Expanding the Reach of Stroke Clinical Trials Utilizing Telemedicine & Remote Research Practices

Abbey Staugaitis, RN, MSN, CCRC
Christopher Streib, MD, MS
October 13, 2021

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Outline

- Overview Remote Research Practices
  - Review “real-world” utilization
- Building remote research infrastructure
- Telemedicine & Remote Research Advisory Group

Remote Research Practice*

Definition: The ability to conduct key elements of clinical trial enrollment, intervention, and follow-up without the clinical research team present in-person

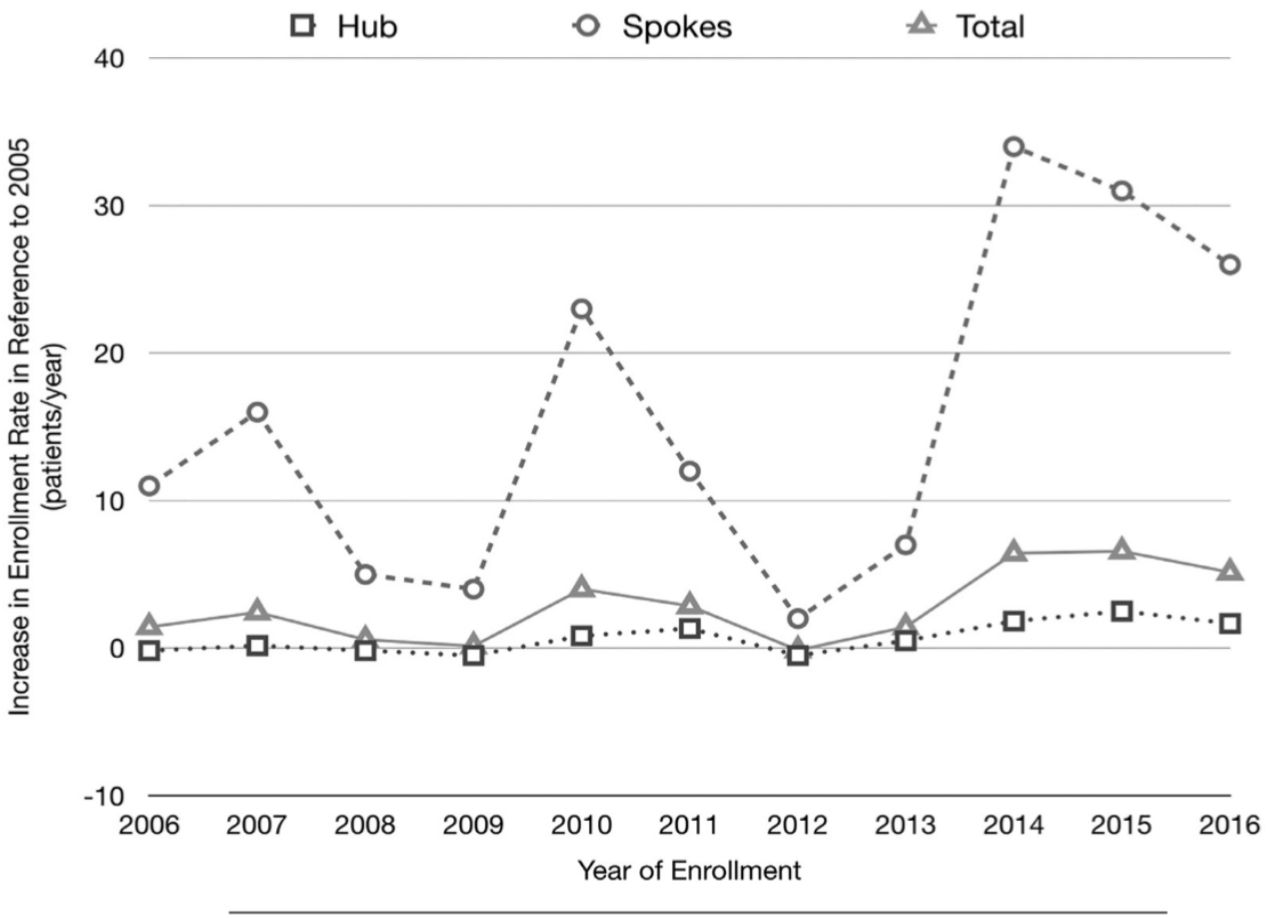
Example: Consenting a patient for MOST over telestroke

