

Coordinating Center Report

CCSS Investigators Meeting

Todd Gibson – CCSS Project Director

June 19, 2019

CCSS

Childhood Cancer
Survivor Study



St. Jude Children's
Research Hospital

An NCI-funded Resource

Outline

CCSS

1. Participant engagement efforts
2. Follow-up 7 survey plans
3. SMN and biological sample updates
4. Active ancillary studies
5. Other activities (NDI, Virtual Pooled Registry, surgery coding)

Participant Engagement

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Objective:

Engage with participants to get a better idea of their thoughts and feelings about the study

3-part strategy

1.

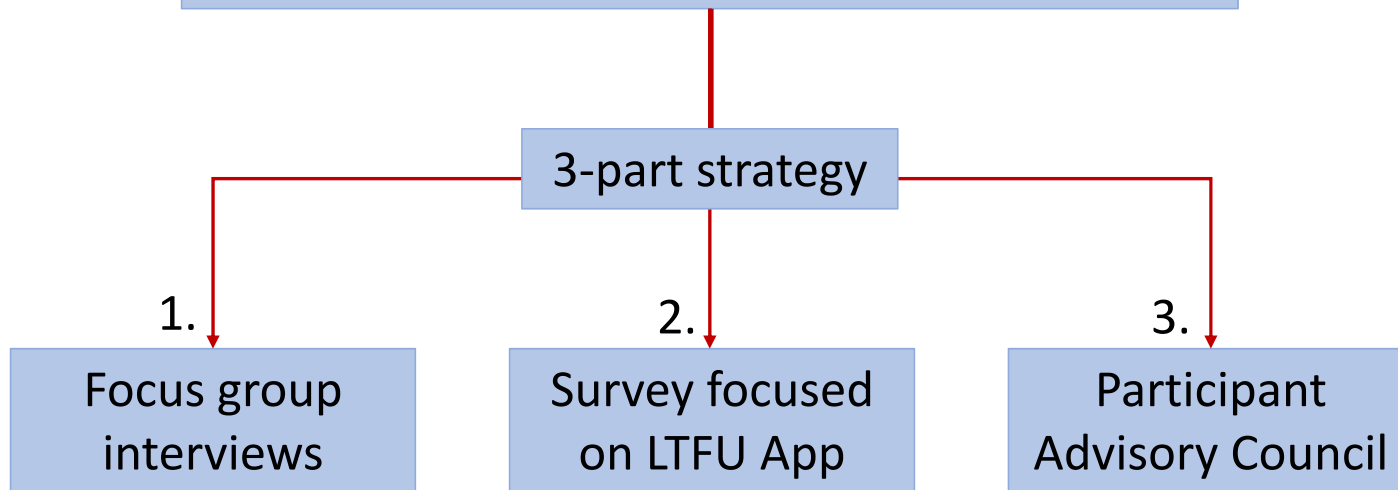
Focus group
interviews

2.

Survey focused
on LTFU App

3.

Participant
Advisory Council



1. Focus Group Interviews

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Goal: Learn about how survivors feel about participation in the Long Term Follow-Up (LTFU) Study (aka CCSS)

- what motivates them?
- what features might increase engagement?

Method: Invited survivors to participate in a phone interview conducted by the Harvard Health Communications Core

Response: Conducted 12 interviews

- Included some participants who did not complete the most recent follow-up survey

Focus Group Interviews

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Key Themes:

Reasons they continue to participate:

- Helping people
- Increasing knowledge (scientific and personal) about late effects
- It's easy

Ways they feel they benefit:

- Learning how they can protect their own health
- Knowing they are helping others

How the study could provide more benefits/ be more useful:

- Knowing how their contributions are advancing knowledge
- An app

Challenges to participating in the study:

- None (11/12); survey could be easier to take (1)

2. App Survey

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- Goal: Learn what participants think about a possible LTFU Study app in a large, generally representative subgroup of survivors
- Method: Sent app survey to 1000 randomly selected LTFU participants
- Response: Received 387 completed surveys

App Survey

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1. First, we have a few questions about your use of smartphones:

a. Do you have a smartphone?

94% replied "Yes"

☐ Yes

☐ No [→ Skip to Question 2.](#)

b. About how many apps do you currently have on your smartphone? _____

91% have at least 10
77% have at least 20

c. About how many of these apps have you used in the past month? _____

91% have at least 5
72% have at least 10
39% have at least 20

d. Would you be willing to download an LTFU app? ☐ Yes ☐ No ☐ Maybe

64%

6%

30%

App Survey Results

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2. Which of the following best describes how you feel about a possible LTFU Study app:

30%

☐ Great idea - I definitely want to have this for my phone

48%

☐ Interesting idea - I will probably give it a try

13%

☐ Maybe interesting - but only if it has the features I really want

9%

☐ Not interested - I have no interest in any type of LTFU app

App Survey

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Desired features for a participant app:

- Ability to complete surveys
- Access to medical resources and advice
- Personalized treatment and education information
- Latest study results, highlights of the impact of the study
- Survivor community/social media/connect with other survivors

3. Participant Advisory Council

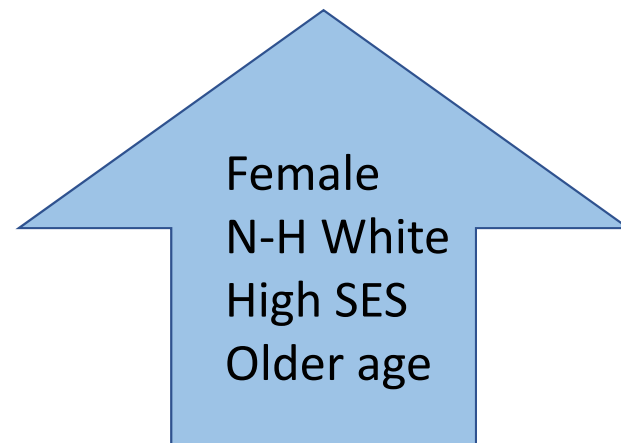
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Goal: Establish a pool of willing study participants who can be available to provide rapid feedback when needed in the future (e.g. surveys, pilot tests, focus groups)

Initial Methodology: Open invitation

Response: To date, 103 participants have volunteered

- 97 survivors, 6 siblings
- Not a representative sample



Participant Advisory Council

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Future Plans:

- Engage PAC for feedback on new communication and study materials
- Initial pilot testing of mHealth activities
- Active recruitment to increase diversity of the PAC

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Follow-Up 7 Survey Development

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Goal: Comprehensive update of health outcomes, behaviors, health care, medical surveillance, etc.

Survey Development: Update the Follow-Up 5 survey

Major sections:

- Updated Race/ethnicity
- Socioeconomic Status
- Medical Care
- Medical Tests
- Prescription Meds
- Subsequent Cancers
- Medical Conditions
- Feelings/Emotions
- Health Habits
- Health and Well-being (SF-36)
- Problem Solving/Cognition
- Hospitalizations/ER Visits

Length: Paper version is 32 pages

Plans for Follow-Up 7 Administration

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New 2-phase survey administration design

Phase 1: Encourage online completion of FU7 survey with full roll-out of the online survey to all participants

Follow-Up 6 Participation: Survivors

Meeting Book
P.18

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	Short		Medium		Long	
	N	%	N	%	N	%
Mailed	10,327	100.0	5,489	100.0	1,640	100.0
Returned	7,839	75.9	4,084	74.4	1,162	70.9
Paper	3,360	43%	1,914	47%	524	45%
Online	2,820	36%	1,596	39%	487	42%
Interviewer	1,659	21%	574	14%	151	13%

Participation results as of May 2019

Plans for Follow-Up 7 Administration

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New 2-phase survey administration design

Phase 1: Encourage online completion of FU7 survey with full roll-out of the online survey to all participants

Why?

