Practical Guide to Training on the Process of using e-Consent

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Agenda

1. Poll
2. Background
3. Preliminary Data about eConsent
4. eConsent Resources
5. Example Training Plan: Process
6. Lessons Learned
7. Pearls from Around StrokeNet
8. Future of the eConsent Program in StrokeNet

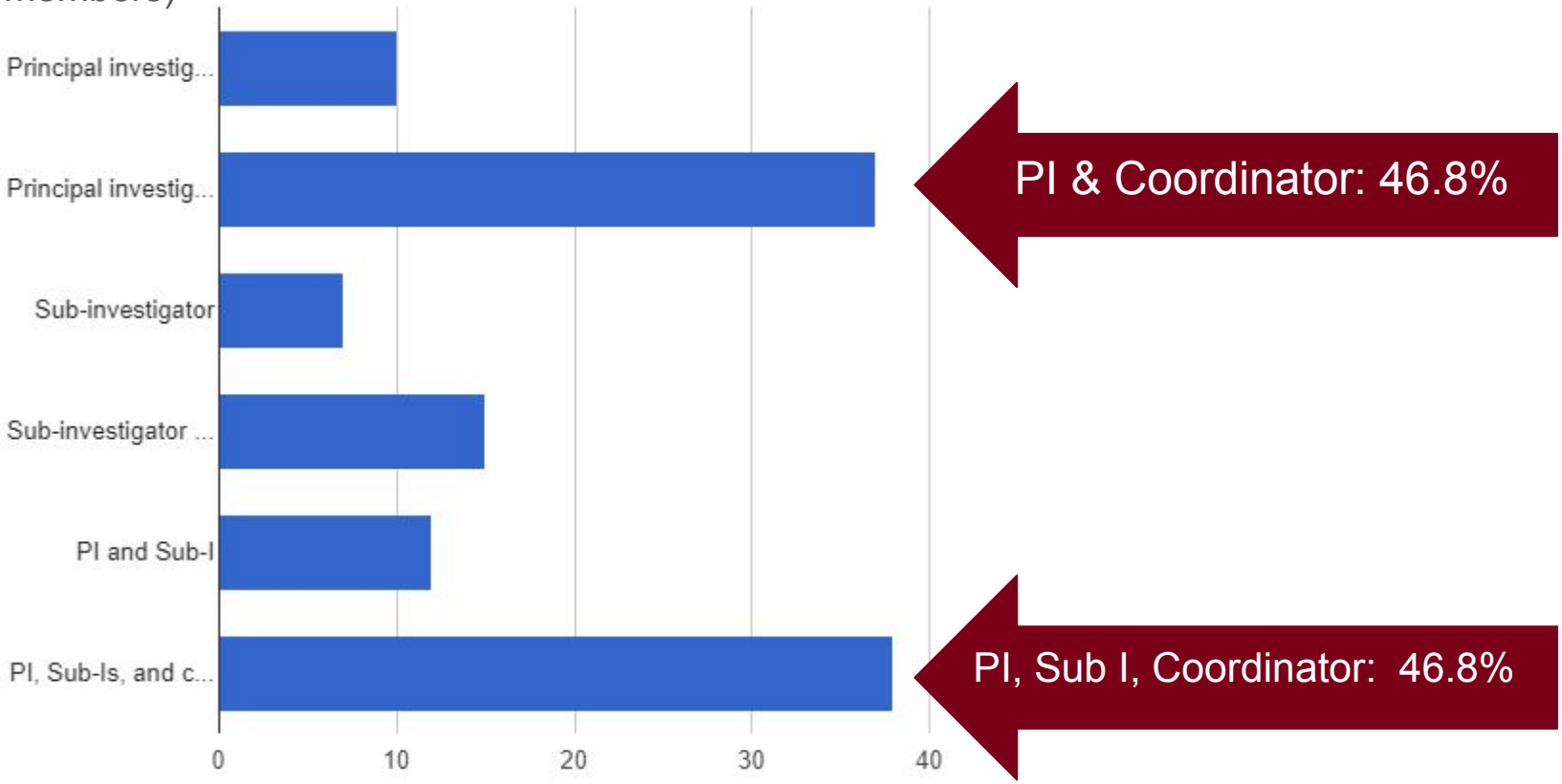
Background:
Barriers from RCC PM Meetings

- ➔ Challenging to use for older patients
- ➔ Some institutions prefer paper for in person interactions
- ➔ Lack of dedicated tablet for research purposes
- ➔ Hesitation to learn a new tool