**while applicable to COVID-19 research restrictions, remote research practices are not specific to COVID-19*

Elements of Clinical Trial Enrollment

1. Screening - identification of potential subjects
2. Informed Consent from patient/LAR
3. Randomization
4. Study intervention
5. Inpatient follow-up: adverse events, secondary outcomes
6. Outpatient follow-up: adverse events, secondary outcomes, primary outcome

Acute Stroke Trial Enrollment through a Telemedicine Network: A 12-Year Experience



Shoirah et al. Acute Stroke Trial Enrollment through a Telemedicine Network. Journal of Cerebrovascular Diseases 2019.

Remote Research Element Examples

	Telestroke	Phone	EMR
Screening	Stroke code/stroke consult		Real-time chart review for I & E during stroke code
Consent	eConsent	eConsent	

Remote Research Element Examples

	Telestroke	Phone	EMR
Randomization	Clinical team randomizes patient	off-site research coordinator randomizes	
Study Intervention	Guide intervention on camera	Coordinate pharmacy, nursing, treating teams	Rigorous protocols and monitoring EMR off-site

Remote Clinical Research Elements

	Telestroke	Phone	EMR
Inpatient Follow-up	Clinical and study follow-up	Study follow-up	Ascertain AEs/SAEs and review outcomes
Outpatient Follow-up			

Remote Research Spectrum Examples

Screen	Consent	Randomize	Intervention	Inpatient Follow-up	Outpatient Follow-up	Examples
						Conventional Trial
						DEFUSE 3 - spoke site recruitment
						TIMELESS - spoke site recruitment

				NA		ALPS - outpatient COVID study
		NA	NA			MARISS - observational

Key **In-person** **Remote**

Adaptability Increases Enrollment

Screen	Consent	Randomize	Intervention	Inpatient Follow-up	Outpatient Follow-up	Examples
						Conventional TIMELESS
	■	■				TIMELESS hub enrollment, no LAR
■	■	■	■			TIMELESS hub enrollment after hrs
■	■	■	■		■	TIMELESS spoke enrollment all hrs
■	■	■	■	■	■	TIMELESS hub enrollment COVID*

Key In-person | Remote

**inpatient stroke care temporarily managed exclusively via inpatient telestroke as part of our pandemic response. TIMELESS enrollments during this period had no in-person contact with the clinical research team for the duration of the study.*

