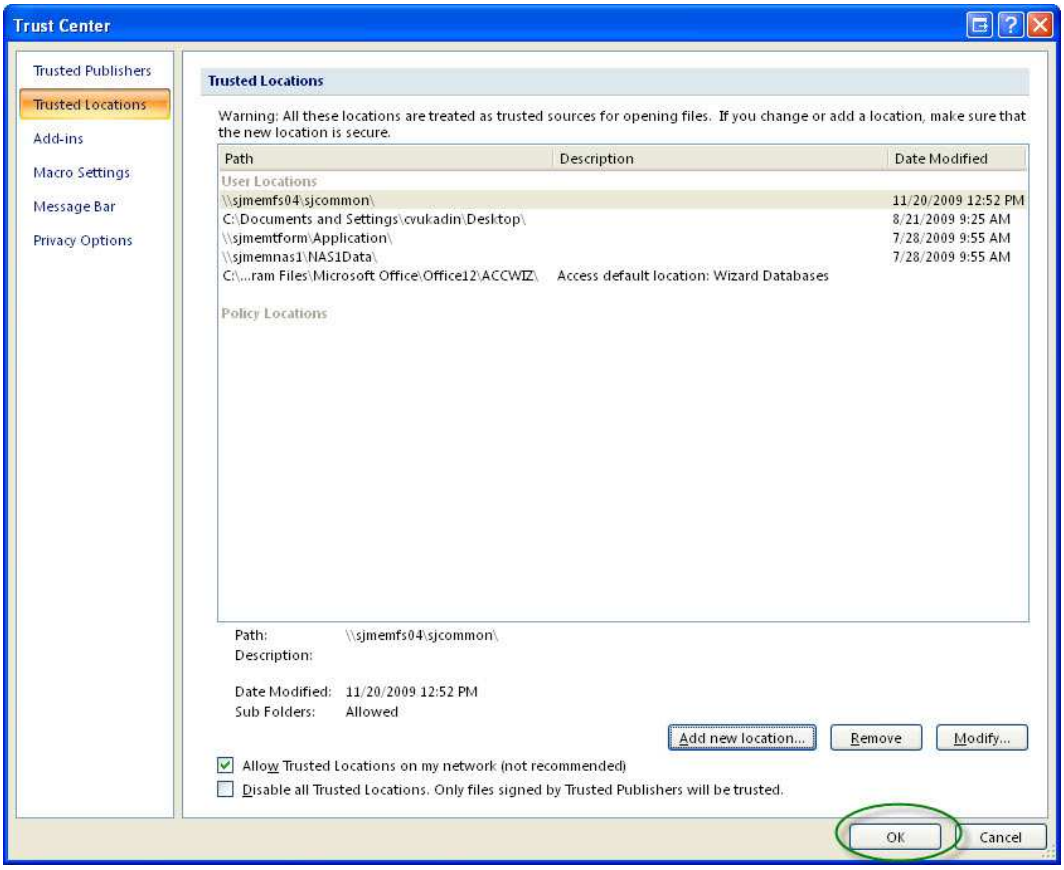
Click on the My Computer icon that should have your login and PC name, then select the S-drive, then click OK.



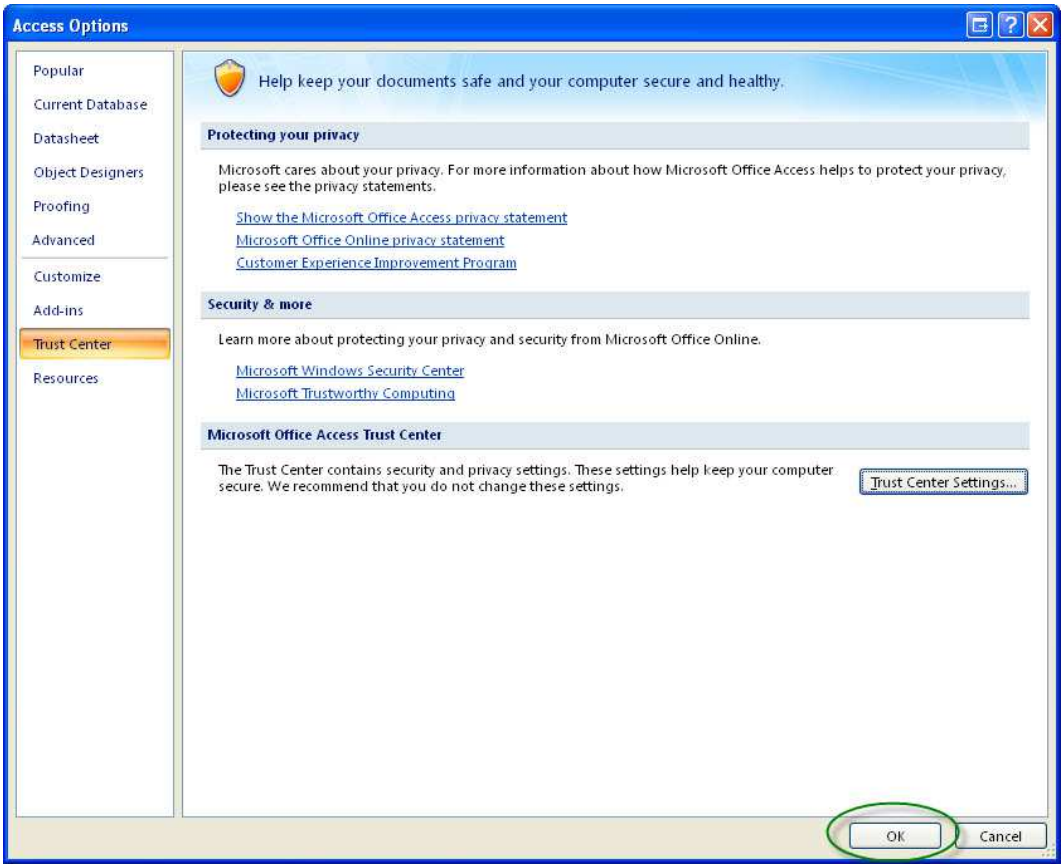
Check the box for Subfolders of this location are also trusted, then click OK.