- Increased efficiency for CCSS
- Improved experience for participants
- **Drive uptake of the new myLTFU platform**

Introduction to myLTFU

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Objective: Easily accessible “home page” for survivors

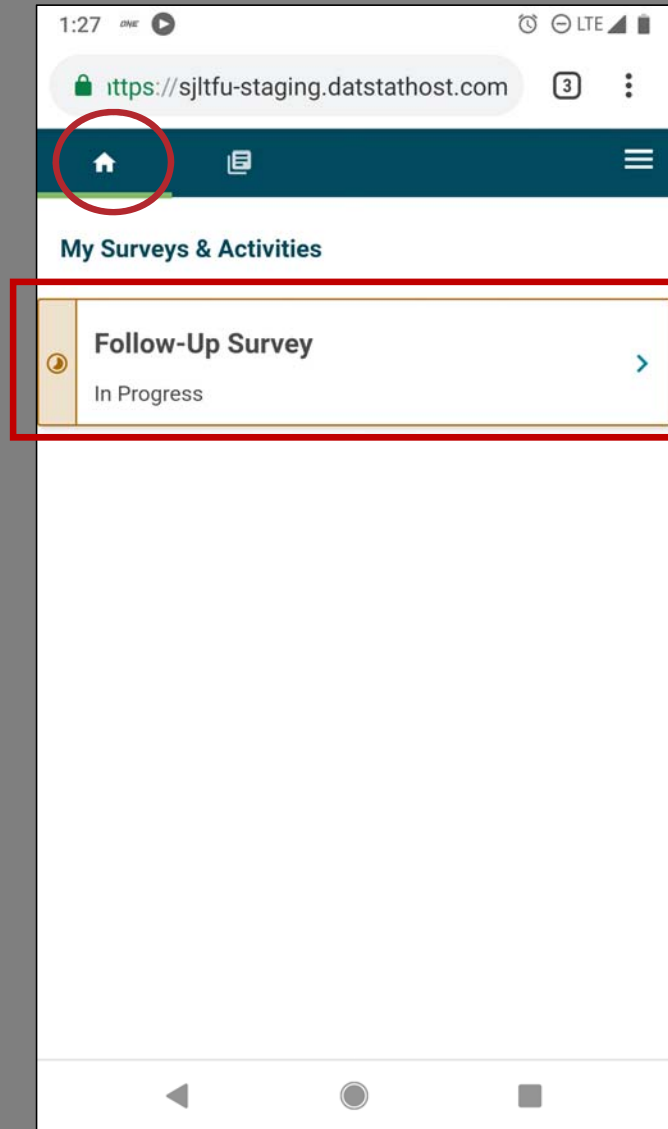
- Complete follow-up surveys
- Summaries of CCSS study results
- Curated survivor-focused resources
- Provide feedback to the study team

Datstat Connect platform: mobile-enabled web application

- Not a native app that requires download
- If interested, participants can easily add an icon to their home screen
- Integrated with our current online survey tool

