

# CCSS Coordinating Center Update

2017 CCSS Steering Committee and Principal Investigators Meeting

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CCSS Project Director

# Outline

- Previous survey (Follow-Up 5) wrap-up
- Plans for next survey (Follow-Up 6)
- Status of ongoing recruitment (4 most-recent institutions)
- SMN confirmation and tissue enrichment
- DNA collection
- Support of ancillary studies
- Expansion surgery coding
- Priorities and challenges

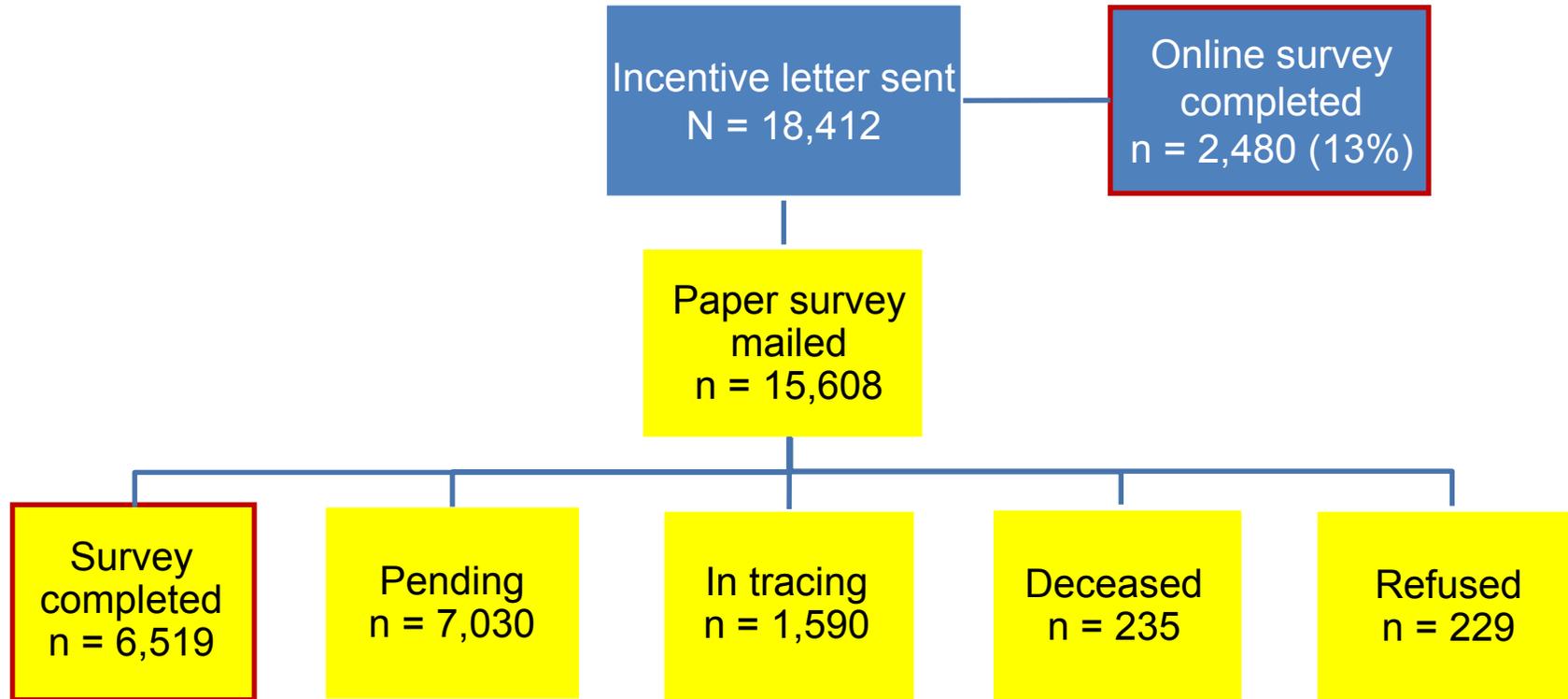
# Follow-Up 5

- Purpose: To provide...
  - 5<sup>th</sup> follow-up of the Original cohort
  - 1<sup>st</sup> follow-up of the Expanded cohort
  - Harmonization of the cohorts going forward
- FU5 survey:
  - Paper questionnaire (36 pages)
  - On-line questionnaire (DatStat)
  - Phone interview (DatStat)

# Follow-Up 5 Administration

- 18,412 survivors and 3,781 siblings eligible for mailing
- Initial mailing was an “iPad incentive” letter
  - Emphasize on-line completion; awarded one iPad per month
- Followed 3 weeks later by full packet with paper survey
- Follow-up emails two weeks after mailing; repeated quarterly
- Follow-up calls began 3 weeks after paper survey mailing
- “Mass resends”, including revised brochure and envelope
- Initial mailing date: June 25, 2014

# FU5 Status as of March 2, 2016



- Total completed surveys = 8,999
- Response rate = 50%

# Consider use of an incentive

Rationale: Need to increase response rate to achieve target participation rate of 70% in a reasonable timeframe

- Targeting persistent non-responders

## Concerns:

- Expense (>8,000 non-responders eligible for mailing)
- **Precedent**
- Logistics
- Front-end vs. back-end