Click OK here



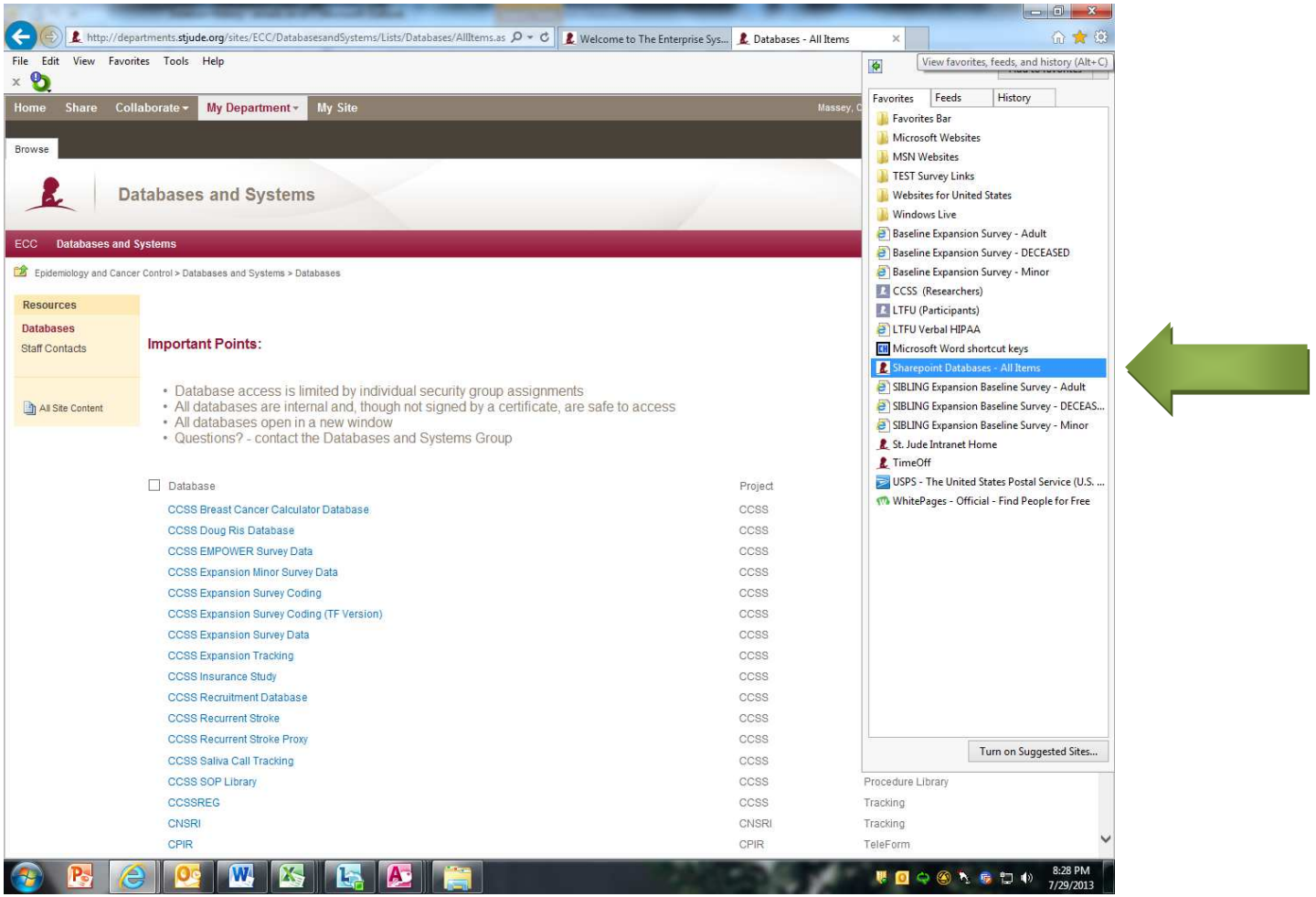
Click OK here



Accessing the Databases

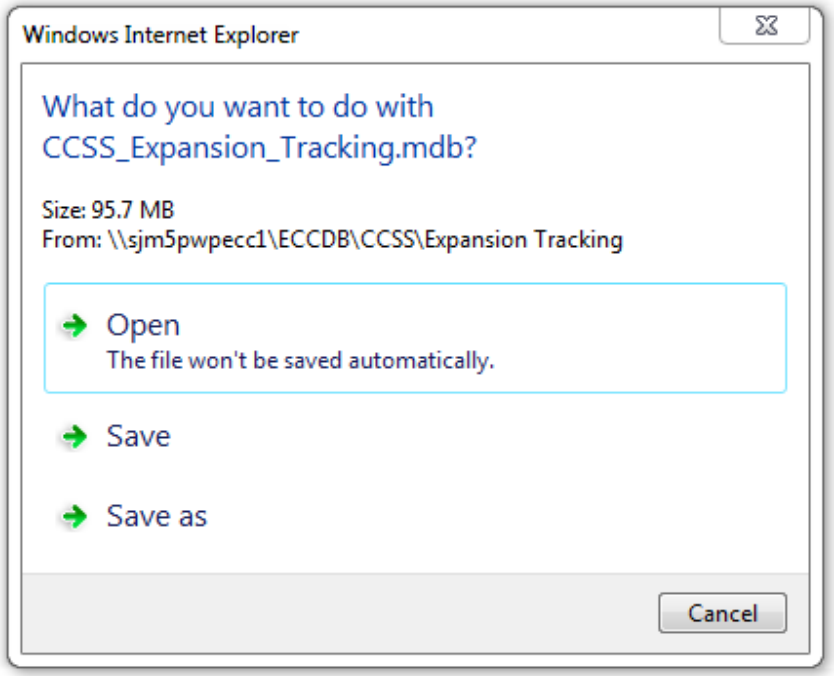
(SOP Library, CCSS REG, CCSS Recruitment, CCSS Expansion Tracking , LTFU Participant, SJLife Tracking)

Step 1: From your favorites bar, choose the link for Databases – All Items (http://departments.stjude.org/sites/ECC/DatabasesandSystems/Lists/Databases/AllItems.aspx).



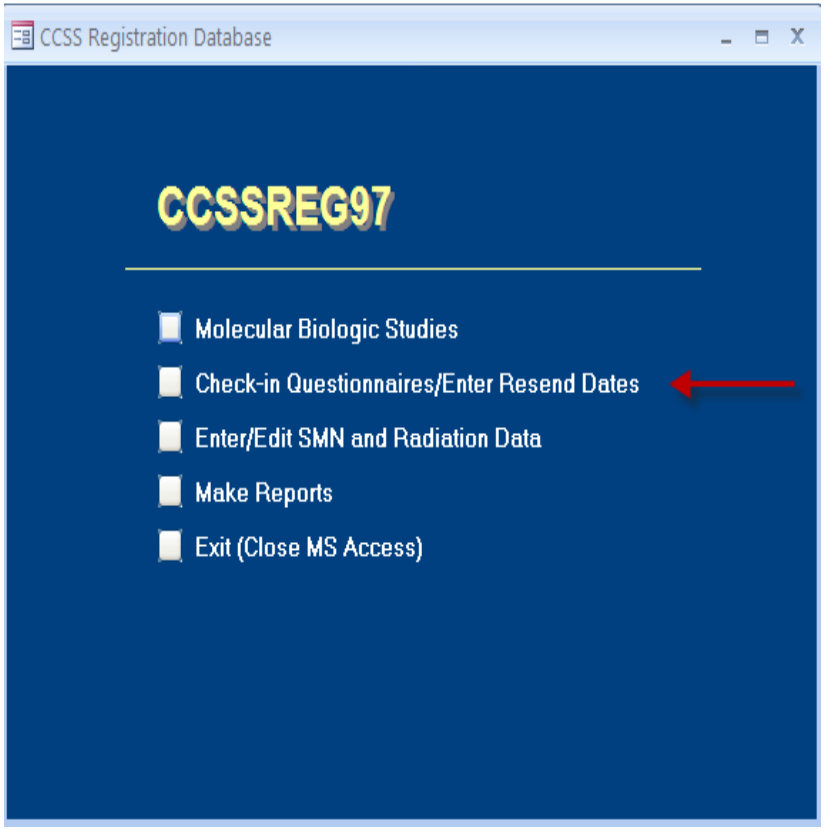
Step 2: Choose the database you need from the list presented by double-clicking the database name (CCSS SOP Library for the SOP library, CCSSREG for the original cohort, CCSS Recruitment Database for the recruitment cases, CCSS Expansion Tracking for the Expanded Cohort, CCSS LTFU Participants Database for post-baseline case and sibling participants, SJLIFE TRACKING READ ONLY (NOT FOR DATA ENTRY) to view St. Jude Life's database)

Step 3: When the "What do you want to do…" window appears, choose the option to Open.

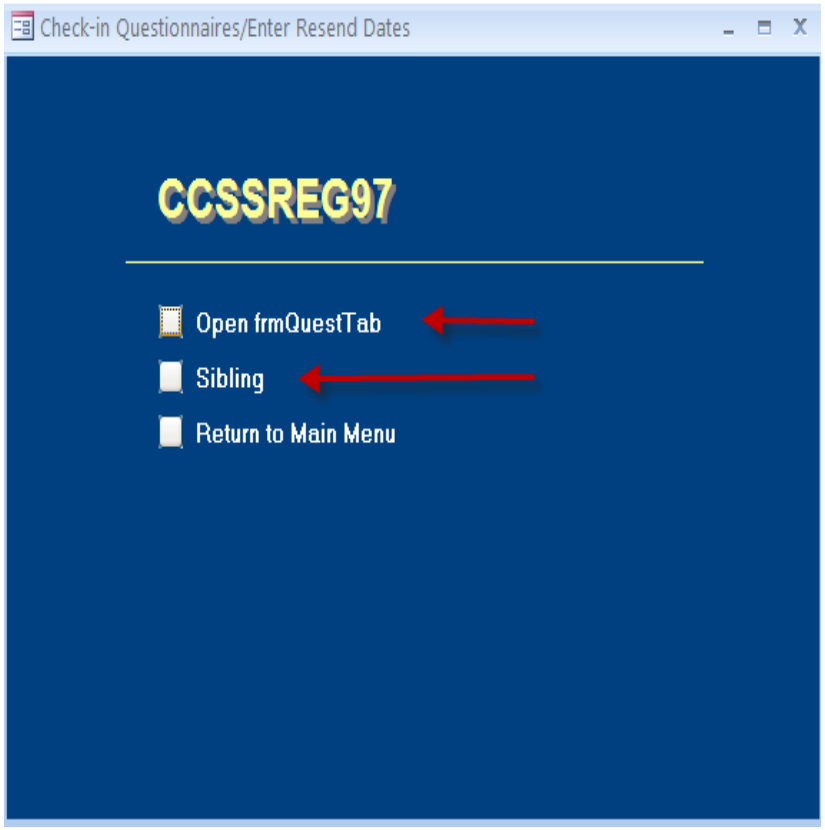


For the REG Database, which houses the Original Cohort participants and siblings:

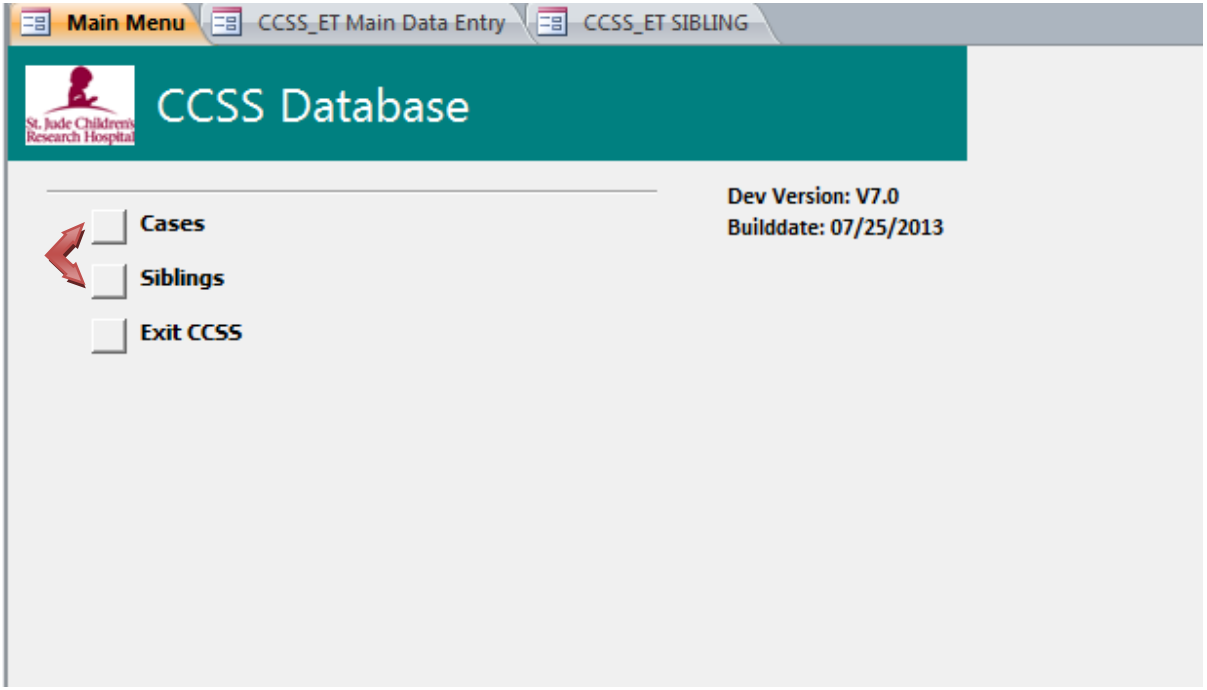
1. **Click on "Check-in Questionnaires/Enter Resend Dates.**



2. **Click on "Open frmQuestTab" or "Sibling", as needed.**



For the Expansion Tracking database, which houses the Expanded Cohort participants and siblings, click on Cases or Siblings, as needed:



Using the On-Line Procedure (SOP) Manual

Background

The manual of procedures (SOPs) for the CCSS Coordinating Center and Call Center is available through the SOP Library. This on-line database is available through Sharepoint. Users can browse a card catalog with brief descriptions of each procedure, search for procedures by key phrase or by user group, and retrieve the most updated version of any procedure. Each procedure indicates which user group(s) use 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

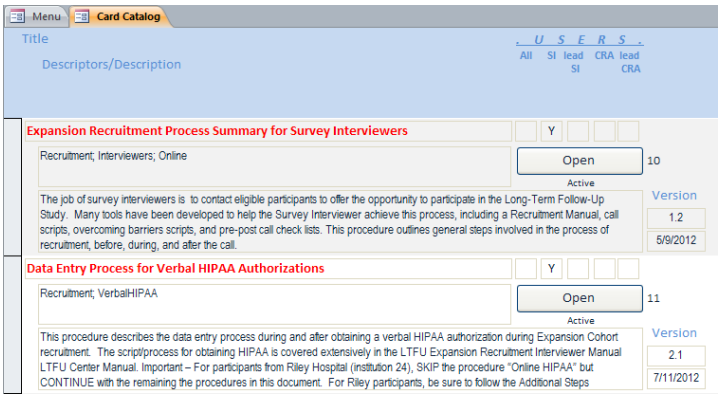
The opening screen for the library presents 6 action options. The **Exit** button closes the library.

1. **Card Catalog** opens a list of every procedure in the library
2. Two search features open different search windows to help you locate a specific procedure or group of procedures:
    a. **Search Key Words** (you key in the word(s) or key phrases)
    b. **Search User Group** (Check which user group or groups you need)
3. Reports:
    a. **CCSS SOP Library** lists every procedure in the library.
    b. **New Procedures** lists all version 1.0 procedures
    c. **Recent Revisions** lists procedures recently updated
    d. **CCSS SOP Library-Expanded**. All procedures together with full 'background' text
    e. **INACTIVE Prodedures**: Procedures no longer active

Each procedure has version number and revision dates shown at the top of the procedure as well as in the library.

Sample Card Catalog screen

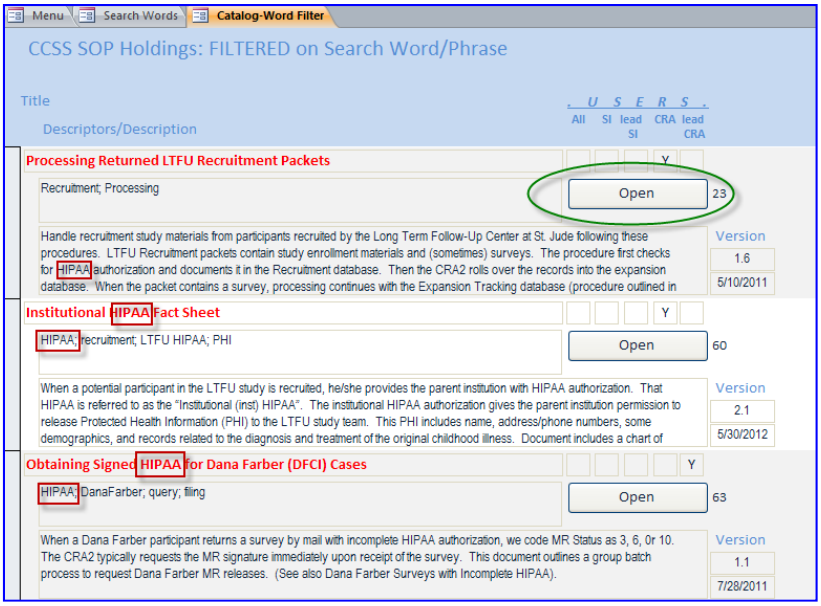
The card catalog lets you scroll through all procedures in the library. The **Open** button opens the procedure (a pdf document) so you can read the procedure. If you have older copies of a procedure on hand, be sure to use the version available from the library. (See the Version number and date shown both on the card catalog and in the upper right corner of each procedure.)