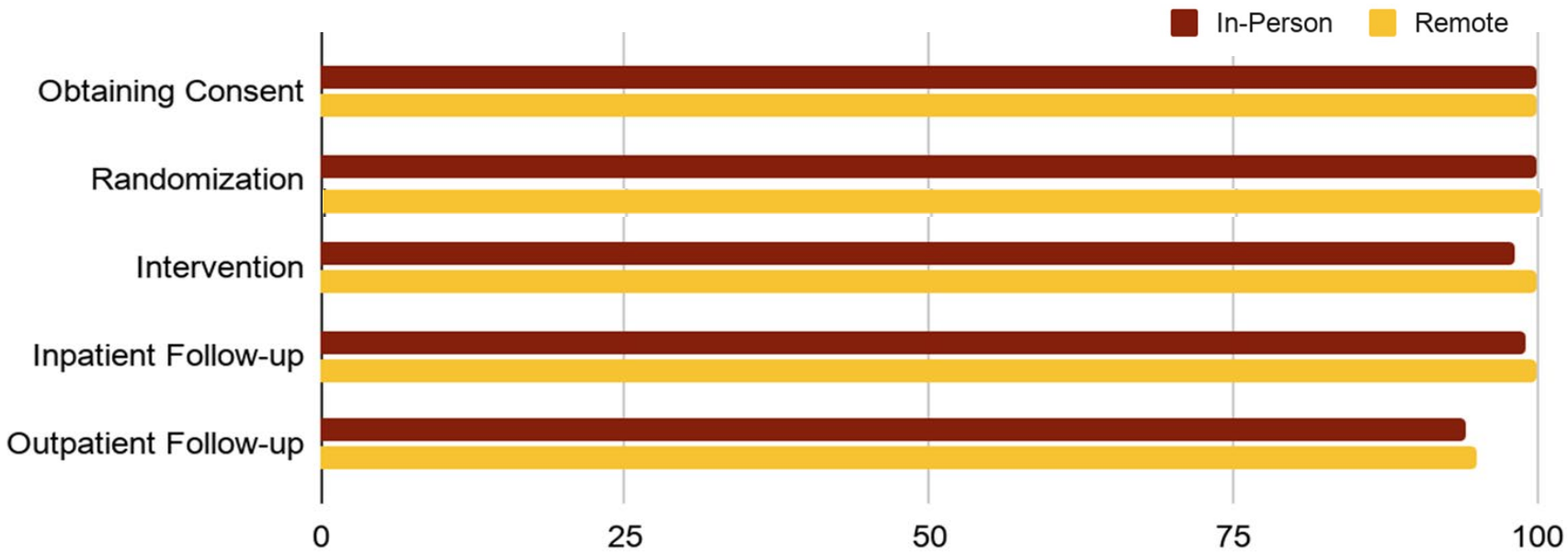
Review of Actual Subject Enrollments

ID	Screening	Consent	Randomization	Intervention	Inpatient Follow-up	Outpatient Follow-up (30)	Outpatient Follow-up (90)
1		+					
2							
3							
4							
5							
6							
7				+			
8							
9							
10							

Key

In-person successful	In-person unsuccessful	Remote unsuccessful	Remote completed succesfully

Internal Trial Enrollment Data



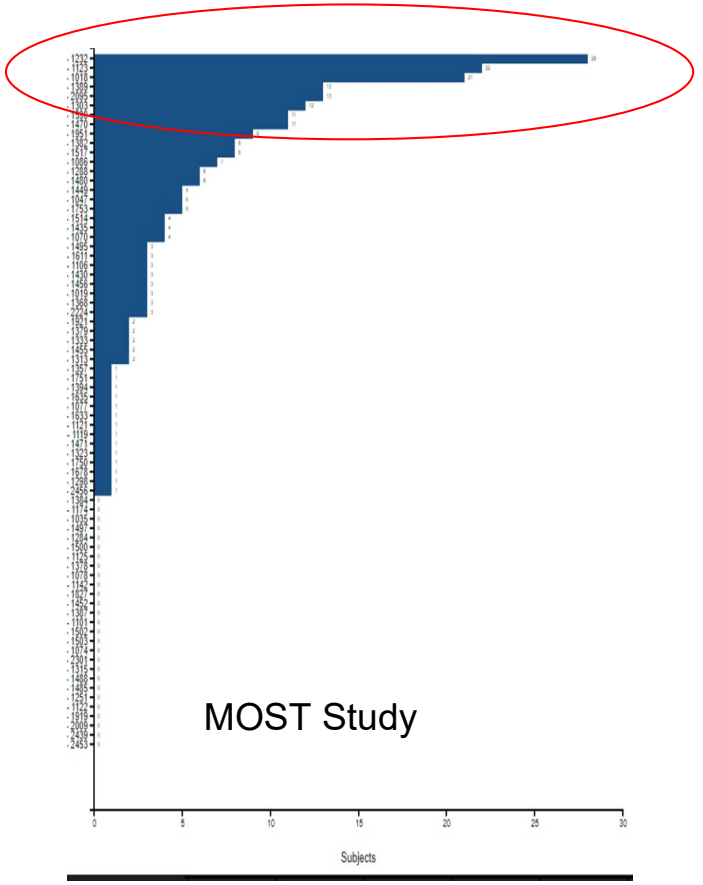
- Trial elements completed successfully in-person 98% (473/481) vs 99% (163/165) via telemedicine (p=1.0)
- Study deviations in-person 5.6% (10/180) vs 2.6% (2/77) via telemedicine (p=0.26)

Advantages of Adopting Remote Research Practices

- Remote practices support 24/7 coverage
  - clinical research team off-site overnight/wknd
  - facilitates consistent workflows
  - increases capture and recruitment
- Complete trials faster (cheaper?)
- Ease burden of clinical research on coordinators, clinical team, and patients
  - enrollments feel routine, not chaotic