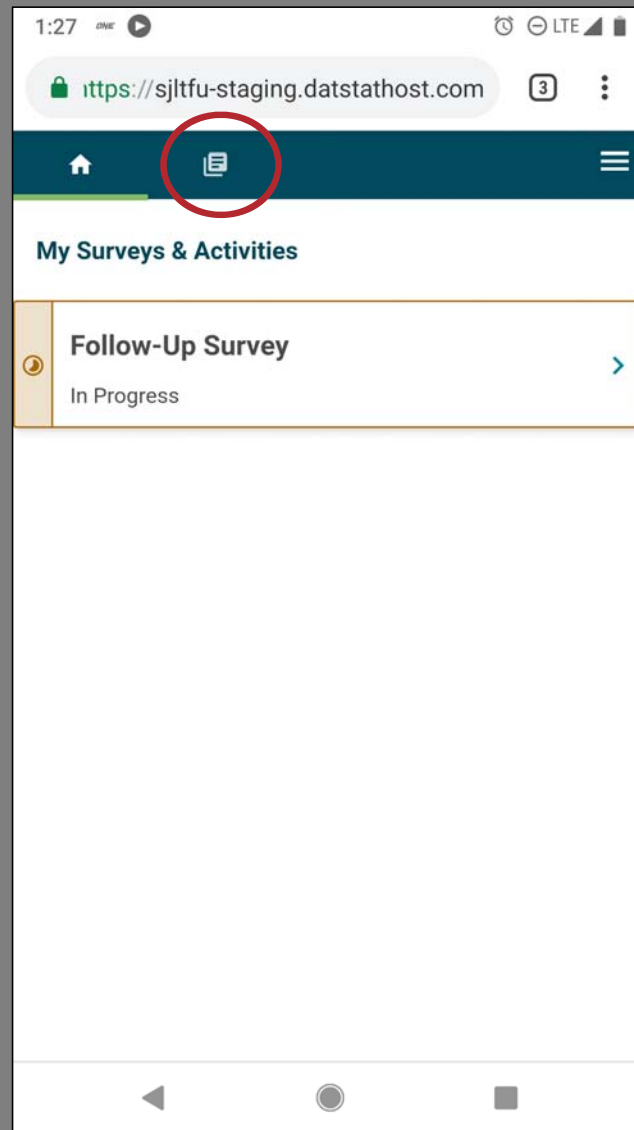
myLTFU

- Screenshots



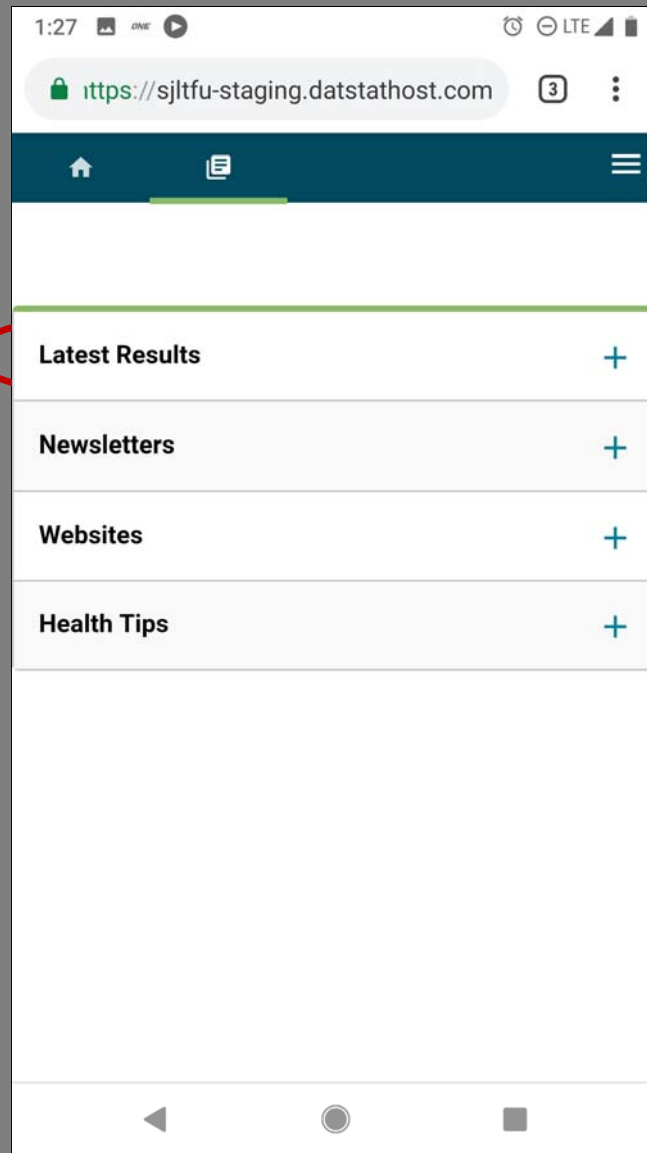
myLTFU

- Screenshots



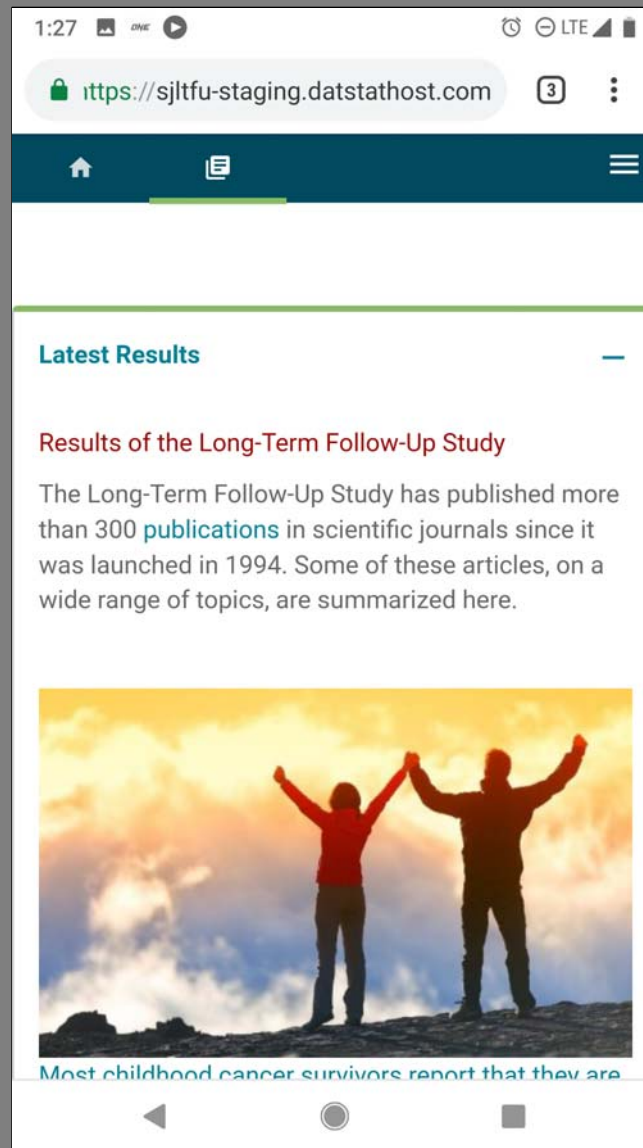
myLTFU

- Screenshots



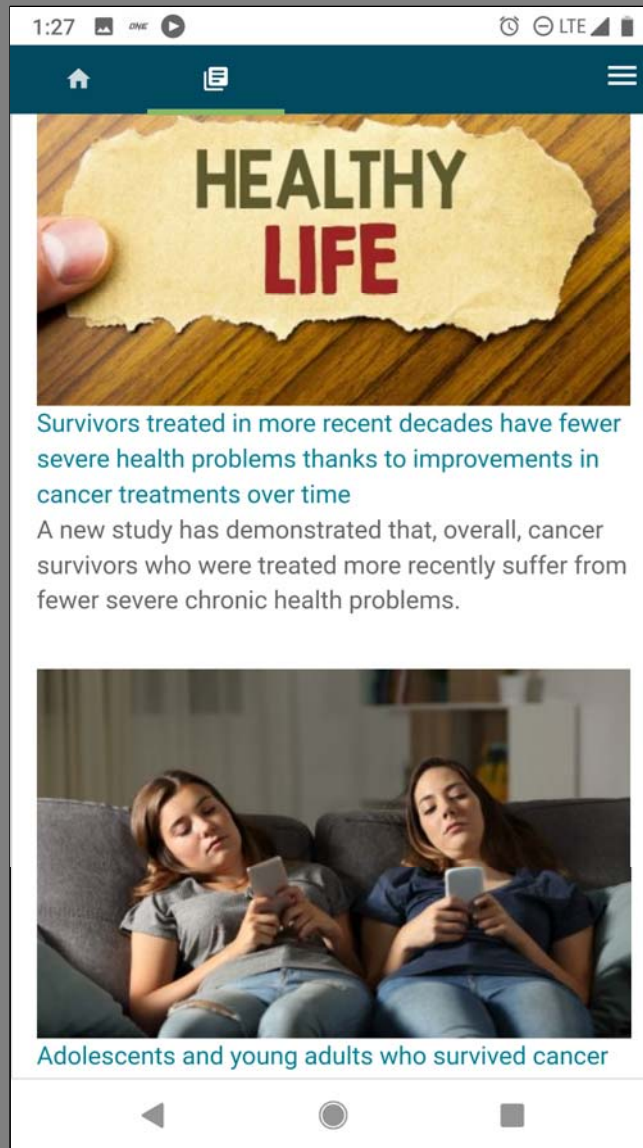
myLTFU

- Screenshots



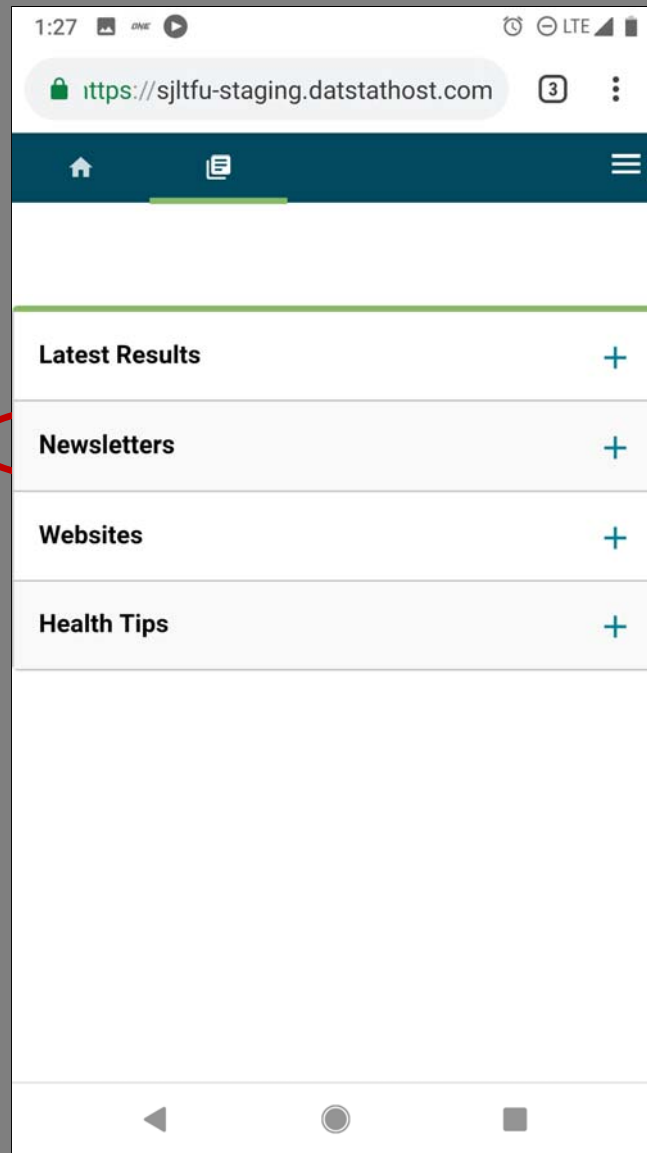
myLTFU

- Screenshots



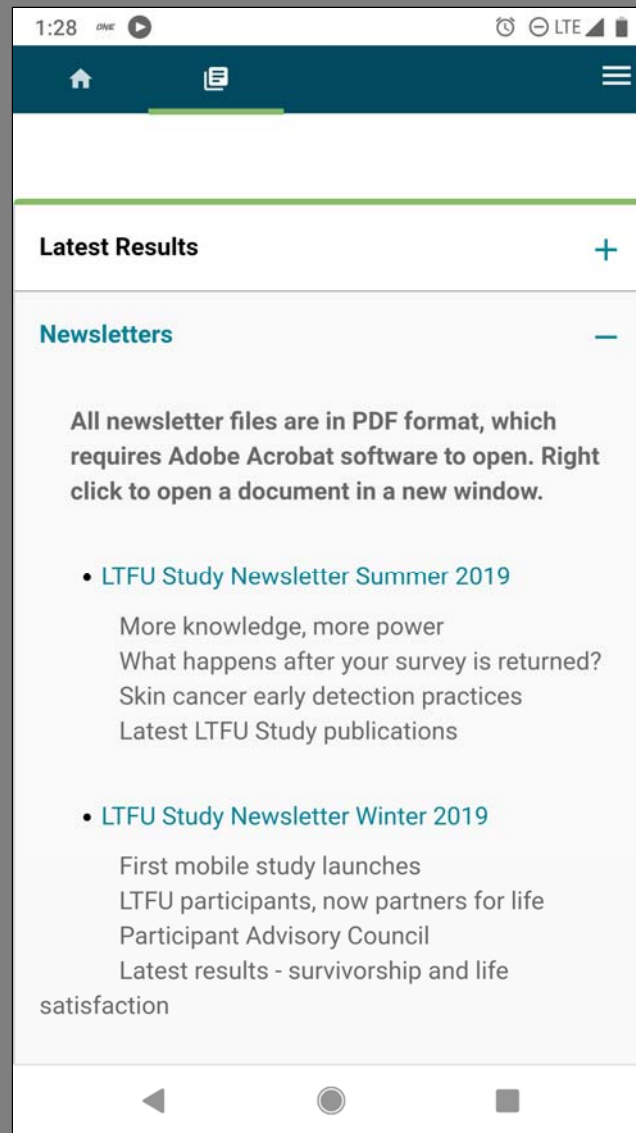
myLTFU

- Screenshots



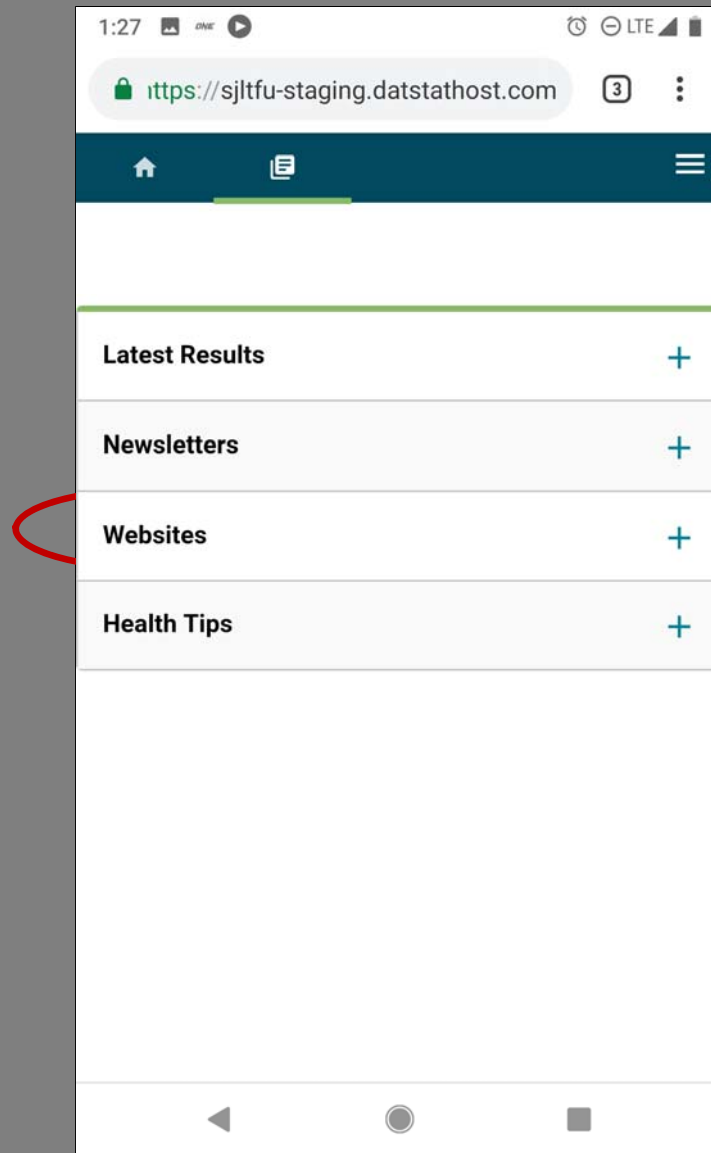
myLTFU

- Screenshots



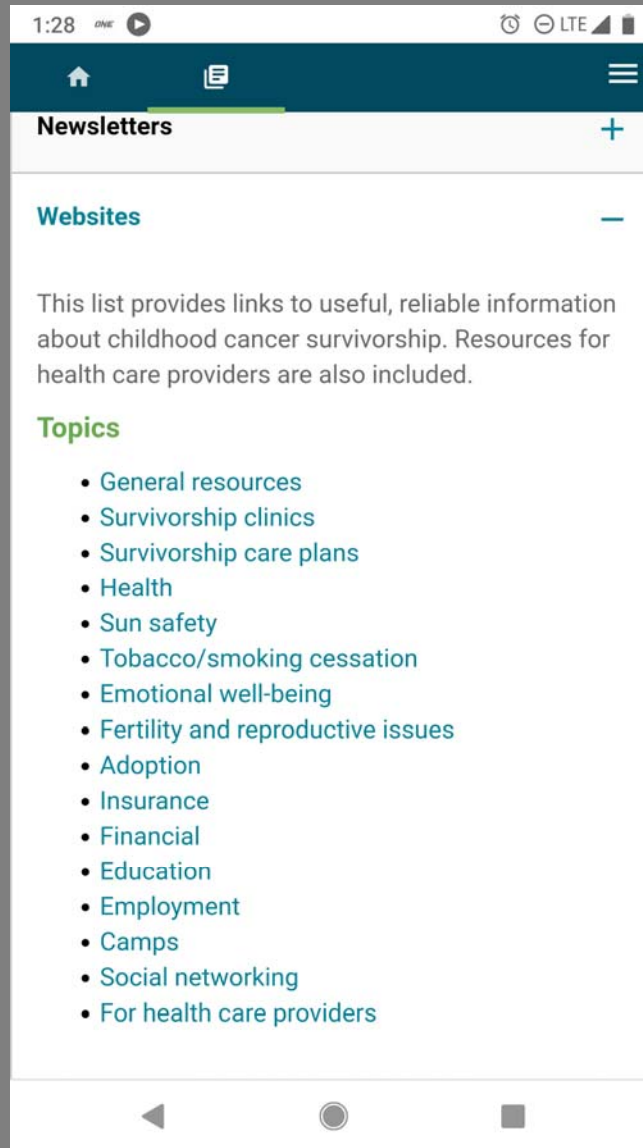
myLTFU

- Screenshots



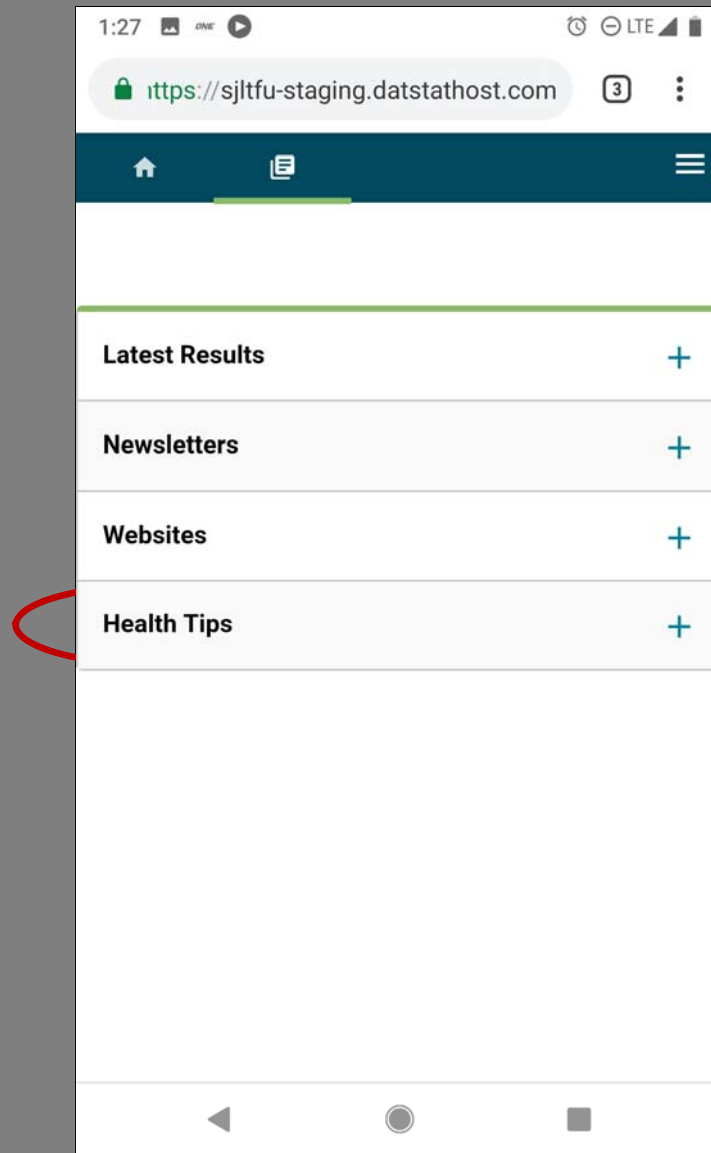
myLTFU

- Screenshots



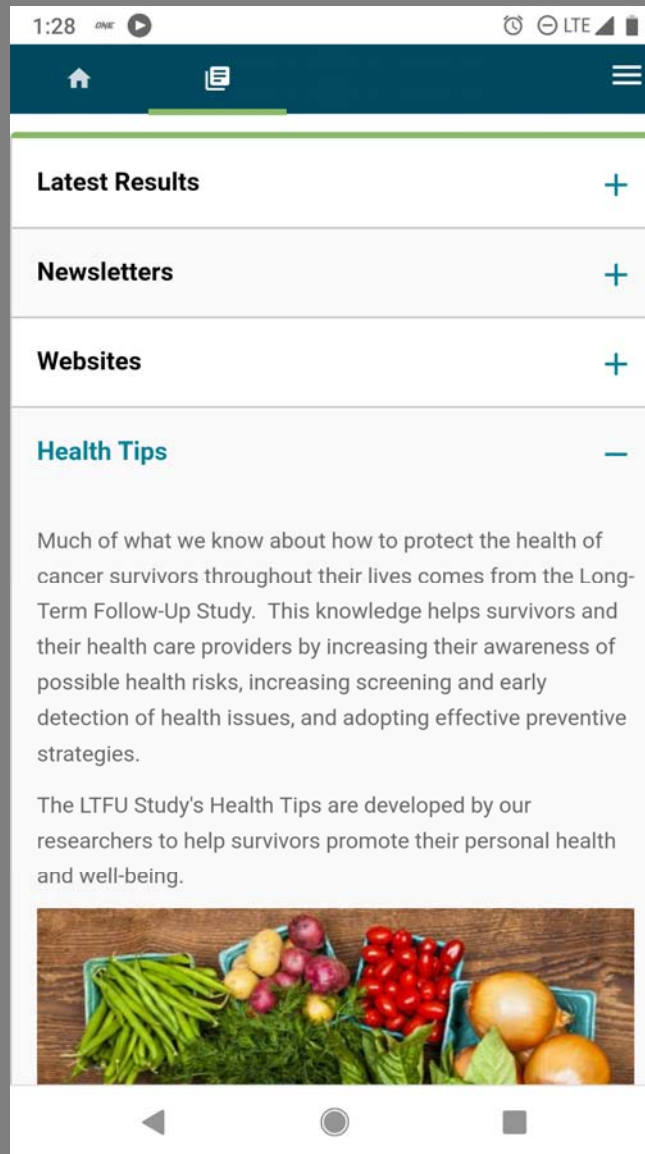