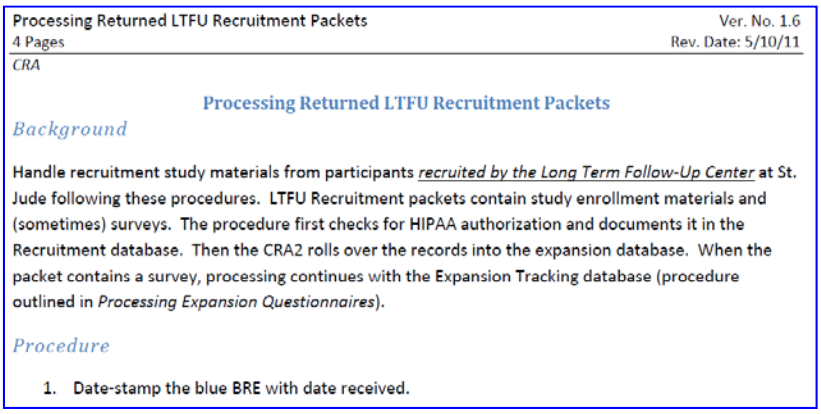


Everyone

Sample Search Screens

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 you need, then click the **Open** button to view the whole 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

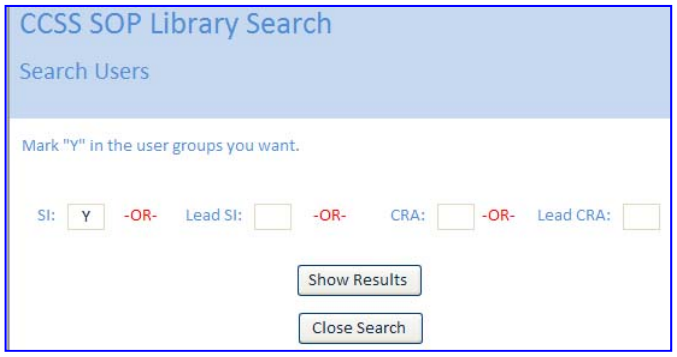
Handle recruitment study materials from participants *recruited by the Long Term Follow-Up Center* at St. Jude following these procedures. LTFU Recruitment packets contain study enrollment materials and (sometimes) surveys. The procedure first checks for HIPAA authorization and documents it in the Recruitment 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*).

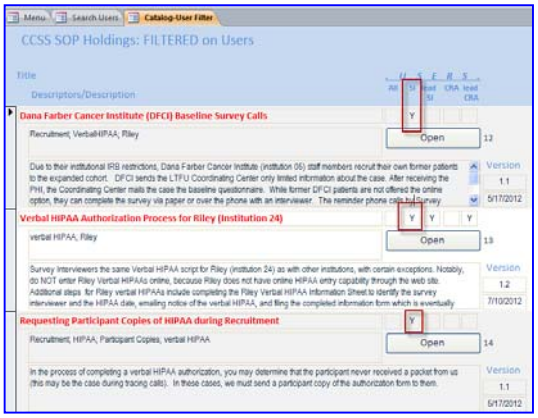
Procedure

1. Date-stamp the blue **BRE** with date received.

Everyone

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 procedures in the library by title and shows the user groups and descriptors.

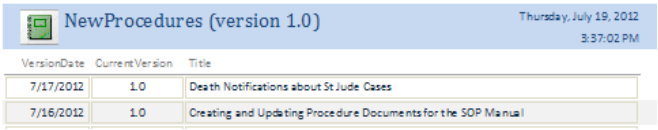
CCSS SOP Library

Ref	Title	All	SI	Lead SI	CRA	Lead CRA	Descriptors
1	CCSS Coordinating Center Manual Introduction	Y	Y	Y	Y	Y	Overview
2	Recruitment Initial Mailing-Queries					Y	Recruitment; query
3	Recruiting Survey Packet Illustration				Y		Recruitment; production
4	Recruiting Production Schedules					Y	Recruitment; schedule; production
5	Spanish Packets-Recruitment Materials				Y		Spanish; recruitment; production
6	Spanish Cover Letters and Authorization Forms – Merging				Y		Spanish; mailing; merge; production
7	HIPAA only Packet Production for Recruitment				Y		Recruitment; HIPAA only; production
8	Recruitment Packet Illustration – Former USC Institutions				Y		Recruitment; mailing
9	HIPAA only Recruitment Packets: Pilot				Y		Recruitment; HIPAA only; cover letters; production
10	Expansion Recruitment Process Summary for Survey Interviewers		Y				Recruitment; Interviewers; Online
11	Data Entry Process for Verbal HIPAA Authorizations		Y				Recruitment; Verbal HIPAA
12	Dana Farber Cancer Institute (DFCI) Baseline Survey Calls		Y				Recruitment; Verbal HIPAA; Riley
13	Verbal HIPAA Authorization Process for Riley (Institution 24)		Y	Y		Y	verbal HIPAA; Riley
14	Requesting Participant Copies of HIPAA during Recruitment		Y				Recruitment; HIPAA; Participant Copies; verbal HIPAA
15	Sending Participant Copies to Verbal HIPAA Recruits			Y			Recruitment; verbal HIPAA; ParticipantsCopy
16	Recruitment Tracing for FedEx Institution Mass Resend		Y				FedEx; recruitment; tracing
17	Shipping Recruitment via Fed Ex					Y	FedEx; recruitment; production
18	FedEx Institution Recruitment Resends					Y	FedEx; recruitment; production
19	Undeliverable and Forwarding Address Updates for Recruitment				Y		Recruitment; Returns; Undeliverable
20	Recruitment Requested Resends-Surveys, Institutional HIPAAs					Y	Recruitment; Resend; production
21	Recruitment Requested Resends – General Information				Y		Recruitment; Resend; production
22	Recruitment Day28 Resend Queries					Y	Recruitment; resend; production

Wednesday, July 18, 2012 Page 1 of 9

Report: New Procedures

Lists all procedures in a "version 1.0" status.



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

Report: Recent Revisions of Procedures

Lists all procedures with a version date within the last couple of months. Does not include "new" 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 7/25/2013 8:47 AM

[202] Current Filename:		Using the On-Line Procedure Manual ver1_1.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

Reasons for participating in LTFU

As telephone survey staff, you will often be asked questions such as "What's the point in continuing to participate in this study?" or be told "I've been healthy since I beat cancer so I no longer need to participate." Rest assured, there are VERY GOOD reasons for everyone we contact to participate, even if you or they don't know it. Therefore, the following are a few possible examples of comments you may encounter regarding this theme, the reasons their information is valuable, and possible ways of responding. If you know the reasons why the research is important, then you will be better equipped to answer these types of questions.

Background Information: The Purpose Of The Long-Term Follow-Up Study

The principal aim of the study is to assess late effects outcomes among survivors of childhood cancer. In plain English, that means, we want to know what happens to survivors of childhood cancer after they've received chemotherapy, radiation therapy and/or other treatments given to cure their disease. About thirty years ago, children started surviving cancer due in part to the introduction of aggressive chemotherapy and radiation therapy treatment programs, along with supportive care such as the ability to give blood transfusions and antibiotics for treatment of infections. While medical advances that have allowed for high survival rates are wonderful, we still don't know the full range of long-term effects of treatment over a person's lifetime. That is, we don't know it unless we study these survivors over a long period of time. From your phone calls to participants, you know that some of the survivors have had significant problems with delayed growth and development, development of subsequent cancers, psychological issues related to their cancer and cancer treatment, and other problems – while other survivors have had few problems. You may think (as do many survivors in the study) that we only want to hear from those who have experienced problems related to their disease or treatment. That is not at all true, however, and the next few pages will describe in simple terms, why it is important for all participants in the study to remain enrolled in the study. This means you are going to learn some research methods! We've chosen to use scenarios as a way to present some of the research concepts along with some possible verbiage you can use when answering questions posed by participants.

Recruitment And Retention

Participants were selected for the study from roughly 30 different institutions throughout the US and Canada. Only selected cancer diagnoses were chosen and only a portion of these selected diagnoses were asked to participate in the study. We use a variety of techniques to ensure participants remain in the study. One technique is mailing the LTFU newsletters to participants every six months. This helps us keep current addresses for participants, and it provides important information for survivors on topics of interest to them. Despite our retention efforts, over time, many participants are "lost" – though not lost in the typical sense of being geographically lost. As the study has continued over the years, the study has lost participants for several reasons, including death, refusal to participate, or because we can no longer find them. In research terms, this is called "lost to follow up."