Advantages Adopting of Remote Research Practices

- Centralized/remote research team covers multiple sites/trials
  - support sites without vascular neurology and/or research coordinators
- Extend effective clinical research to spoke sites outside the large academic centers



Advantages Adopting of Remote Research Practices

- Integration of research into clinical care promotes diversity: bring trials to patients through remote research practice

Integrating Research into Community Practice — Toward Increased Diversity in Clinical Trials

Janet Woodcock, M.D., Richardae Araojo, Pharm.D., Twyla Thompson, Pharm.D., and Gary A. Puckrein, Ph.D.

The Covid-19 pandemic has underscored health inequities affecting racial and ethnic minority and other underserved communities in the United States, highlighting, among other critical needs, the importance of increasing the diversity of participants in clinical trials. Clinical trials provide evidence of medi-

There is considerable evidence that clinician recommendations play an important role in helping patients to consider participating in clinical trials.[2] Yet such engagement is not widespread. Multiple barriers impede clinician engagement in research, starting with a lack of awareness and knowledge about clinical research. Many U.S.

example, less than 8% of patients with cancer participate in clinical trials, even though more than 50% will participate when offered the opportunity.[3] Community clinicians can't present these opportunities to their patients if the trials are not accessible.

Typical site-selection practices

Building Remote Research Infrastructure: UMN Example

- Strong telemedicine competencies
- Define and delegate “in-house” and remote tasks
- Reliable real-time communication
- Mock Remote Consent Training
- Cross-trained coordinator pool comfortable with remote enrollment processes*

*Consider pooling with other departments

Telemedicine Practice

- Telestroke training is part of practice orientation for all new providers
  - “Webside Manner”
- Proficiency with advanced features of telestroke technology
  - Adding family, coordinators, or interpreters to calls
- Telestroke is routinely utilized for stroke care including inpatient and outpatient settings
- Active 24/7 screening from all stroke/NCC providers

Communication & Execution Plan

- Properly timed, succinct communication with “in house” clinical team:
  - Pharmacy: early notification, de-escalation, or “order is in”
  - Clinical team for necessary info: mRS, NIHSS, LKW, etc
  - Translator Services: pre-consent conversion overview, coordinating the call
- Establish who performs “in-house” tasks when research team is remote
  - deliver or pick-up study medication
  - procure labs (example: R-kit orders for lab draws)

Implementation: Being Remote Changes the Flow of Conversations

- Verify ability to connect remotely
  - Tech & internet availability
  - Establish time needed at the start of the conversation
- Thoughtful introduction of the research
  - Provide remote consent context (clinical introduction)
  - Plan for lack of human connection/non-verbals
- “Downtime”’ alert plan including use of back-up paper consent forms
- Be prepared to use short-form and interpreters

Training: Mock Consent Sessions

- Demonstrate technology/point-out resources
- Practice the remote enrollment workflow in a near-real world setting
  - parallel notification/communication with coordinators
  - eConsent
- Develop eConsent/remote consent “internal script”
  - Exposure to the “hard” questions
- Experienced PIs/coordinators observe and provide feedback