Background: Workflow Survey Results, Summer 2023

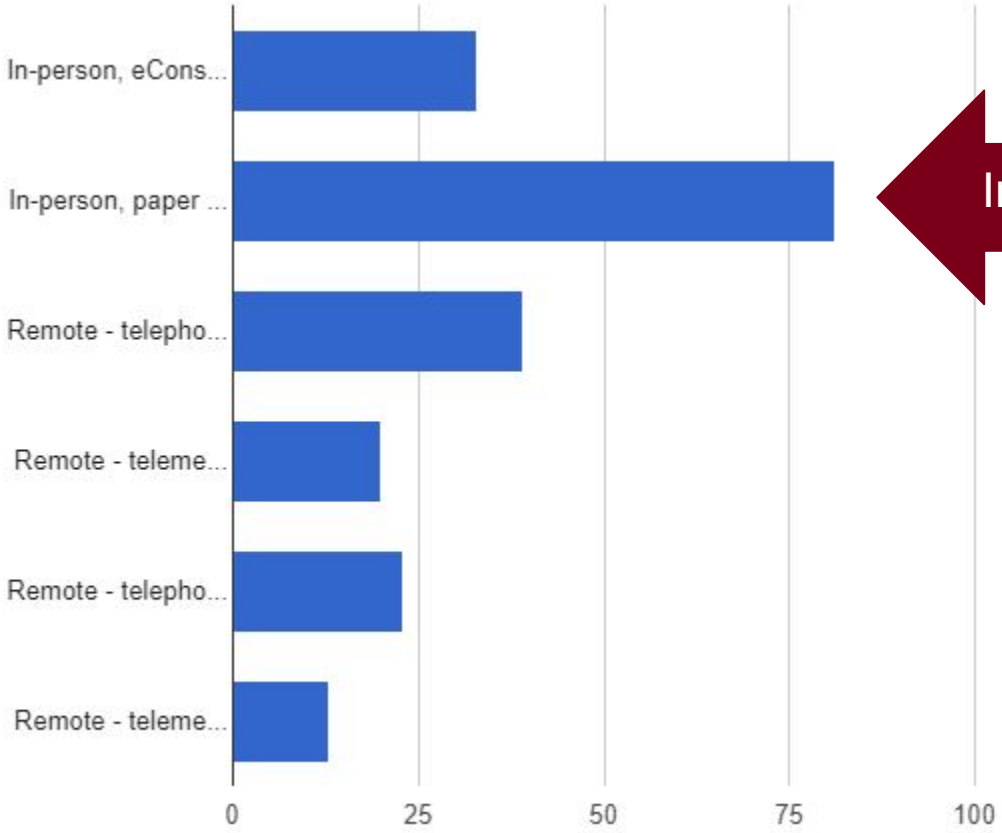
Who obtains consent?

(the choices with more than one role listed indicate real-time collaboration of multiple study members)



Background: Workflow Survey Results, Summer 2023

What Method is Utilized for Consent?