Participants who leave the study, for whatever reason, may have a profound impact on the study results. While anyone can withdraw at any time without penalty, their continued participation is optimal from a research perspective. This is because there is strength in numbers – the greater the number of participants the more convincing (or valid) the findings. When participants tell you they are no longer interested in participating in the study, it is important to find out why and address any misconceptions they may have about their participation.

The following are common scenarios we encounter, your possible response, and the reason behind the response.

Scenario #1: "The Healthy Participant"

Participant states:

"I've been in this study a long time. Nothing has changed. I don't want to do this anymore" Or "I've been healthy since I had cancer. Is my information still useful?"

Possible Response:

The information you provide continues to be valuable over time because the goal of the study is to assess the long-term impact of having had childhood cancer and cancer treatments, whether you have personally had cancer-related health issues or not. It is encouraging and important news for us, the cancer community generally, and to children and families currently battling childhood cancer to hear from people who have led healthy lives since surviving cancer. Your participation helps give us a realistic picture of the long-term effects of childhood cancer.

Reason the information is valuable:

We need all the people who are enrolled in the project to continue to participate. If we only collect information from people who are the sickest, then, it appears that all survivors of childhood cancer have problems. These results are called 'biased' because only the sickest individuals remained in the study. In other words, the only data we might have would indicate that outcomes are poor for all childhood cancer survivors, when in fact, that assumption is far from accurate. The purpose of the study is to try and understand the OVERALL impact of having survived childhood cancer, including the effects of the treatment. We can't do that very well if all the participants who continue to stay healthy drop out of the study. Furthermore, we have many participants who remained healthy for years before they developed a problem related to their cancer. While nothing may have changed for any given participant since they had cancer up to the present date, there is no way to know that it will or will not change in the future without following up with them.

Scenario #2: "Unrelated Health Problems"

Participant states:

"The survey is long and asks a lot of questions that don't have anything to do with my cancer." Or, "My current health problems are unrelated to my cancer."

Possible Response:

Researchers attempt to gain a comprehensive view of what life is like for survivors of pediatric cancer, which is why the survey may seem long and may ask questions you find to be unrelated to your childhood cancer.

Reason the information is valuable:

This study looks at many effects that are potentially associated with having survived pediatric cancer and its treatments. For example, some illnesses that most people consider part of aging may occur at an earlier age in survivors of pediatric cancer. Also, although health-related questions comprise most of the questions, researchers are not only interested in medical outcomes. For instance, researchers may want to know whether people that survive pediatric cancer make about the same income, more income, or less income compared to people who didn't have pediatric cancer. Or they may want to know if they tend to smoke more or less than people who didn't have pediatric cancer. Why do the researchers care? Well, there may be something unique about the population of childhood cancer survivors that impacts factors such as income levels, smoking rates, education levels, marriage status, etc. This is not the same as saying having had childhood cancer causes certain outcomes; it merely shows trends among survivors. The information provided by our participants can be used to support the need for additional resources, changes in insurance regulations, and increasing education for medical providers in the community who provide care to survivors of pediatric cancers.

Scenario #3: "Concerned over security of information provided"

Participant states:

"What do you do with my personal information?" Or "Why do you need to know my income?"

Possible Response:

We keep all your answers confidential. Only researchers have access to the information you give. In fact your name and other personal identifiers are removed from the information you give us. Every person is assigned a unique identification code and there are several steps that need to be done to link the names and the ID's to your personal information. No data are ever stored on laptops and only authorized individuals have access to the data. We also have a Certificate of Confidentiality. This means that we will not provide information to insurance companies or other agencies.

Reason the information is valuable:

First, the information gathered is kept confidential. With the many news reports of stolen computers containing personally identifiable information, it is only natural to wonder about the safety of the information participants provide. Data are never stored on laptops and there is a series of checks to ensure confidentiality. Second, researchers look at the group as a whole, and not at individual participants. Individual health outcomes and behaviors will vary among participants. Data are presented as the averages from various questions that are used as the outcome. So for instance, personal income levels are not used to in any way "mark" an individual or to pass judgment on them, but rather used to generate an average income level for the participant group as a whole based on the responses of everyone who participates. Data reports might read something like this: "Participants who have received cranial irradiation after the age of three generally make $13,000 less than those who have not received cranial irradiation." Nowhere in the reports will it list "Participant James Monroe" makes $13,000 less than Participant Mike Adams."
NOTE: Please see also the document *PHI Concerns Version 4* located at Z:\SJShare\SJCOMMON\ECC\Interviewers\Calling Tools.

Scenario #4: "Of what benefit is the study to me?"

Participant states:

"How is this study supposed to help me?"

Possible Response:

The goal of the study is to identify the late effects of disease or treatment and to pass that information along to you so that you and health care providers will be able to control some of the health outcomes. We gather all the information from participants and provide some feedback to you in the newsletter. Also, your experiences are used to help improve outcomes for future families and children who have or will have similar experiences.

Reason the information is valuable:

Information received from this study may not directly help survivors. Many participants say they feel good about contributing to medical knowledge to help future generations. Some participants learn more about the importance of medical follow-up and early diagnosis of conditions that are associated with their childhood cancer through reading the newsletter or by filling out the survey. The main benefit comes from the knowledge gathered from the thousands of people who participate, which in turn is used to learn more about childhood cancer, improve future treatment methods, and improve follow-up procedures for future survivors – with an overall goal of reducing negative outcomes and improving lives.

Scenario #5: Siblings "Why Am I In This Study?"

Sibling participant states:

"I don't understand the point of my participation as a sibling."

Possible Response:

As a sibling, you are a vital part of this study. The information you give, combined with that of all the siblings, is used as the comparison group against which we measure the survivors' outcomes. If as a whole the outcomes for the sibling group are different than the survivor group (those that had cancer), it gives us valuable information about what the long-term effects of cancer survival and cancer treatments are. Without siblings' participation, the results of the study would not be valid.

Reason the information is valuable:

In research, it is important to have a comparison group. The siblings provide exactly that. The survivors of childhood cancer who are participants in the study are called "cases". The siblings are called "controls" (the comparison group). Let's say we are interested in answering the following question: "Do survivors of childhood cancers have an increased risk of developing a subsequent cancer?" Since we already know about the cases, we know we can follow them over time and count the number of subsequent cancers. But doing that alone will not tell us whether the risk of developing a subsequent cancer is higher, the same, or lower than it is for other groups. Thus, we need to compare that number to a "control" group. Since it would be impossible and unreasonable to ask every single person in the U.S. and Canada who did not have childhood cancer to fill out the survey, there must be a smaller group of people to use as the control group. Similarly, it wouldn't make much sense to compare the survivors to another group totally unlike them because then any differences found between the two groups could be the result of reasons other than what the researchers want to answer. The trick in defining a control group is to identify a group that is most similar to the cases – and one that is "reachable". Therefore, siblings who were healthy at the time of recruitment are an excellent choice for the control group because they have the same parents and were likely raised in the same environment as the participants. In this way they are similar to the cases (except they didn't have cancer and weren't personally exposed to cancer treatment). Also, they are "reachable" in the sense that we have already identified and contacted the survivors and families of survivors who are willing to participate. Having a comparison group enables us to answer the question we posed: "Do survivors of childhood cancers have an increased risk of developing a subsequent cancer?" We can follow the participants and count the number of cancers they develop and compare that to the number of subsequent cancers the sibling controls develop. Having the control group enables investigators to compare health events, life events, and lifestyle choices between the cases and the controls.