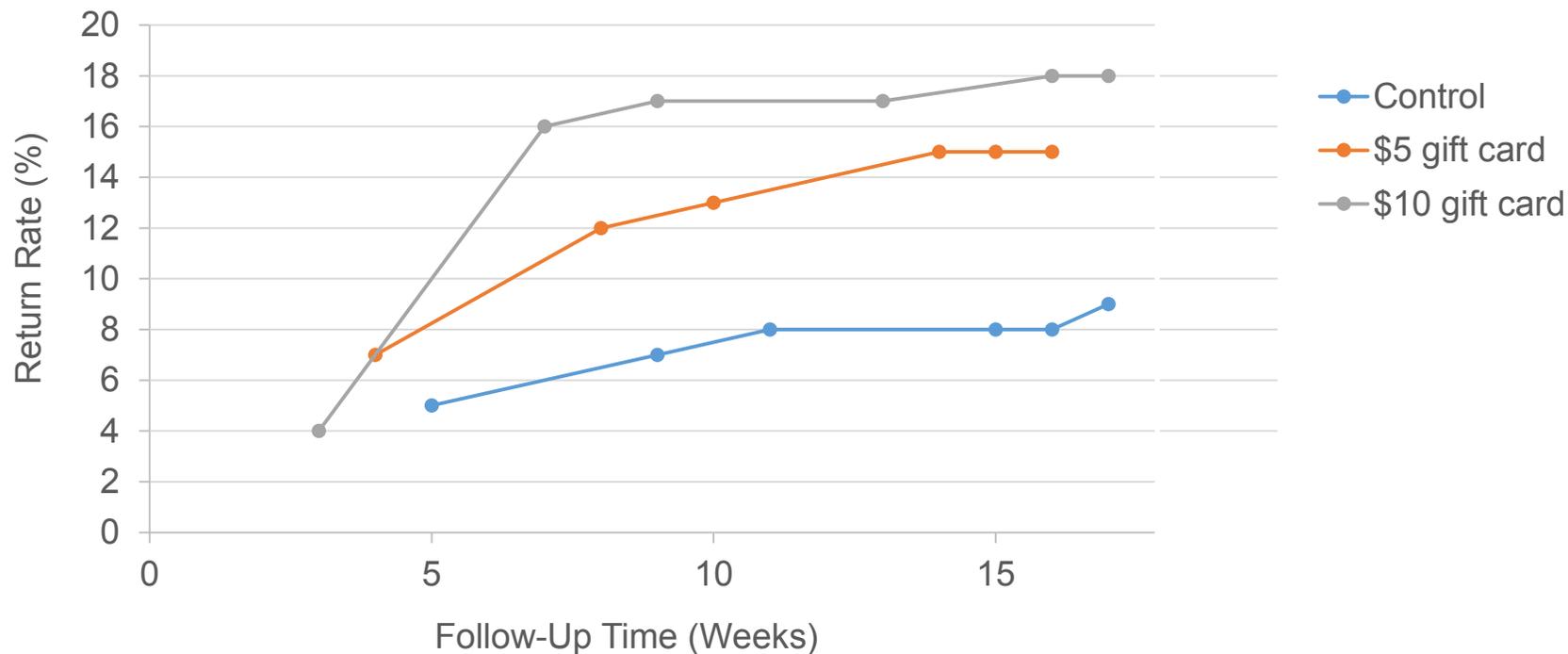
# FU5 Front-End Incentive Pilot Study

Participants randomized to one of three mailing arms:

Control (n=300)  
Packet with brochure and  
cover letter

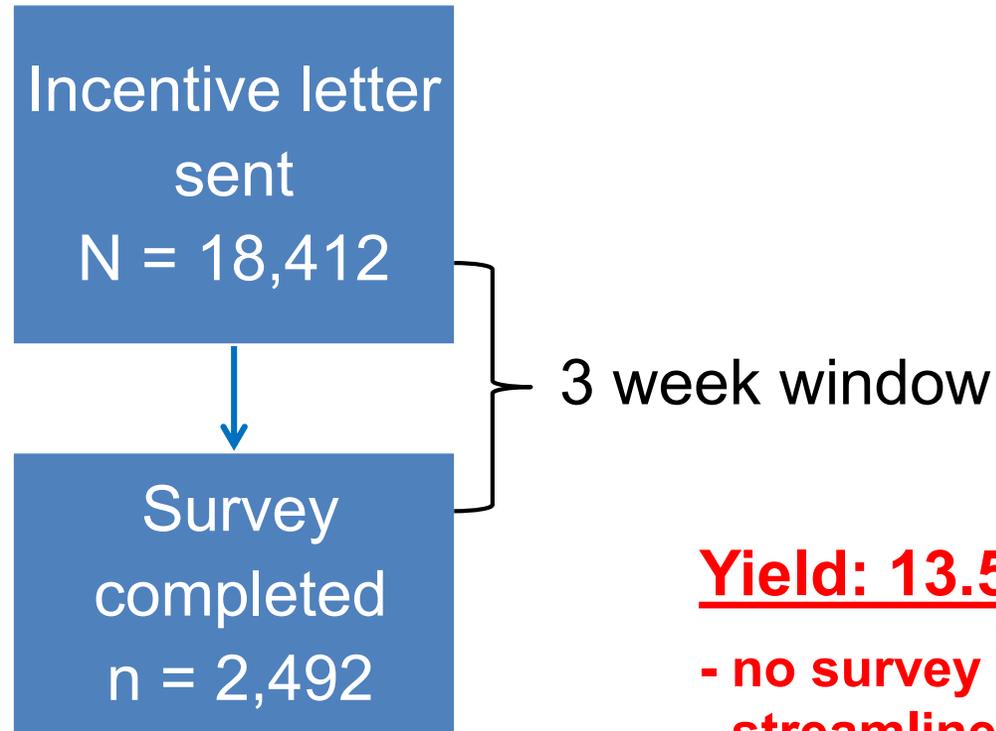
Low Incentive (n=300)  
\$5 gift card included,  
envelope says "gift enclosed"

High Incentive (n=300)  
\$10 gift card included,  
envelope says "gift enclosed"