myLTFU

- Screenshots



myLTFU

- Screenshots



Features in development or planned for the future:

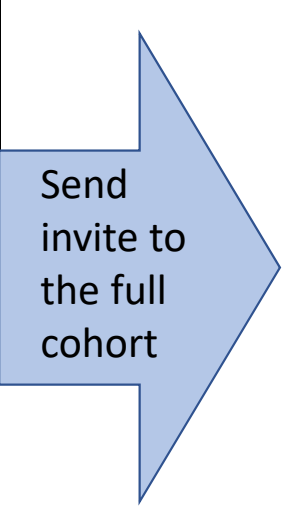
- Personal history of CCSS participation
- Learn about other CCSS research opportunities
- Personalized health links based on treatment history
- Interactive view of survey results
- Video messages

Plans for Follow-Up 7 Administration

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Phase 1: Encourage online completion of FU7 survey with full roll-out of the online survey to all participants

August 2019



Send
invite to
the full
cohort

Invitation to complete online survey

- Email invite with link to myLTFU (have email address for ~ 75% of the cohort)
- Postcard via mail to all participants
 - Explain benefits of online survey and myLTFU
 - Provide info to access survey
 - **Announce paper version will be coming, still a great option if preferred**

Follow-Up 7 Phase 1 Postcard

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LTFU
Long-Term Follow-Up Study

More knowledge = More power

→ Your new LTFU survey is online now!

for today's survivors
and future generations



Thanks to what we've learned,
survivors are living longer, healthier lives.