In person, paper: 93.6%

Background: MOST eConsent Use Data

The first participant enrolled using eConsent: July 2020

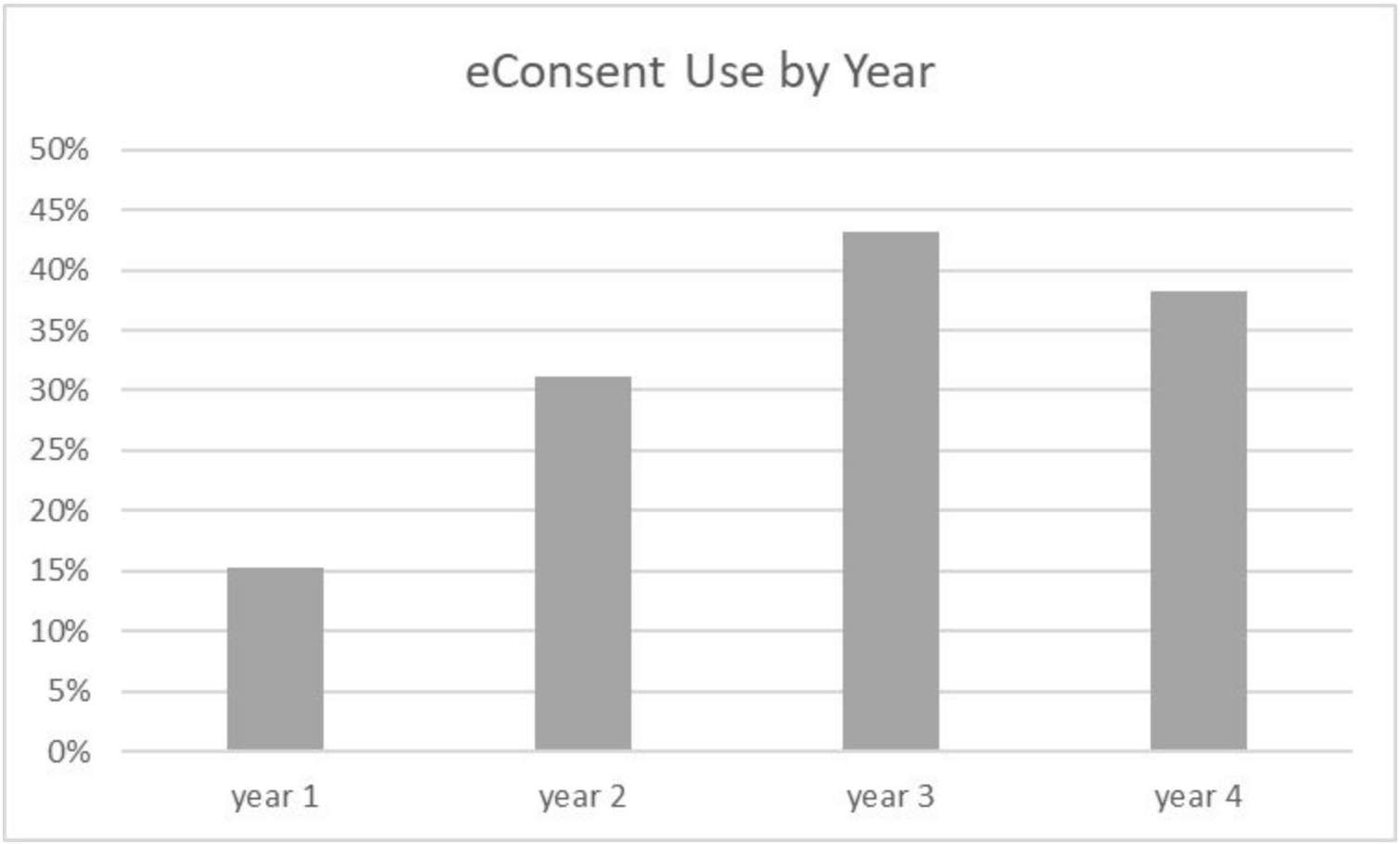
- 56.1% of sites adopted eConsent
  Subsequently, 173 participants (33.7%) were enrolled via eConsent
- **80 (15.6%)** of all enrollments were **remote** eConsent

Background:MOST eConsent Use Data[+]

Characteristic	Paper, in person	eConsent, in person	eConsent, remote	P-value*
Total number of Sites, N(%)	55(96.49)	19(33.33)	25(43.86)	
Enrollment, N(%)	337(66.08)	93(18.24)	80(15.69)	<0.001

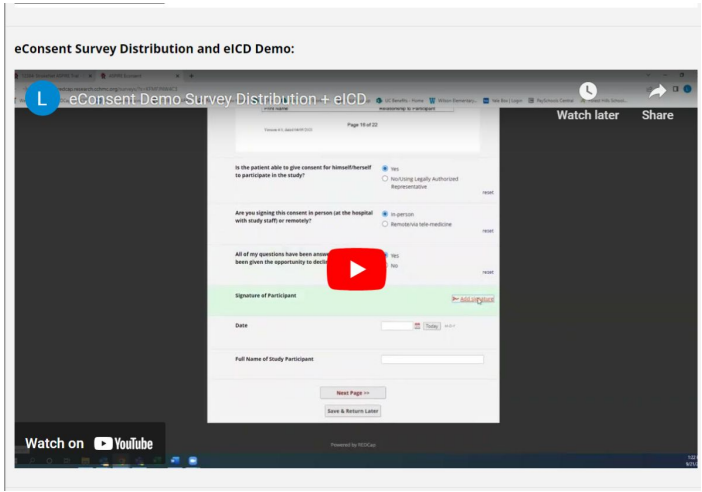
*For test of enrollments, data queries, and consent deviations, the p-value is from a Chi-Squared test of Equal Proportions. For the test of time from hospital arrival to subject randomization, the p-value is from a Kruskal-Wallis test.