## Incentive:

- iPad drawings to promote use of electronic survey

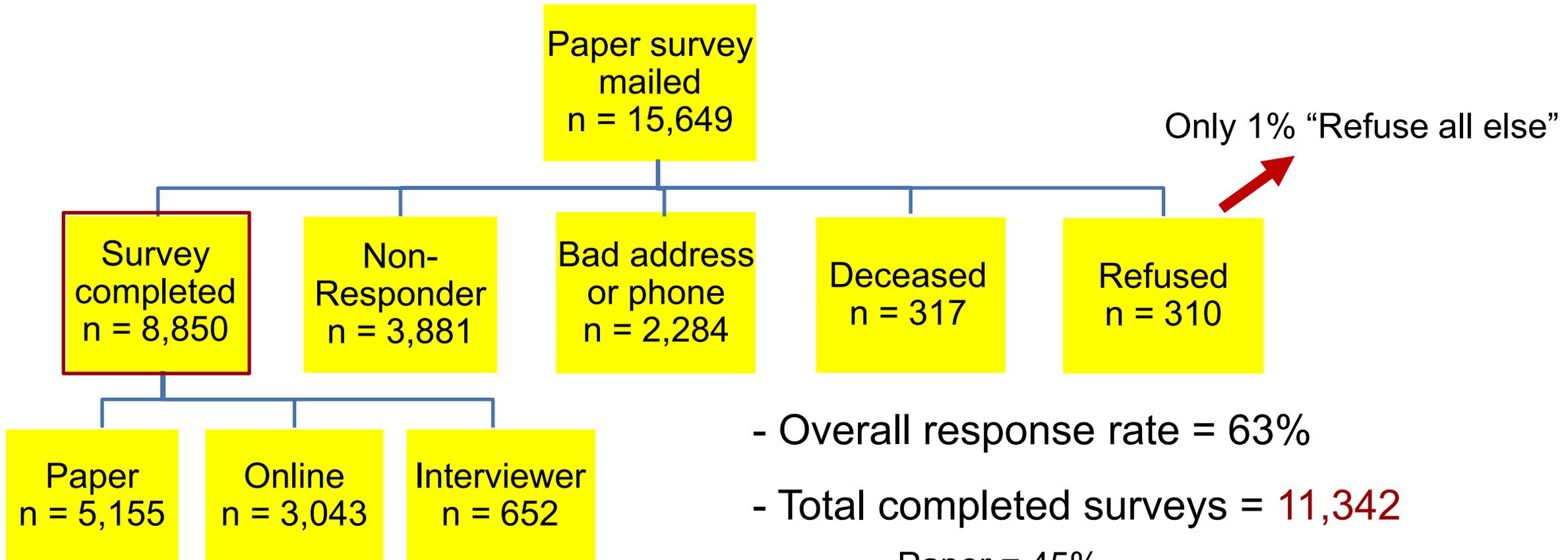


**Yield: 13.5 %**

- no survey mailings required
- streamlined data capture and error checking

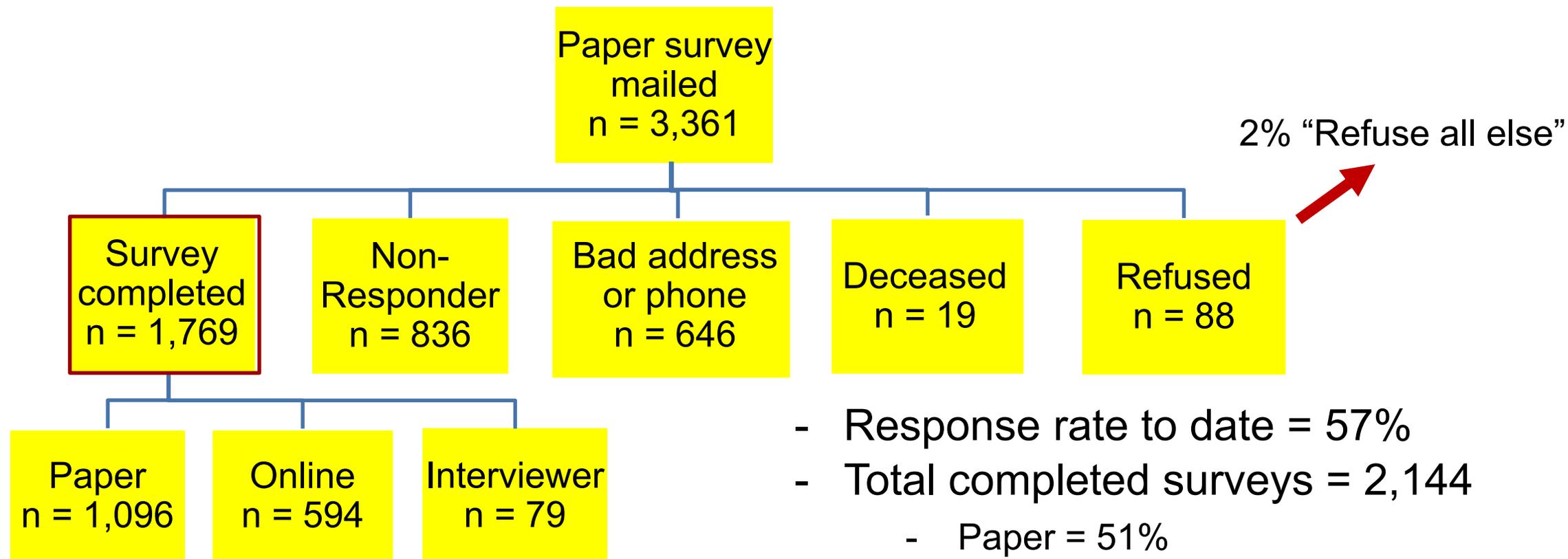
# Final FU5 Status: Survivors

(Meeting Book P. 18)



- Overall response rate = 63%
- Total completed surveys = **11,342**
  - Paper = 45%
  - Online = 49%
  - Interviewer = 6%

- 3,781 iPad letters sent to siblings: 3 week yield = 10%



- Response rate to date = 57%
- Total completed surveys = 2,144
  - Paper = 51%
  - Online = 45%
  - Interviewer = 4%

# Follow-Up 5 Activities

- Statistics from Follow-Up 5 efforts:
  - 84,548 FU5-related packets mailed
  - 70,855 phone calls
  - 54,198 follow-up emails to non-responders
  - 15,240 tracing phone calls

# Follow-Up 5: Future Plans

- Follow-Up 5 data freeze target June 2017
  - SMN confirmation process ongoing

## Why was participation lower for FU5?

- Underlying societal factors impacting all studies
- Specific factors impacting FU5