Let's keep learning, together.

More convenience

[icon]

- Save the new myLTFU portal to your screen
- Open it to complete your survey on a secure mobile-friendly platform
- Answer survey questions anywhere, on any device
- Pause and return whenever you want

More benefits for you

[icon]

- Receive a \$10 gift card after completing your survey
- Have the option to donate the amount of your gift card to LTFU research
- Complete your survey online by date xx, 2019 and enter raffles for Apple Watches
- Use the myLTFU portal to see how your survey responses compare with other participants
- Log in to access health resources tailored to you (coming)

More benefits for others

[icon]

- Faster results = Improve care more quickly
- Reduced mailing and printing costs = More funds for LTFU research
- Less paper = Healthier environment

→ **Log in to your online survey:**

URL: XXXX.XXXXXXXX.XXXX
User name: XXXXXXXX
Password: XXXXXXXX

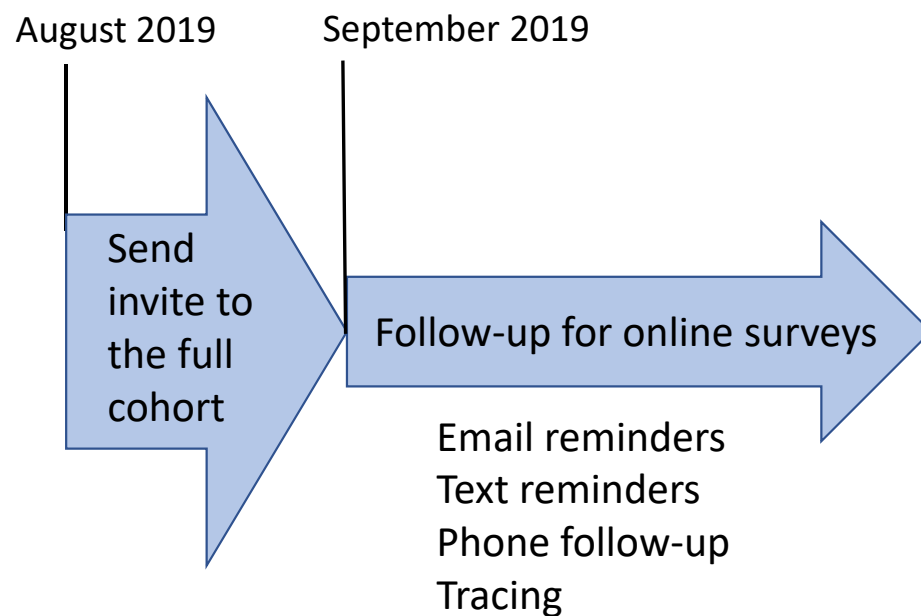
Prefer to complete it another way? You can still complete your surveys on paper or by phone with an LTFU interviewer if you prefer. We'll start mailing paper versions in January 2020.

Questions or concerns? We're happy to help Visit: ltfu.stjude.org | Call toll-free: 1-800-775-2167 | Email us: ltfu@stjude.org

Plans for Follow-Up 7 Administration

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Phase 1:

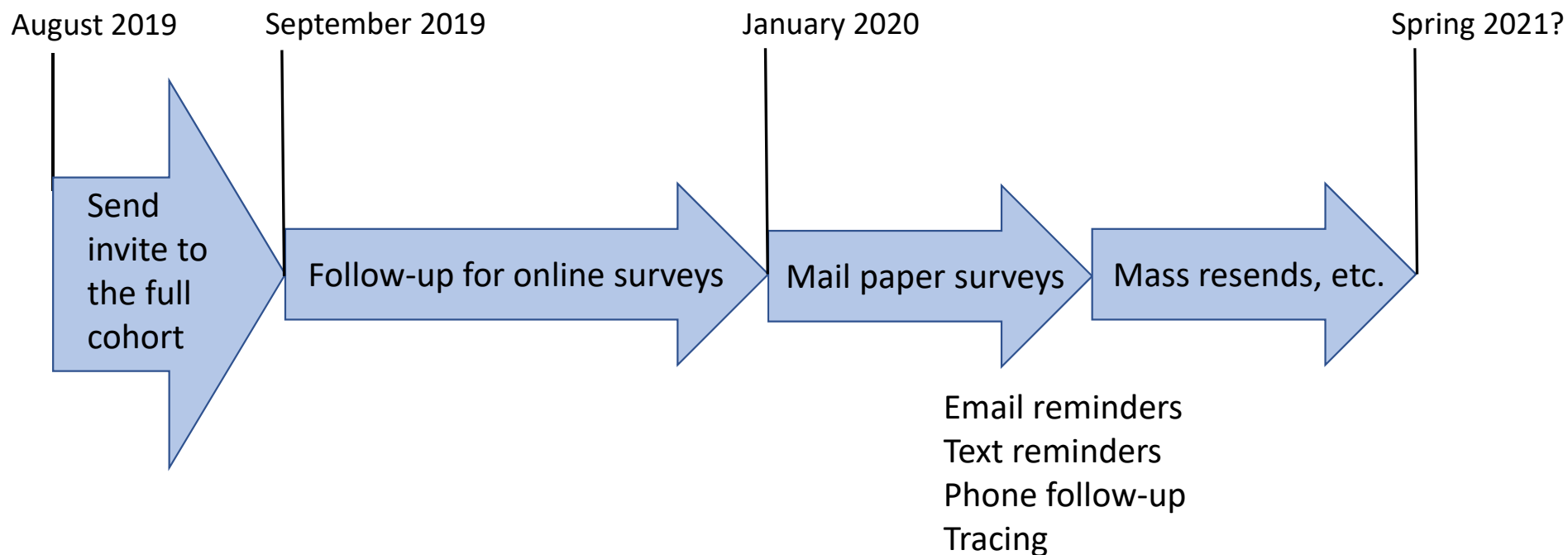


Plans for Follow-Up 7 Administration

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Phase 1:

Phase 2: Typical process (same as FU6 survey)



Follow-Up 7 Incentive Plan

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Phase 1:



Invite to full cohort for online survey

1. **\$10 incentive delivered upon completion of the survey**
2. **Complete survey to be entered into monthly drawings for an Apple/Android smart watch**

Follow-Up 7 Incentive Plan

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Phase 1:

Invite to full cohort for online survey

1. **\$10 incentive delivered upon completion of the survey**
2. **Complete survey to be entered into monthly drawings for an Apple/Android smart watch**

Phase 2:

Mail paper surveys to all nonresponders

1. **Front-end \$10 cash incentive included with the survey packet**
 - All participants receive same monetary incentive opportunity