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

TYPES OF CANCER AND CODES

Last number of the CCSSID indicates cancer type. (example: 13107803, last number is a "**3**," indicating Hodgkin's)

Number	Cancer	Description
1	Leukemia	A cancer of the blood or bone marrow. Leukemia is a broad term covering a spectrum of diseases.
2	Central Nervous System	A disease in which malignant (cancer) cells form in the lymph tissue of the brain and/or spinal cord. The lymph system is part of the immune system and is made up of the lymph, lymph vessels, lymph nodes, spleen, thymus, tonsils, and bone marrow. Lymphoma can start in the brain, spinal cord, or meninges (the layers that form the outer covering of the brain). Because the eye is so close to the brain, primary CNS lymphoma can also start in the eye (called ocular lymphoma).
3	Hodgkin's	A type of cancer originating from white blood cells called lymphocytes, characterized by the orderly spread of disease from one lymph node group to another and by the development of systemic symptoms with advanced disease. The survival rate is generally 90% or higher when the disease is detected during early stages, making it one of the more curable forms of cancer.
4	Non-Hodgkin's Lymphoma	A cancer that originates in your lymphatic system, the disease-fighting network spread throughout your body. In non-Hodgkin's lymphoma, tumors develop from lymphocytes — a type of white blood cell. Non-Hodgkin's lymphoma is more common than the other general type of lymphoma — Hodgkin's disease. Many different subtypes of non-Hodgkin's lymphoma exist.
5	Kidney	Several types of cancer can develop in the kidneys. Wilms' tumor accounts for about 6% of childhood cancers and is the most common type of kidney cancer in children. Incidence of Wilms' tumor is higher in girls younger than the age of 5 and in African Americans.
6	Neuroblastoma	Neuroblastoma is a malignant (cancerous) tumor that develops from nerve tissue. It occurs in infants and children. Children treated for neuroblastoma may be at risk for getting a second, different cancer in the future.
7	Soft Tissue Sarcoma	Rhabdomyosarcoma is a malignant (cancerous) soft tissue tumor found most often in children. The most common sites are the structures of the head and neck, the urogenital tract, and the arms or legs.
8	Bone	Primary bone cancers (cancers that start in the bones) occur most often in children and adolescents. Two types occur in children: Osteosarcoma (uncommon, accounting for almost 3% of all new childhood cancer cases in the U. S.) and Ewing sarcoma (less common, a little more than 1%).
9	Case Control-reference to sibling control ID	A type of epidemiological study design. Case-control studies are used to identify factors that may contribute to a medical condition by comparing subjects who have that condition (the 'cases') with patients who do not have the condition but are otherwise similar (the 'controls'). Relatively inexpensive and frequently-used type of epidemiological study that can be carried out by small teams or individual researchers in single facilities.

Sources:
http://en.wikipedia.org/wiki/Leukemia
http://health.yahoo.com/lymphoma-treatment/brain-cancer-primary-central-nervous-system-lymphoma-treatment-patient-information-nci-pdq/healthwise--ncicdr0000258030.html
http://en.wikipedia.org/wiki/Hodgkin's_lymphoma
http://www.urologychannel.com/kidneycancer/index.shtml
https://health.google.com/health/ref/Neuroblastoma

Internet Resources

http://www.kadmf.org/ The **Kelly Anne Dolan Memorial Fund** provides advocacy, education, information and financial assistance for the uninsured needs of families caring for terminally, critically and chronically ill, seriously disabled or severely injured children.

http://www.thesamfund.org/ The **SAMFund** is a unique non-profit organization created to assist young adult survivors of cancer with a successful transition into their post-treatment life, by providing financial support through the distribution of grants and scholarships.

http://www.stmfoundation.org/otherscholarships.html The **Stephen T. Marchello Scholarship Foundation** is a nonprofit organization for the purpose of allocating post secondary scholarship monies to survivors of childhood cancer.

http://www.ulmanfund.org/ The **Ulman Cancer Fund for Young Adults (UCF)** to fill the void that exists in health care services. Since 1997, the UCF has been working to provide young adults and their families with a unique and comprehensive system of support. Its mission is to provide support programs, education and resources, free of charge, to benefit young adults, their families and friends, who are affected by cancer, and to promote awareness and prevention of cancer.

http://www.hospitalsoup.com/onlinesearch.asp Find the Best Hospitals, Health Care Systems, Clinics, Nursing Homes and other medical facilities across America and Internationally. With healthcare and medical center listings from around the globe, HospitalSoup.com is your #1 Source for choosing health care, doctors, jobs and employment resources on the Web

https://extapps.ama-assn.org/doctorfinder/recaptcha.jsp **Doctor Finder** provides you with basic professional information on virtually every licensed physician in the United States. This includes more than 690,000 doctors

http://medlineplus.gov/ General health information source, MedlinePlus is the National Institutes of Health's Web site for patients and their families and friends. Produced by the National Library of Medicine, it brings you information about diseases, conditions, and wellness issues in language you can understand. MedlinePlus offers reliable, up-to-date health information, anytime, anywhere, for free.

http://www.pharma-lexicon.com/ A dictionary of over 200,000 medical, pharmaceutical, biomedical & healthcare acronyms and abbreviations. Plus medical news and searches for the medical, pharmaceutical or healthcare professional.

http://www.drugs.com/ the most popular, comprehensive and up-to-date source of drug information online, providing free, peer-reviewed, accurate and independent data on more than 24,000 prescription drugs, over-the-counter medicines & natural products.

http://acor.org The **Association of Cancer Online Resources** a unique collection of online cancer communities designed to provide timely and accurate information in a supportive environment. It is a free lifeline for everyone affected by cancer & related disorders

http://www.cancer.org/ The **American Cancer Society's** website

http://amputee-coalition.org The **Amputee Coalition of American Online Community**, is the nation's leading organization on limb loss, dedicated to enhancing the quality of life for amputees and their families, improving patient care and preventing limb loss.

http://www.beyondthecure.org Information for survivors of childhood cancer presented by the National Children's Cancer Society

http://www.campdream.org/ ***Camp Mak-A-Dream*** is operated by Children's Oncology Camp Foundation and is a medically supervised, cost-free camp for children (ages 6-13), teens (ages 14-18) and young adults (ages 18-25) with cancer and their siblings (ages 6-17). The facility is located approximately 65 miles east of Missoula, Montana on I-90 at the Gold Creek exit, just 3/4 of a mile south of the Interstate.

http://www.cancer.ca The **Canadian Cancer Society** website

http://www.childrensoncologygroup.org/ The **Cure Search- Children's Oncology Group**, provides key information to help support children and their families from the time of diagnosis, through treatment and following cure.

http://www.fertilehope.org **Fertile Hope** is a non-profit organization dedicated to helping cancer patients faced with infertility

http://grouploop.org **Group Loop** is an innovative and groundbreaking program of the Cancer Support Community for teens impacted by cancer – both teens diagnosed with cancer and teens close to someone with cancer.

http://liddyshriversarcomainitiative.org/ The **Liddy Shriver Sarcoma Initiative** undertakes activities that help improve the quality of life for people dealing with sarcoma. Central to this mission are our goals of increasing public awareness of sarcoma and the lack of young adults in cancer-based clinical trials and raising funds for sarcoma-related research.

http://limbsforlife.org The **Limbs for Life Foundation,** information on providing a financial bridge between low-income amputees and the quality prosthetic care needed to restore their lives.

http://www.cancer.gov The **National Cancer Institute** website

http://www.nwtsg.org **The National Wilms Tumor Study (NWTS)** is currently conducting a Late Effects Study (LATE) designed to identify treatment related conditions that may develop in participants who were originally treated on one of our five clinical trials. Another one of our goals is to serve as a resource for anyone ever diagnosed with Wilms tumor and their families.

http://www.canceradvocacy.org/ **The National Coalition for Cancer Survivorship** is the oldest survivor-led cancer advocacy organization in the country and a highly respected authentic voice at the federal level, advocating for quality cancer care for all Americans and empowering cancer survivors.

http://cancer.med.upenn.edu/ **Oncolink**- Abramson Cancer Center of the University of Pennsylvania, providing comprehensive information about specific types of cancer, updates on cancer treatments and news about research advances.

http://www.patientadvocate.org **Patient Advocate Foundation's Mission Statement**
Patient Advocate Foundation is a national non-profit organization that seeks to safeguard patients through effective mediation assuring access to care, maintenance of employment and preservation of their financial stability.

http://planetcancer.org **Planet Cancer**, a community of young adults with cancer.

http://www.survivorshipguidelines.org/ The Children's Oncology Group Long-Term Follow-Up Guidelines for Survivors of Childhood, Adolescent, and Young Adult Cancers

http://www.curesearch.org/ an online resource for patients, their families and support systems, that provides up-to-date information about the various types of children's cancer along with research trials, definitions and descriptions of tests, procedures and treatments and information to help families manage the emotional aspects of caring for a child with cancer.

https://www.cure4kids.org/ the leading education and collaboration web site dedicated to supporting the care of children with cancer and other catastrophic diseases worldwide.