# “Participation rates in epidemiologic studies”

## Two central reasons for increased nonparticipation in scientific studies:

### 1. More people refusing participation

- Proliferation of research studies
- General decrease in volunteerism
- Salience of the research topic/disillusionment with science
- Epidemiologic studies have become increasingly demanding

# “Participation rates in epidemiologic studies”

## Two central reasons for increased nonparticipation in scientific studies:

### 2. More difficulty finding/reaching participants

- Harder to contact: unlisted phone numbers, cell phones, increased call screening
- More people working >50 hours per week
- Increased movement of women into the workforce/dual-career families
- Increases in unsolicited mail and phone calls

# Follow-Up 5 Wrap-Up

## Why was participation lower for FU5?

- Length of survey?
- Societal and environmental changes?
- Seven year gap between surveys for Original cohort?
- Reduced engagement/commitment for Expanded cohort?
- Difficulty contacting participants
  - 14% of survivors ended FU5 efforts designated as “In tracing”

# Outline

- ~~• Follow-Up 5 survey~~
- Plans for next survey (Follow-Up 6)
- Recruitment for new institutions
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- Priorities and challenges

# Follow-Up 6

- Goals: Re-engage the cohort; Establish solid participation as a foundation for future activities
- Strategy:
  - Shorter survey
  - Incentive
  - Improved communication materials and strategy – partnership with HCC
- Timeline: Initiate July 2017

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# Ongoing Recruitment of New Institutions

Goal: Recruit participants from four new institutions to increase the racial/ethnic diversity of the cohort

Institution	Initial Mailing Date
Cook Children's Hospital	4/23/2014
University of Chicago	8/5/2015
Lurie Children's Hospital	8/5/2015
Children's Hospital of Orange County	10/21/2015

# Ongoing Recruitment of New Institutions

(Meeting Book P. 16)

Name	Eligible	HIPAA Returned		Baseline Completed		
		n	% Eligible	n	% HIPAA	% Eligible
Cook Children's Hospital	526	351	66.7%	267	76.1%	50.8%
University of Chicago	349	226	64.8%	181	80.1%	51.9%
Lurie Children's Hospital	782	463	59.2%	368	79.5%	47.1%
Children's Hosp. of Orange County	468	240	51.3%	170	70.8%	36.3%
<b>Total</b>	<b>2,125</b>	<b>1,280</b>	<b>60.2%</b>	<b>986</b>	<b>77.0%</b>	<b>46.4%</b>

# Ongoing Recruitment of New Institutions

- Experience consistent with Expanded cohort recruitment
  - Seven year effort
- Targets per institution:
  - 70% HIPAAs returned
  - 80% of those with HIPAA completed baseline questionnaire
- Challenge: limited/outdated contact information
  - Massive tracing effort