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Collection of DNA

Meeting Book
P.20

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Blood, buccal swab, **Oragene saliva kits**

Completed kits go to CCSS Molecular Biology resource in Cincinnati

Kits Sent	Overall Survivors (n = 19,189)		Overall Siblings (n = 4,004)	
	<i>N</i>	<i>% of Sent</i>	<i>N</i>	<i>% of Sent</i>
Returned	10,348	54%	1,643	41%
Refused	1,383	7%	290	7%
Pending	5,266	27%	1,424	36%
In Tracing	1,778	9%	615	15%
Deceased	414	2%	32	1%

Collection of DNA

Meeting Book
P.20

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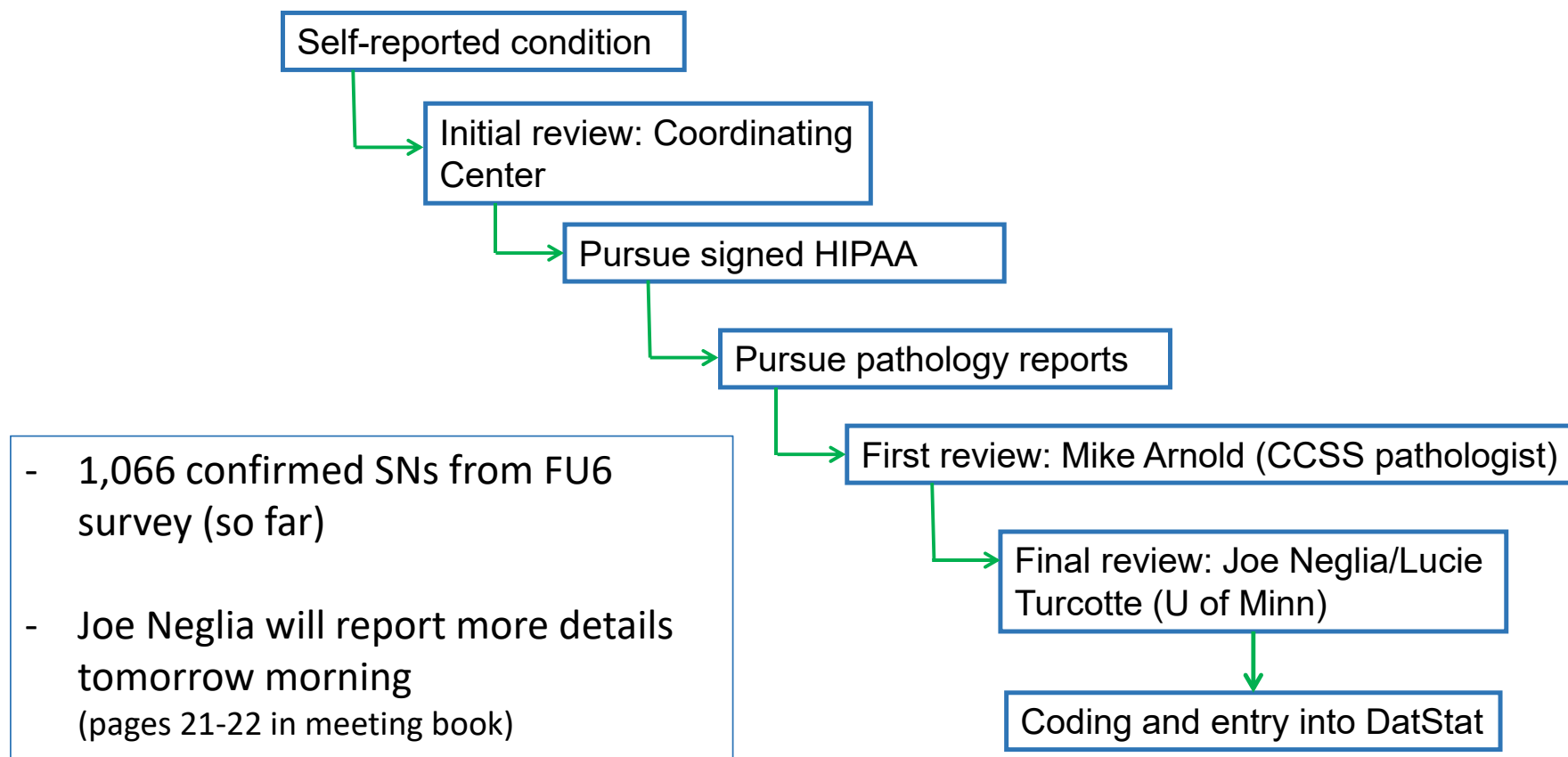
Recent efforts have focused on replenishment/enhancement of DNA among participants who previously provided a sample

Mailed Oragene kits to 5,516 participants for replenishment since May 2018

Received kits from 3,349 (61%)

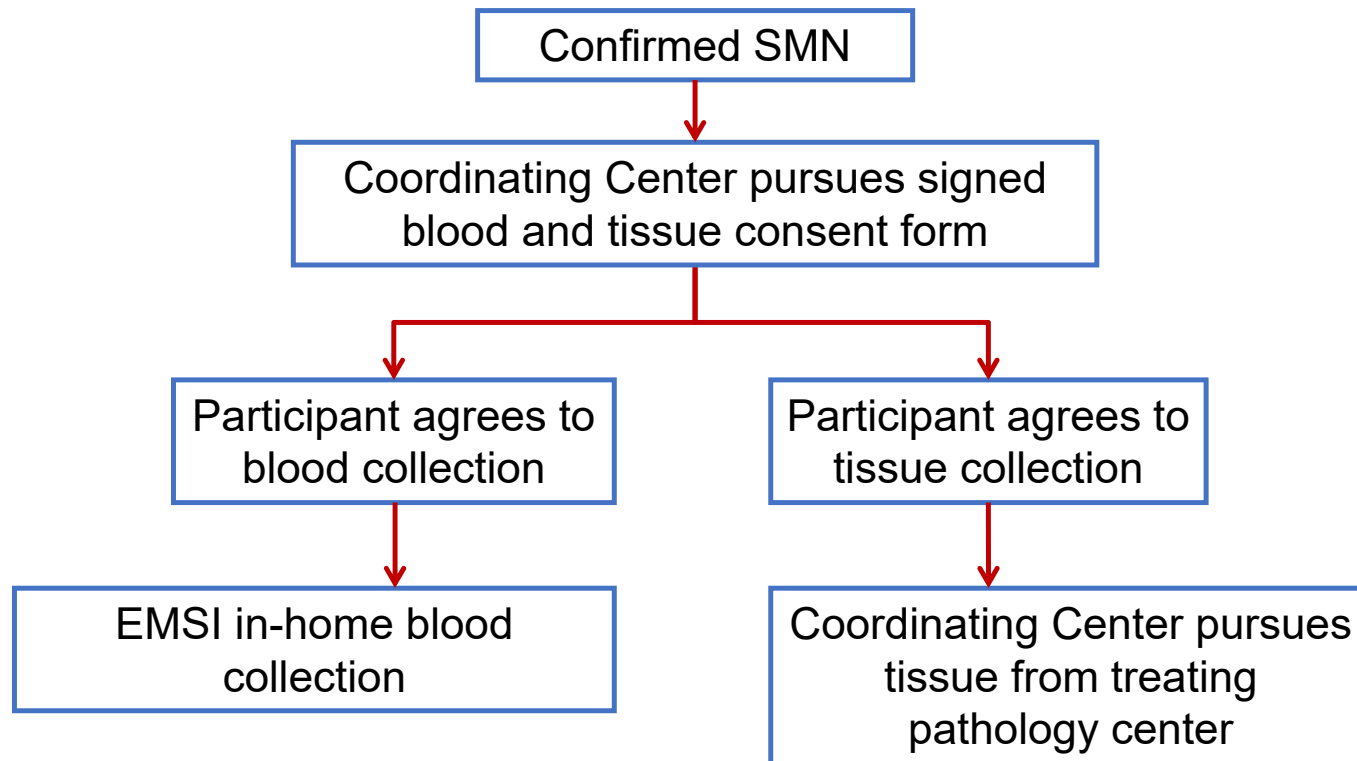
Subsequent Neoplasm Review and Confirmation