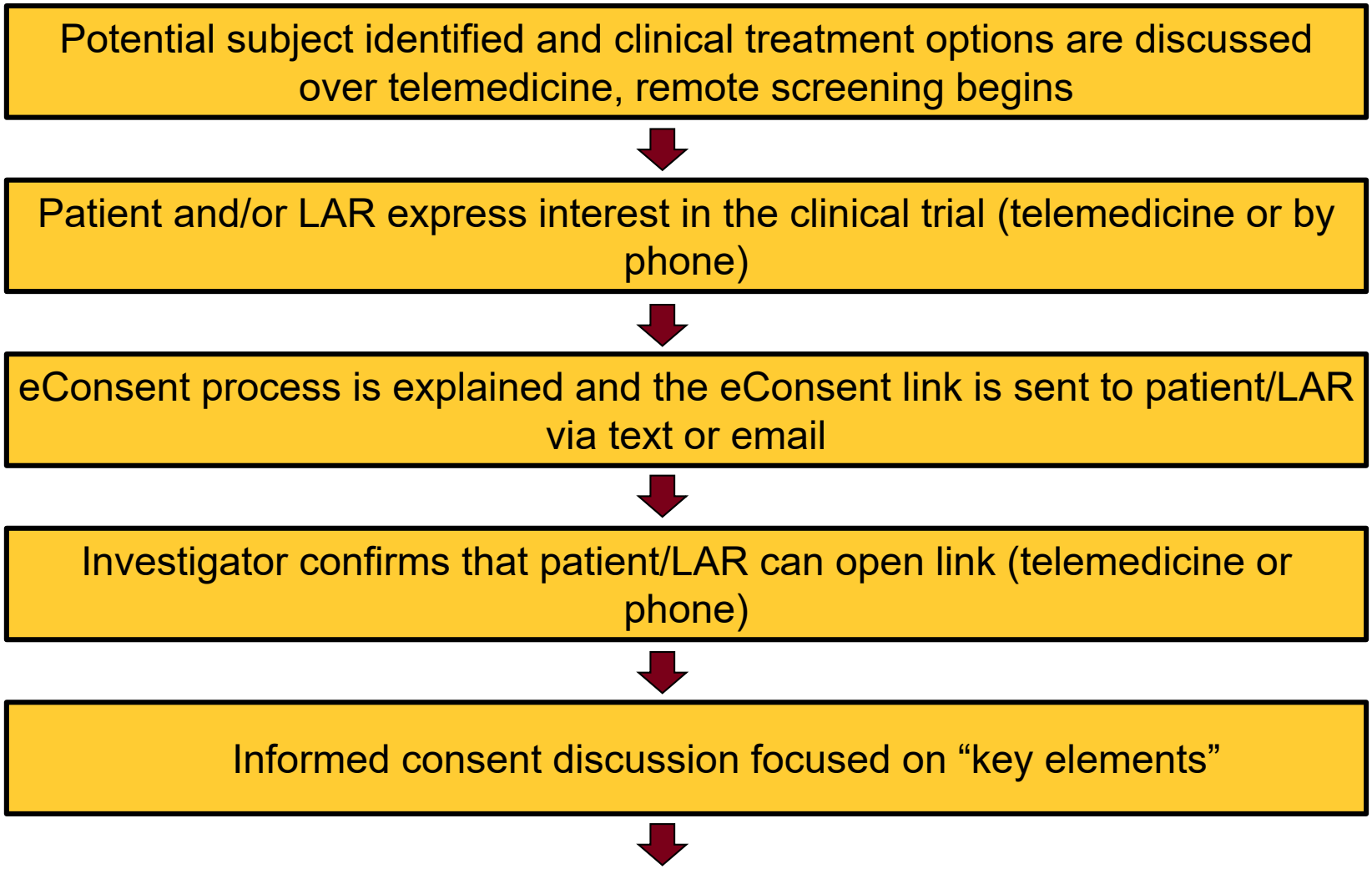
Telemedicine Clinic & Remote Research

- Communication from IP stay to Telestroke Clinic staff
  - EPIC phone encounter note
- Map subject's outpatient telestroke clinic pathway
  - Coordinate with schedulers
  - Account for consent conversation time (outpatient trials)
  - Virtual clinic rooms for research consent or follow up
- Assist subject/family in setting up MyChart account PRIOR to discharge

Technology Supporting Remote Research

- eConsent (provided by StrokeNet)
- Video conferencing beyond telemedicine (zoom at the UMN)
- Real-time communication platform
- EMR (e.g. Research Integrated MyChart)
- EMR (example: telephone encounters)