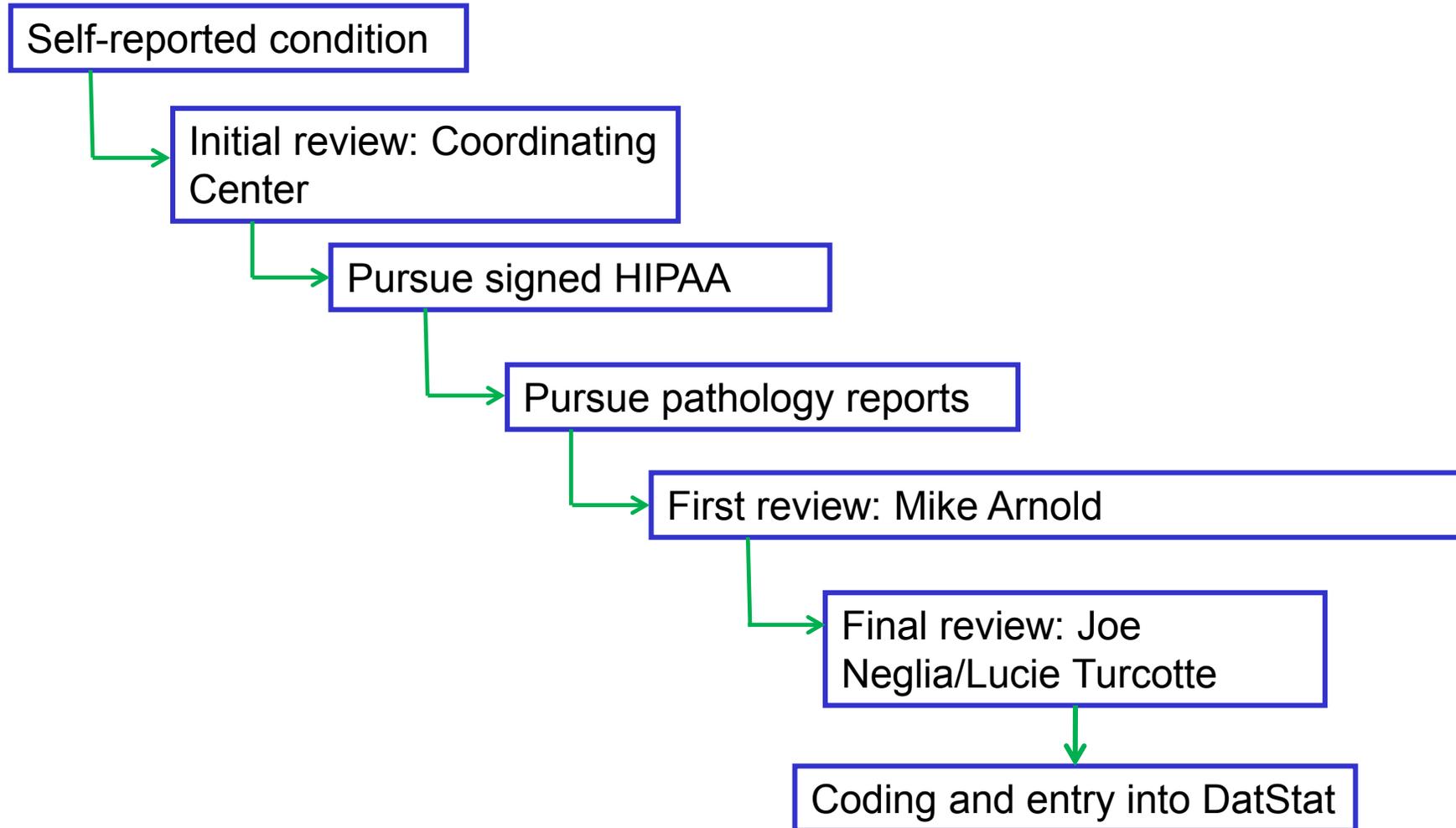
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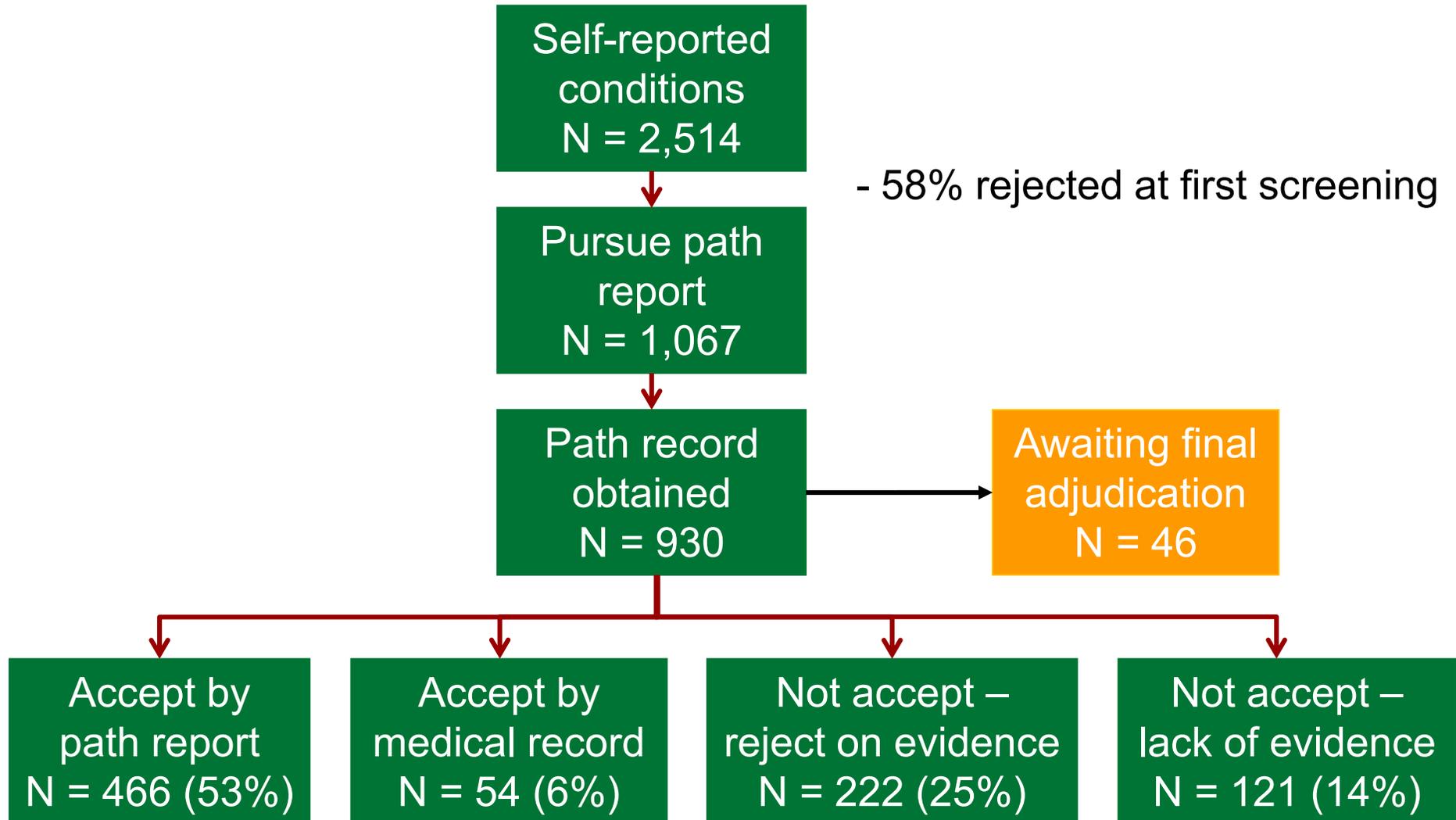