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Collection of Blood and SMN Tissue

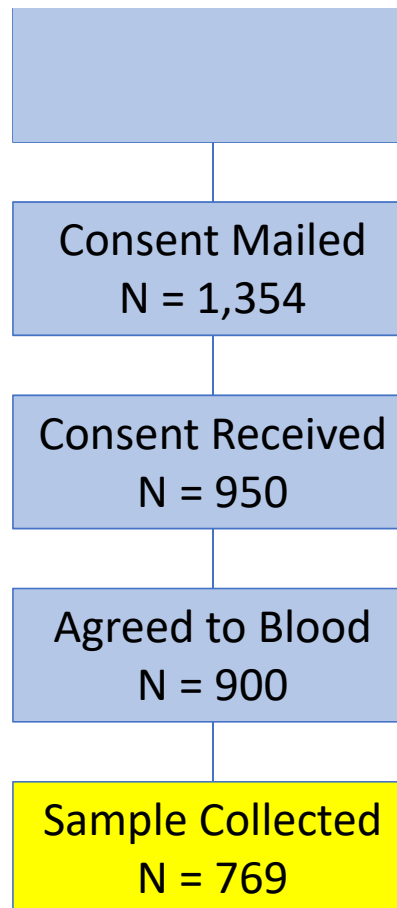
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SMN Blood Collection

Meeting Book
P.24

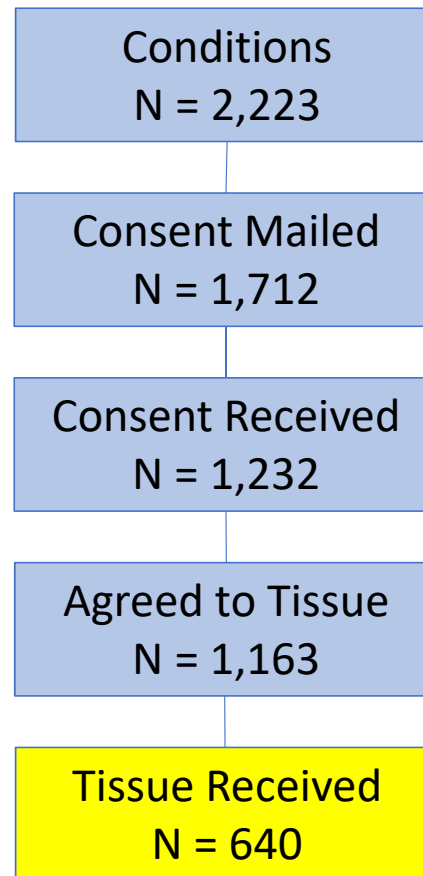
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SMN Tissue Collection

Meeting Book
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SMN Biorepository Inventory

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SMN	Number of Cases with Tissue Type			
	H&E Slides	Unstained Slides	Scrolls	Blocks
TOTAL CASES	652	422	182	267

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Coordinating Center Activity for Ancillary Studies

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Communicating
Health
Information &
Improving Coordination with
Primary Care



Preparing to support three newly funded studies:

- Breast Cancer Treatment and Outcomes (PI: Turcotte)
- Health Insurance Navigation Program (PI: Park)
- SLEEP Insomnia mHealth Intervention (PI: Brinkman/Krull)

Outline

CCSS

1. Participant engagement efforts
2. Follow-up 6 survey update
3. Follow-up 7 survey plans
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- 6. Other activities (NDI, VPR, surgery coding)**

National Death Index

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Previous NDI search was conducted in 2015

- Identified deaths through December 31, 2013

Goal: Perform updated NDI search in 2019

- Received supplement from NCI to fund NDI search
- Currently available NDI file covers deaths through December 31, 2017

Status: Application approved by NDI staff

Cohort file submitted to NDI

Results to be available in July

Manual review process and data freeze by Fall 2019

Virtual Pooled Registry Cancer Linkage System

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Goal of VPR: To provide a single portal to facilitate efficient, standardized linkages between study cohorts and multiple state cancer registries

- Potential for huge benefit to CCSS: Improve on self-report, reduce burden of record reviews for SMN confirmation

CCSS selected for pilot testing of Phase 1

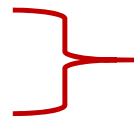
- Initial linkage and release of registry-specific match counts
- Successfully completed test linkages with 34 state registries

Phase 2: Obtain individual-level data on the matched cases

- Each registry has its own requirements for releasing data
- VPR working to develop and get registry approvals for:

Templated Data Use Agreement

Templated IRB/Registry application



Avoid need for 50 separate applications

Expanded Cohort Surgery Coding

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- Working with surgeons from Boston Children's Hospital
 - Christopher Weldon, MD, PhD
 - Brent Weil, MD
 - Arin Madenci, MD
 - Brian Dieffenbach, MD
 - Andrew Murphy, MD (St. Jude)
- Surgery records received for almost 9000 cases
- Review of surgical records and ICD-9 coding, database entry
- Started summer 2017; completed June 2019
- Integration into CCSS frozen data set in process

Priorities

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Short-term:

- Complete FU6 recruitment and data freeze
- Develop myLTFU and launch FU7 survey
- Adjudicate NDI search results via manual review and freeze data
- Maximize recruitment and participant support for mHealth studies
- Recruit for CHIIP and EMPOWER2
- Pursuit of SMN tissues, Oragene kits

Long-term:

- Maximize participation in myLTFU
- Achieve >70% response rate for FU7 survey
- Successful implementation of Eureka/mHealth studies
- Support new initiatives for competitive renewal
- Integrate with VPR

CCSS Coordinating Center

CCSS

The Coordinating Center Team

Aaron McDonald

James Ford

Arnethia Anderson

Ollie Battle

LaKeisha Bonner

Shelia Crutcher

Harmony Farner

Tolly Gillenwaters

Komal Kochar

Carol Lee

Janna Lipford

Renee Massey

Twanna Smith

Lauren Williams

Dayton Rinehart

Netha Banks

Yaniz Booth

Carrington Briggs

Andrew Cobble

Robbin Daniels

Donna Davis

Patti Davis

Elizabeth Johnson

Patricia Key

Barbara Lewis

Lanika Matthews

Telisa McKinney

Kathleen Rothammer

Maria Sanchez

Tishana Sharp

Chris Vukadinovich

Christie Cooper

Ricardo Duran

Lu Lu

Nicole Wilson