Background: MOST eConsent Use Data



StrokeNet eConsent Resources

- StrokeNet eConsent REDCap Training
  - eConsent Basics
  - eConsent Survey Distribution and eICD Demo
  - Record Status Dashboard and File Repository Demo
  - StrokeNet Central eConsent SOP
- Trial-specific “eConsent How to Document”



https://redcap.link/StrokeNet_eConsent_Training

StrokeNet eConsent Resources

Anthony Rogers
Technical Administrator
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- REDCap Support
- Technical Support
- Alerts *
- Remote Research and Telestroke Advisory Group (REACT)

Tech and Tools: Tablets, Cases

The most valuable features are:

- long battery life
- good connectivity
- durability (case)
  - Get a case that can be dropped
  - Get a screen cover
- screen size= 8-12 in (portable but larger)
- Consider accepting a donated device or purchasing a used device

Example: Amazon Fire is around $100.

https://www.pcmag.com/picks/the-best-cheap-tablets

Example: Didactic Training

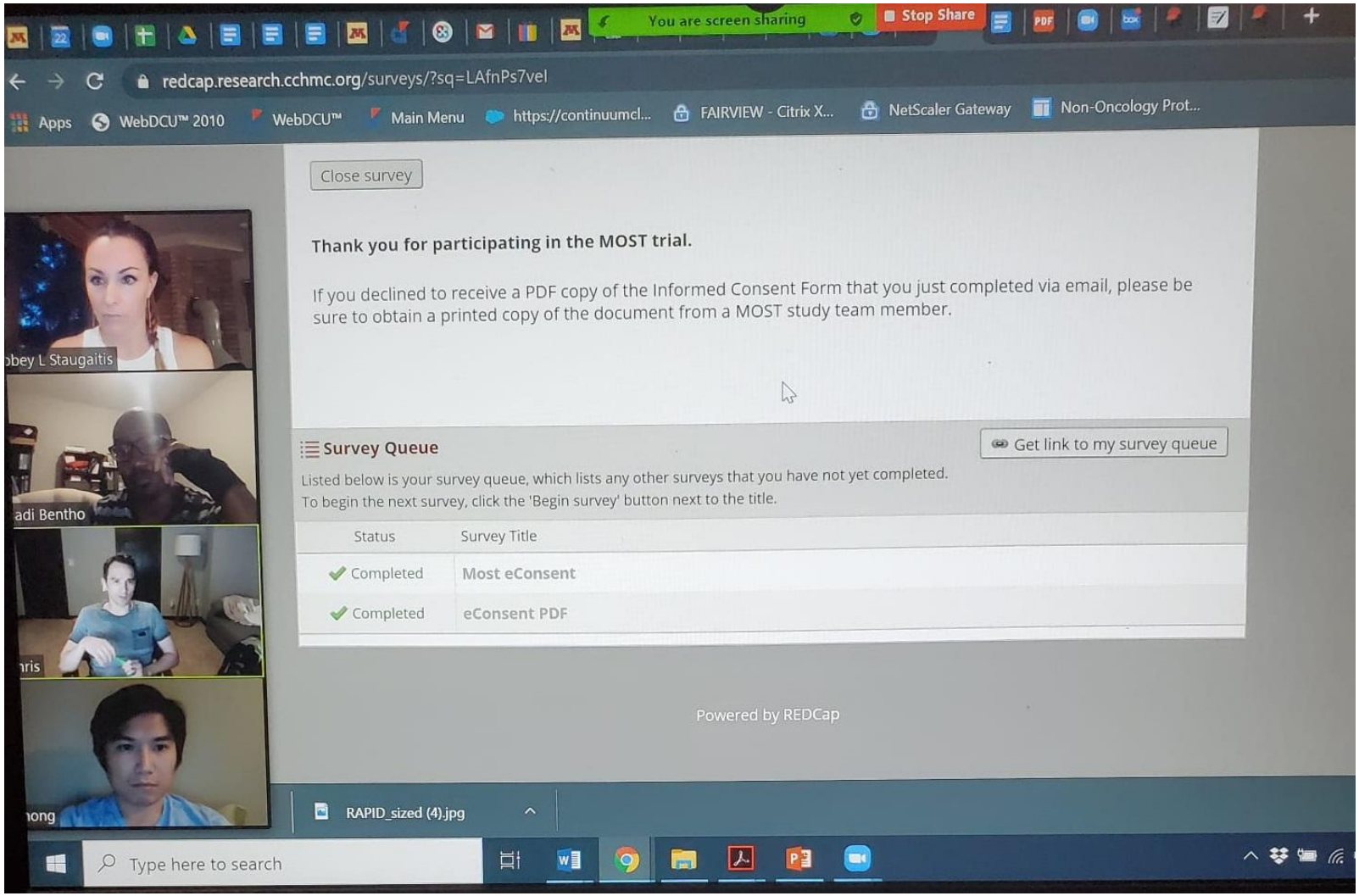
2016-2017	2017-2018	2018-2019	2019-2020	2020-2021	2021-2022	Academic Year
					+	1:1 Pre-Arrival Onboarding Coaching
					+	Monthly Research Operations Meeting
			+	+	+	Mock Remote Consent with eConsent
		+	+	+	+	Boot Camp Didactic Instruction*
	+	+	+	+	+	PRN Didactic Research Updates
	+	+	+	+	+	Shadowing Faculty-Led Enrollments
+	+	+	+	+	+	HSP, Protocol, & HIPAA training