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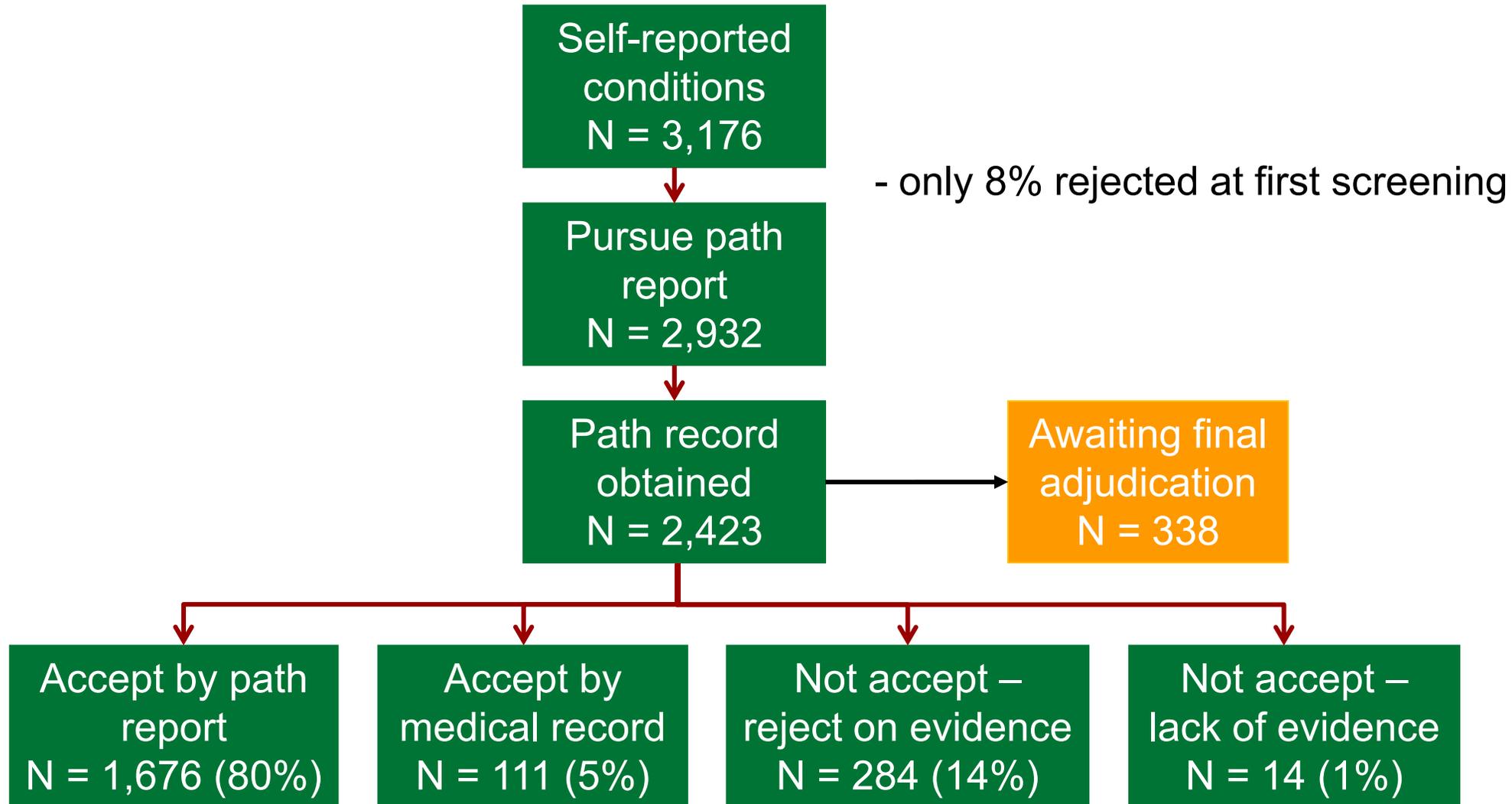
# SMN Activities