Acute Remote Enrollment Process



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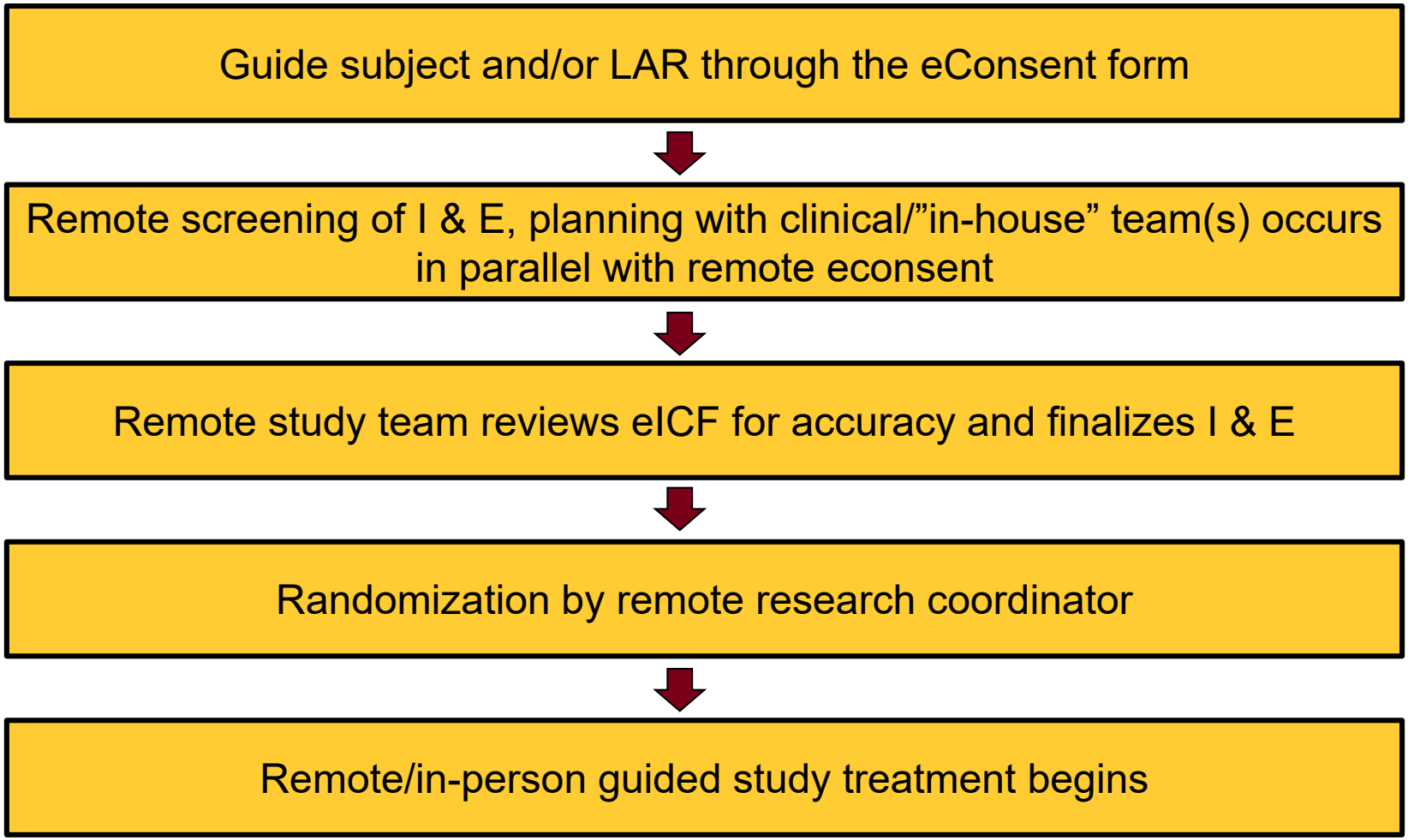

Telemedicine & Remote Research Advisory Group

The mission of this group is to expand access to clinical research through remote clinical research practices with a focus on feasibility, efficacy, and best practice.

Telemedicine & Remote Research Advisory Group

The mission will be achieved through concerted efforts at innovation and implementation of remote clinical research practices, including, but not limited to:

- telemedicine
- electronic informed consent
- centralized coordination of research at spoke sites

Look for a survey soon!

Acknowledgements

Dr. Navdeep Sangha and Denise Gaffney

UMN Acute Care Research Coordinators

UMN Stroke & Neurocritical Care

UMN Department of Emergency Medicine

Contact Information

Abbey Staugaitis, RN, MSN, CCRC
StrokeNet RCC 18 Program Manager
University of Minnesota, Dept of Emergency Medicine
staug002@umn.edu

Christopher Streib, MD, MS
streib@umn.edu