St. Jude Life Food Frequency Questionnaires

Background

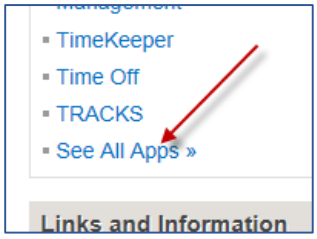
Participants complete an online Food Frequency Questionnaire (FFQ) as part of their St. Jude Life visit. Currently, Janna Lipford (CRA) has the primary responsibility of adding the appointment to her Outlook calendar (based on what is in MILLI), finding the patient in clinic, setting up the survey on a computer, and following the login instructions for each participant. If she is not able to cover an appointment, then she emails Aaron McDonald who ensures a staff member can take care of the appointment. The assigned staff member will not usually need to stay with the participant as he or she completes the questionnaire, although the staff member does need to check to see that the participant has logged out after the appropriate amount of time has passed.

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.

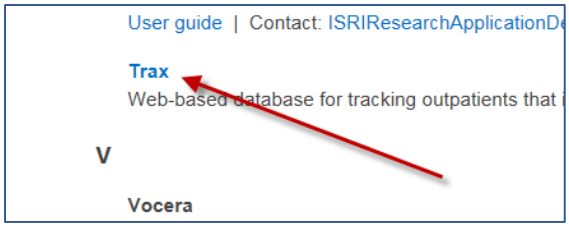
The participants will be in the Translational Trials Unit (TTU).

Procedure

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.

C. 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**.
   i. If the appointment cannot be confirmed and has been rescheduled, please notify Janna Lipford and Aaron McDonald.
   ii. 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.

D. Using the computer, **check the person into the FFQ appointment**:
   i. Click on Clinical Desktop from the homepage.
   ii. Enter your user name and password.
   iii. Click on Clinical Desktop.
   iv. Click on the icon for Power Chart P134.
   v. Click "Patient" from the task bar then select Search.
   vi. Find the participant by MRN.
   vii. Double click the Participant's name.
   viii. Select "Research Assistant".
   ix. Click **OK**.
   x. When the patient page displays, click on Patient Schedule.
   xi. Locate the ACT SJLIFE Food Questionnaire appointment in the patient's schedule. Right-click the appointment. Use the pop-up menu:
      a. To check in, select Check In…
      b. To check out, select Check Out…

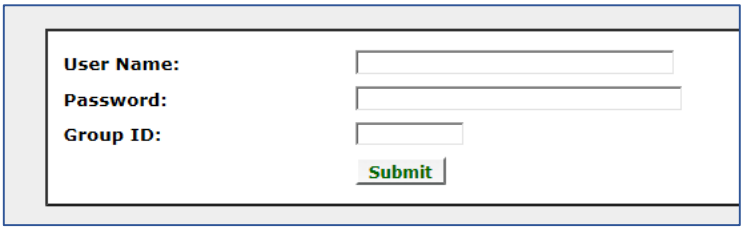
2. If the **patient does not show up for the appointment** (i.e., more than 15 minutes late for the appointment), please notify Jenny Lanctot and Aaron McDonald via email that the patient was a "no show."

3. **Access the Food Questionnaire** on the computer in the room:
   A. Log on to the computer using your login.
   B. Go to the website: https://www.nutritionquest.com/login/
      i. Enter the patient's user name – this is the participant's Medical Record Number (MRN).

NOTE: If the MRN does not work, call Shavon Dale, Aaron McDonald, or Janna Lipford (see the points of contact list below).

ii. Enter password: sjlife

iii. Enter Group ID: 245



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.

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)

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

4. **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.

**Important* – The FFQs should be completed using the website. You should rarely, if ever, need to use the paper-based FFQ.

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_6.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

Using MILLI for FFQ Appointments

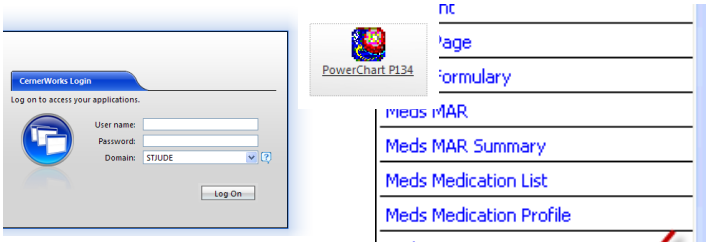
Background

St Jude Life participants complete the Food Frequency Questionnaire (FFQ) online, after a project staff person logs them into the online system. The FFQ is an appointment in MILLI. Part of the FFQ Interviewer Procedure is to check the individual in (and out of) the FFQ appointment using MILLI.

Procedure

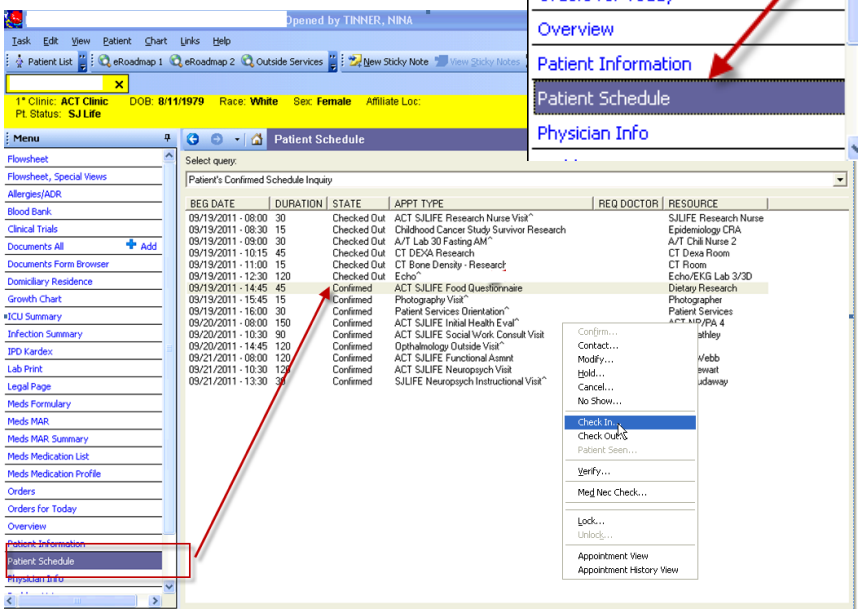
This procedure illustrates the appointment check in/out process used in MILLI.

1. Use the Internet browser to go to the Intranet. http://home.web.stjude.org/
2. Click on **MILLI** in the Popular Tools and Apps section



3. Log in with your username and password.
4. Click on the icon for **PowerChart P134**
5. Find the participant by MRN.

6. When the patient page displays, click on **Patient Schedule**
7. Locate the **ACT SJLIFE Food Questionnaire** appointment in the patient's schedule. Right-click the appointment. Use the pop-up menu:
   a. To check in, select Check In…
   b. To check out, select Check Out…



Revision Record

Printed 3/9/2015 1:19 PM

(164) Current Filename:		Using MILLI for FFQ Appointments ver 1_0.doc	
Revision No.	Date	Responsible Author	Change Description
1	9/20/11	J.Bates	Initial Development
1.1	3/9/15	Lipford/McDonald	Log-in screen change

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.

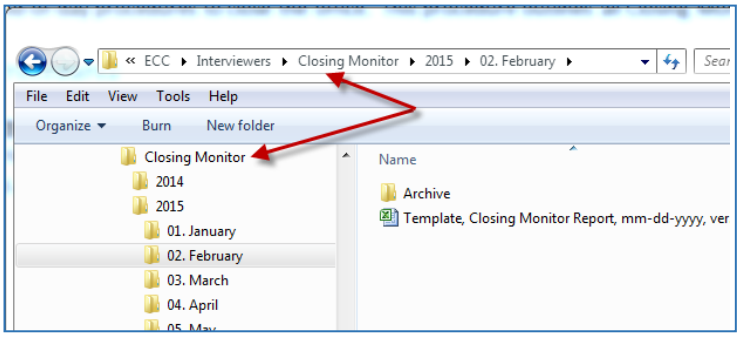
Completing and Submitting the Closing Monitor Report

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.