- CCSS outcomes identified by self-report
- Second malignant neoplasms - leading cause of late mortality
- This warrants additional efforts to:
  - Confirm and accurately identify SMNs
  - Collect SMN tissue samples

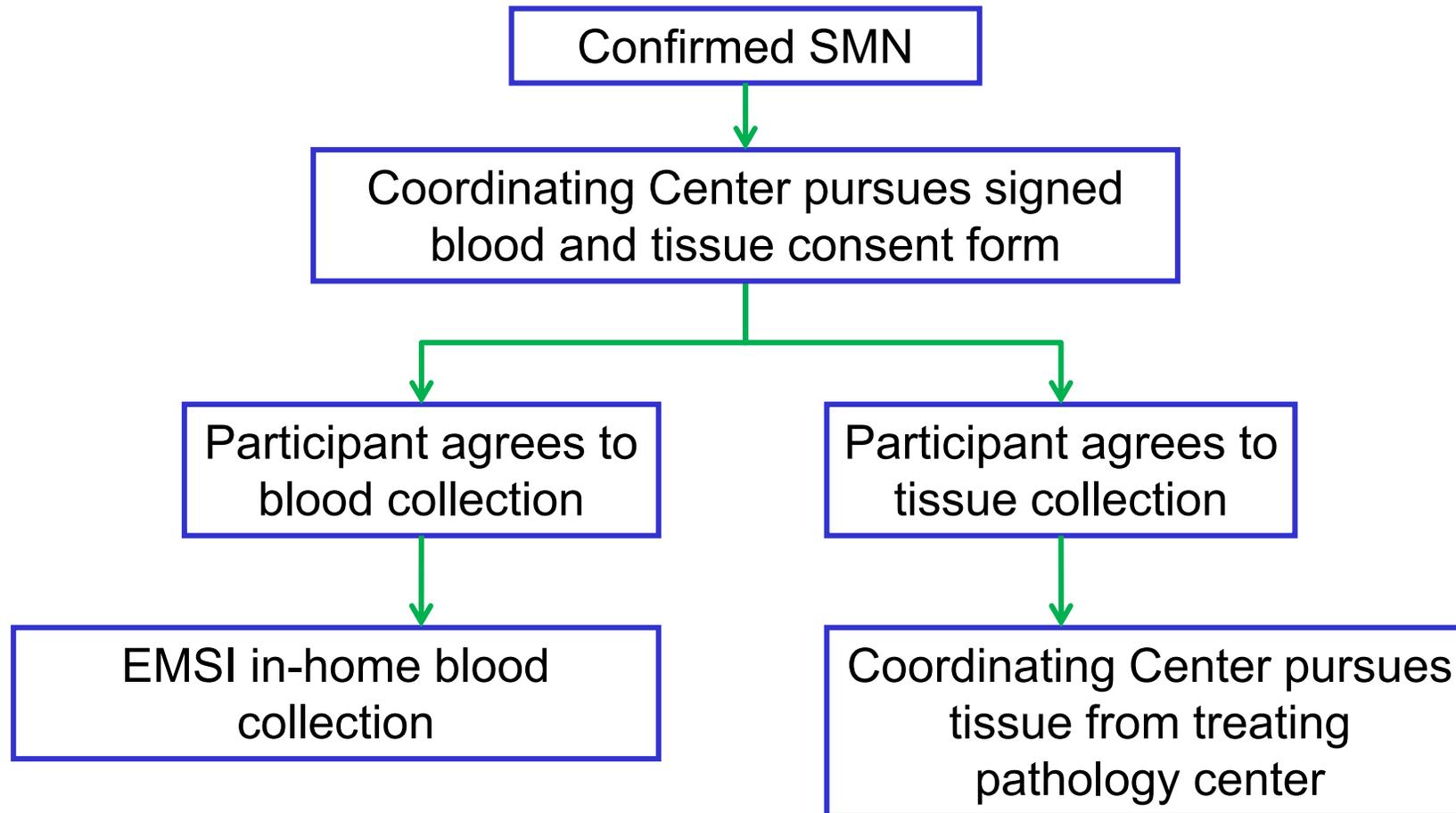
# SMN Confirmation Process



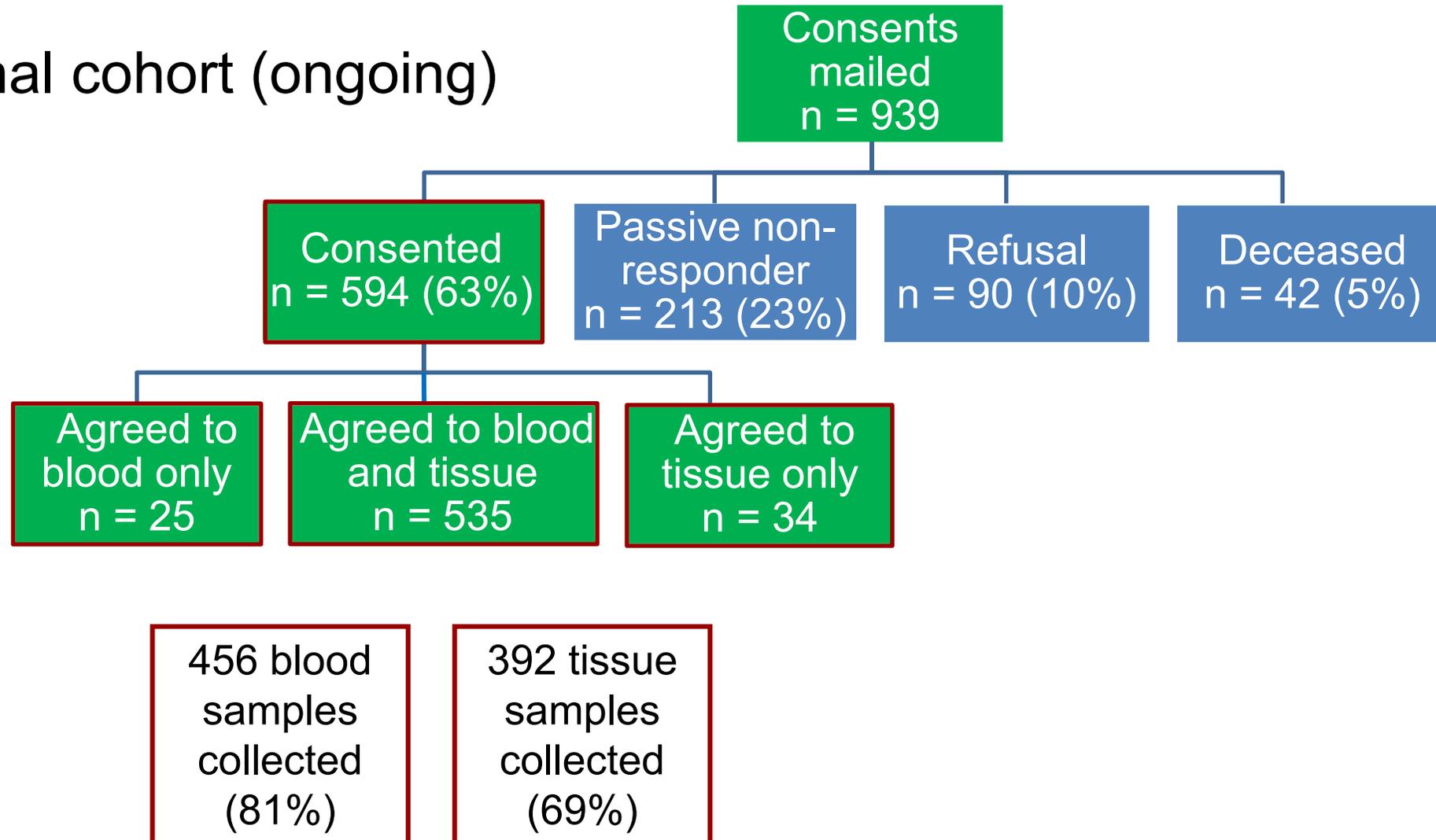




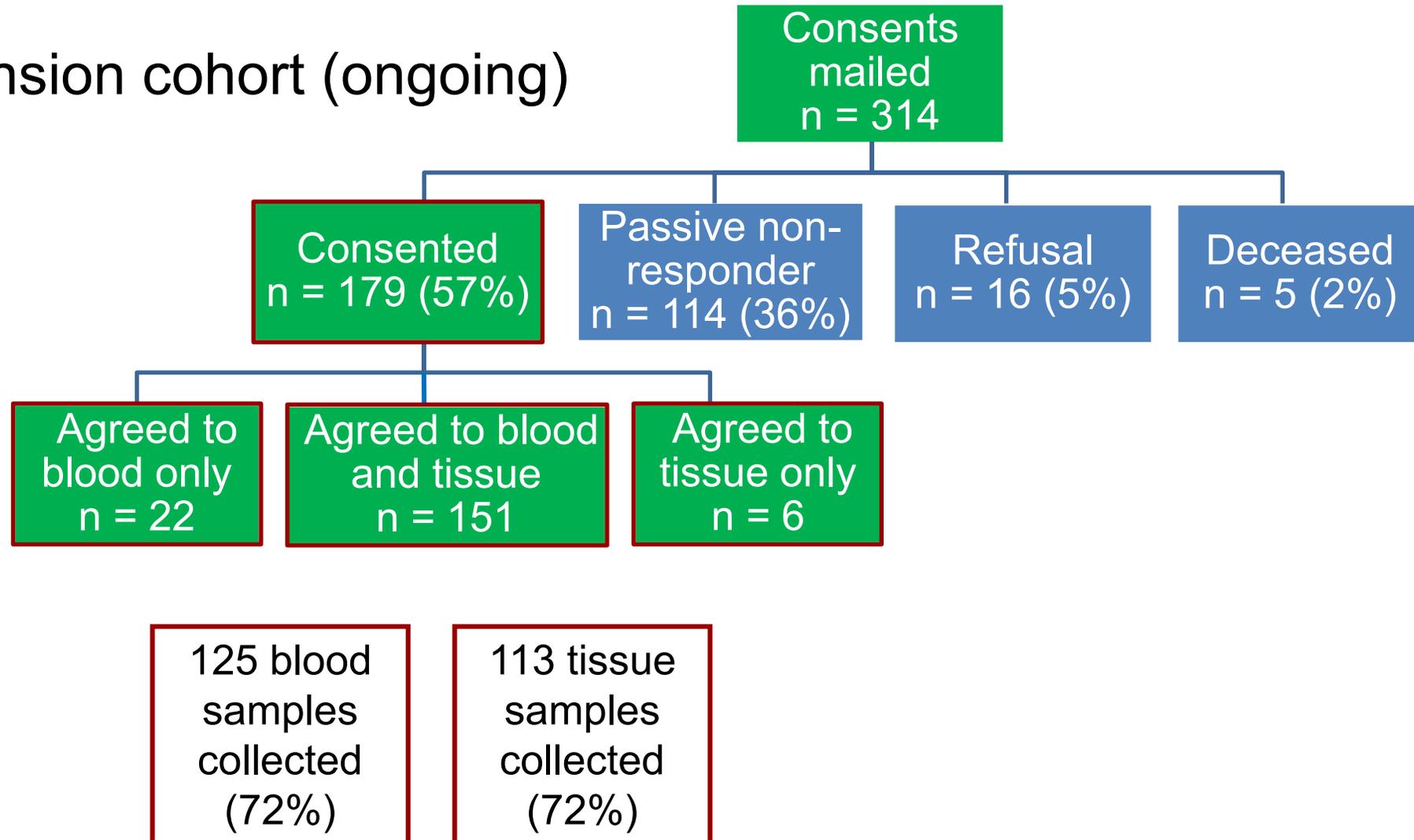
# SMN Blood and Tissue Collection Process



Original cohort (ongoing)



## Expansion cohort (ongoing)



# SMN Blood and Tissue Collection

- Continuing to pursue conditions identified in FU5 as they are accepted
- Competitive renewal calls for collecting 400-500 additional SMN specimens
  - In competitive renewal application: 259 SMN cases with specimens
  - As of May 2017: 419 SMN cases with specimens

## Sources:

- Re-pursuit of original cohort
- Ongoing pursuit of expanded baseline
- FU5 + FU6 SMNs

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# DNA Collection

(Meeting Book P. 20)

- Blood, buccal swab, Oragene mouthwash kits
- Completed kits go to CCSS Biorepository for processing and storage



Kits Sent	Original Cohort Cases (n = 8,530)		Original Cohort Siblings (n = 2,712)	
	<i>n</i>	<i>% of Sent</i>	<i>n</i>	<i>% of Sent</i>
Returned	4,691	55%	1,014	37%
Refused	822	10%	199	7%
Pending	2,069	24%	1,073	40%
In Tracing	670	8%	403	15%
Deceased	278	3%	23	1%

- Major effort to obtain DNA from Expanded Cohort (ongoing)
  - \$25 front-end incentive

Kits Sent	Expanded Cohort Cases (n = 8,959)		Expanded Cohort Siblings (n = 841)	
	<i>n</i>	<i>% of Sent</i>	<i>n</i>	<i>% of Sent</i>
Returned	4,651	52%	419	50%
Refused	346	4%	35	4%
Pending	3,277	37%	349	42%
In Tracing	649	7%	38	5%
Deceased	36	0.4%	0	0%

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- Provide support for extramurally-funded ancillary studies

Current studies:

- ASK (PI Alan Geller)
- EQUAL (PI Emily Tonorezos)
- CHIIP (PI Eric Chow)

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# Expanded Cohort Surgery Coding Effort