Mock eConsent Training

Purpose/Agenda

- Navigation of the eConsent platform (and other resources)
- Trainee conducts a “mock” remote consent on camera (with PM or coordinator as the LAR; start with clinical care explanation and then transition to clinical trial consent conversation)
- Trainee receives feedback about the mock consent session from the group

Mock eConsent Training



Mock eConsent Workflow Example

- Trainee receives phone call from ED attending (PI)
- Trainee activates ACRC via TigerConnect (text app)
- ACRC sends eConsent link
- Trainee calls LAR to give clinical update and information on clinical trial
- Trainee consents LAR

Lessons for eConsent: Remote

1. Clinical team should introduce study
2. Obtain call-back number where LAR can be reliably reached, even while traveling
3. May need multiple phone numbers or email addresses
4. Explain eConsent process prior to sending link to eICF
5. Anticipate follow-up calls

Lessons from eConsent: In Person

1. Ensure device wifi connectivity (EDs/MRI/CT)
2. Larger screens preferred
3. Entire clinical team able to navigate eConsent application smoothly: device location, passwords, bookmarks, links
4. Hard copies of forms may still be necessary

Other Training Tips & Pearls

- Map your workflow
- Use the practice link with a variety of people
- Have an experience team member demo a consent conversation
- Have a “guided consent talking points” document
- Have answers to high-yield questions prepared for the trainee
- Have an experienced team member observe a trainee an offer feedback

eConsent: Future

NIH StrokeNet

PREVENTION | TREATMENT | RECOVERY

A A A

English

A A A

Spanish/Español

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Institutos Nacionales de Salud (National Institutes of Health, NIH)/Número de protocolo 03496883 (FASTEST)

CONSENTIMIENTO PARA PARTICIPAR EN UN ESTUDIO DE INVESTIGACIÓN

Organismo de financiación/Título del estudio:	**Institutos Nacionales de Salud (National Institutes of Health, NIH)/"Ensayo de rFVIIa para accidentes cerebrovasculares hemorrágicos administrado en el momento más temprano (rFVIIa for Acute Hemorrhagic Stroke Administered at Earliest Time, FASTEST)"**
Número de protocolo:	**03496883 (FASTEST)**
Investigador principal (médico del estudio):	**Chris Streib, MD**

eConsent: Future

Email alert will be sent to individuals with project access when **remote consent attestation** is required but missing

From:	donotreply@cchmc.org
To:	rogersat@ucmail.uc.edu
Subject	Remote Consent Attestation Need Completion
Message:	Please complete the Remote Consent Attestation for record ID 2 and participant name Sister test. Survey Link: https://redcap.research.cchmc.org/surveys/?s=CtqM6Nv4E7z65dd7

eConsent: Future

Email alert will be sent to individuals with project access when **subject ID instrument** is required but missing

From:	rogersat@ucmail.uc.edu
To:	rogersat@ucmail.uc.edu; osinsklr@ucmail.uc.edu
Subject	Subject ID #secure
Message:	Please enter the Subject ID for Record ID **9** in REDCap. Please click on link **https://redcap.research.cchmc.org/surveys/?s=6zcjjJuTzwWvd5S7** to enter in the information.

eConsent: Future

Email alert will be sent to individuals with project access when **any record is incomplete**

From:	rogersat@ucmail.uc.edu
To:	rogersat@ucmail.uc.edu; francoci@ucmail.uc.edu
Subject	Sister Incomplete Record #secure
Message:	Please log into REDCap and address incomplete Record ID **10**. Please delete if there is no PHI data collected.

Thanks To:

- REACT Core
  - Co-Chair Chris Streib
- CRP Core
- MOST Publications Committee
- UMN ACRC Coordinators and Research Fellows
- StrokeNet NCC Leadership Team

Questions?

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