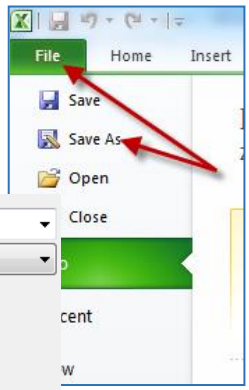
ii. Open the Excel file named **Template, Closing Monitor Report, mm-dd-yyyy**.

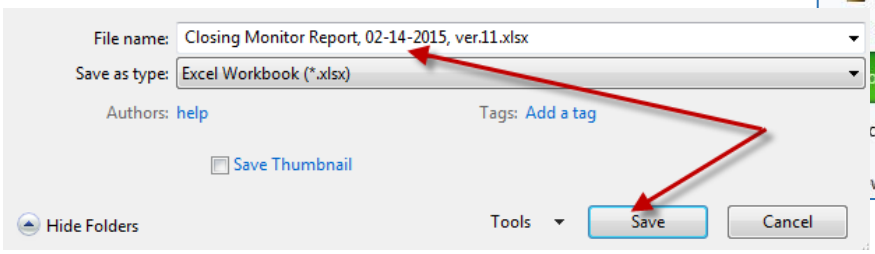
B. In the report template, save the report with the current date *before saving any data*.

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.

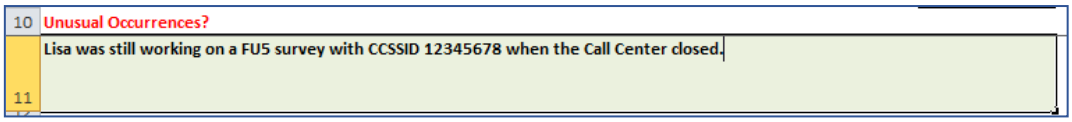
47	Tomorrow's Appointments	Appointment Time (Calendar Order)	CCSSID or SIBID	SI ID Who Set Appointment	SI ID Sched to Cover Appt	Appointment Type
48	1	5:00:00 PM	23456789	170	170	FU5 Survey
49	2	11:00:00 AM	87654321	166	163	Expired Case Baseline

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:

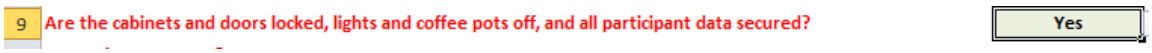
a. Verify that the entries in the closing report match the Call Center calendar and the emails received from SIs during the day.
b. If the imbalance remains unresolved, **report the imbalance** in the **Unusual Occurrences** cell (row 11). *EXAMPLE: DEB indicates 3 FU5 surveys. Calendar events plus emails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

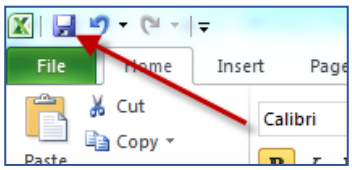


EXAMPLE 2: The power went out at 8:30pm.

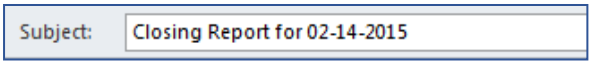
H. After ensuring that the cabinets and doors are locked, the coffee pot burners are turned off, and all participant data has been secured, populate the appropriate light-green cell (G9) with "Yes".



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

New Survey Interviewer Post Training Checklist

SI _____ **Date** _____

General

1. SI Training and Orientation binder
2. LTFU Expansion Recruitment Interviewer Manual
3. Campus tour
4. Self-scheduling
5. Clocking in and out
    a. Timeclock - where to clock in/out
    b. PC – TimeKeeping system
    c. Occurrences and progressive discipline
6. Journal?
7. Call Assignment workbooks
8. Building and department tour
9. Emergency procedures
    a. Fire drills
    b. Extinguisher
10. Confidentiality agreement
    a. HIPAA
    b. Protecting Privacy
    c. Locking PC
11. Monthly training meetings
12. Continued Education
    a. LTFU Study site
    b. CCSS Site
    c. St. Jude workshops and seminars
    d. Mandatory training classes
    e. CITI Training
13. Break periods
14. Communication
    a. Email, background, signature (see policy 50.011)
15. Locating participants
    a. Databases
    b. SJL Database
    c. Using MILLI
16. Equipment
    a. Computer
        i. U drive

   ii. Z drive
   iii. Desktop Icons
   iv. Saving documents to desktop vs. saving a shortcut
b. Printers and faxes
c. MS Lync

17. Review training checklist
18. Review interviewer training binder
19. Dry erase board
20. File cabinet A
    a. Forms and procedures
    b. Call Center Appointment calendar
    c. Incentives
        i. Employee of the Quarter
        ii. Brilliant Ideas program
        iii. Project based
21. Posted information
22. Closing Monitor duties
23. The SOP library
24. CCSS protocol
25. Current goals
26. Future goals
27. Mentor?
    a. Experience
        i. What did you learn from your mentor
            1. Positive impressions
            2. What could be done better?
28. Calls
    a. Incoming
    b. Outgoing
        i. Frequency
        ii. Time of day
        iii. Day of week
        iv. Messages
29. Preparedness
    a. Transferring calls
    b. Taking messages
    c. Checking voicemail
    d. Incoming Call guidance
    e. Protecting PHI
    f. When to get help
30. Pay schedule?

31. Working cases: Recruitment and Baseline
    a. Pre call, during call and after call
    b. Databases
32. Data entry
    a. Recruitment
    b. Baseline
33. Helping people
    a. Smile
    b. Tone
    c. Identifying and handling barriers
    d. Controlling the discussion towards a decision
34. Non-English speaking cases
    a. Spanish
    b. Other languages
35. Baseline overview
36. Minor and Expired participant surveys
37. Pronunciation of drugs and genetic terms
38. Oral presentation: read aloud
    a. HIPAA
    b. Informed Consent
39. Database documentation for various outcomes using SOPs (x1 in English and x1 in Spanish, if appropriate)
    a. Recruitment
    b. Baseline
40. “Reasons for Participating in the LTFU”
41. Review audit form (SOP: Survey Interviewer Phone Contact Check-Off List).
42. Effort certification
43. Delegation of Responsibility (DOR) Log
44. Review the following SOPs:
    a. Expansion Recruitment Process for Interviewers
    b. Entering Recruitment Holds and Resuming Work on the Case
    c. Data Entry Process for Verbal HIPAA Authorizations
    d. Verbal HIPAA Authorization Process for Riley (Institution 24)
        i. Developing confidence in reading the HIPAA, informed consent, and survey and in pronouncing the terms to make a professional presentation to our participants
    e. Requesting Participant Copies of Recruitment HIPAA
    f. Emailing LTFU Internet Links to Expanded Cohort Cases
    g. Importance of reading all information in the survey (instructions, questions, and answers) exactly as they are written
    h. Decoding CCSSID
    i. Handling Additional Phone Numbers

j. Assessing and Addressing Cognitively Impaired Potential CCSS Participants
k. Use of Care of Field
l. Death Notifications about St. Jude Cases
m. Processing Refusals: Participants, Proxies, and Associates
n. Call Center Appointment Calendar
o. Using and Creating Participant MS Word Call Logs (Phone Contact Log)
p. Expansion Baseline Survey Calls
q. Dana Farber Cancer Institute (DFCI) Baseline Survey Calls
r. Expansion Baseline Online (Verbal) Consent Procedures
s. Partially Completed Survey Tracking Log
t. Email Appointment Reminders for Baseline Surveys
u. Sending a Missed Appointment Follow-Up Email
v. Sending Spanish Thank You Notes
w. Survey Interviewer Tech Support Procedures
x. Questions to Ask to Determine Why a Person is Calling
y. Importance of not saying things like “survey”, “gift card”, “something important” or otherwise pushing the limits of what we say in voice messages
z. Importance of being conservative instead of liberal with information provided in voicemail or to associates
aa. CCSS Call Center Scheduling Policy
bb. Survey Interviewer Self-Scheduling

45. Review FFQ
46. Questions and answers