- Working with surgeons from Boston Children's Hospital
  - **Christopher Weldon, MD, PhD**
  - **Brent Weil, MD**
  - **Arin Madenci, MD**
  - Andrew Murphy, MD
  - Israel Fernandez-Pineda, MD
  - Kevin Oeffinger leading as Chronic Disease Working Group Chair
- Surgery records received for almost 9000 cases
- Review of surgical records and ICD-9 coding
- Status: Completed database development and validation testing
- Active research group: 1 publication, 3 manuscripts in development



# Challenges and Opportunities

## Challenges

Participant burden

Fundamental shifts in the study population

Need for incentives

Resource management

## Opportunities

App-based communication, text messaging

Improved communication materials

Focus on engagement

# Acknowledgements

## The Coordinating Center Team

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James Ford

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Shelia Crutcher

Harmony Farner

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Carol Lee

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Renee Massey

Kenya Powers

Twanna Smith

Jessica Uhrich

Lauren Williams

Dayton Rinehart

Netha Banks

Carrington Briggs

Andrew Cobble

Robbin Daniels

Donna Davis

Patti Davis

Yaniz Fernandez

Elizabeth Johnson

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Kathleen Rothhammer

Tishana Sharp

Amy Wolford

Chris Vukadinovich

Christie Cooper

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# Acknowledgements

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Assistant Coordinator: James Ford, (Ph.D.-to-be)

Databases and Systems: Chris Vukadinovich



# Childhood Cancer Survivor Study

The Childhood Cancer Survivor Study is a NCI-funded resource (U24 CA55727) to promote and facilitate research among long-term survivors of cancer diagnosed during childhood and adolescence.

Investigators interested in potential uses of this resource are encouraged to visit:

<http://ccss.stjude.org>