



# Process for Review of PI and Non PI Personnel for Multi-Site Studies

Stacey Goretzka, CIP  
IRB Manager, Medical University of South Carolina  
SMART IRB Ambassador

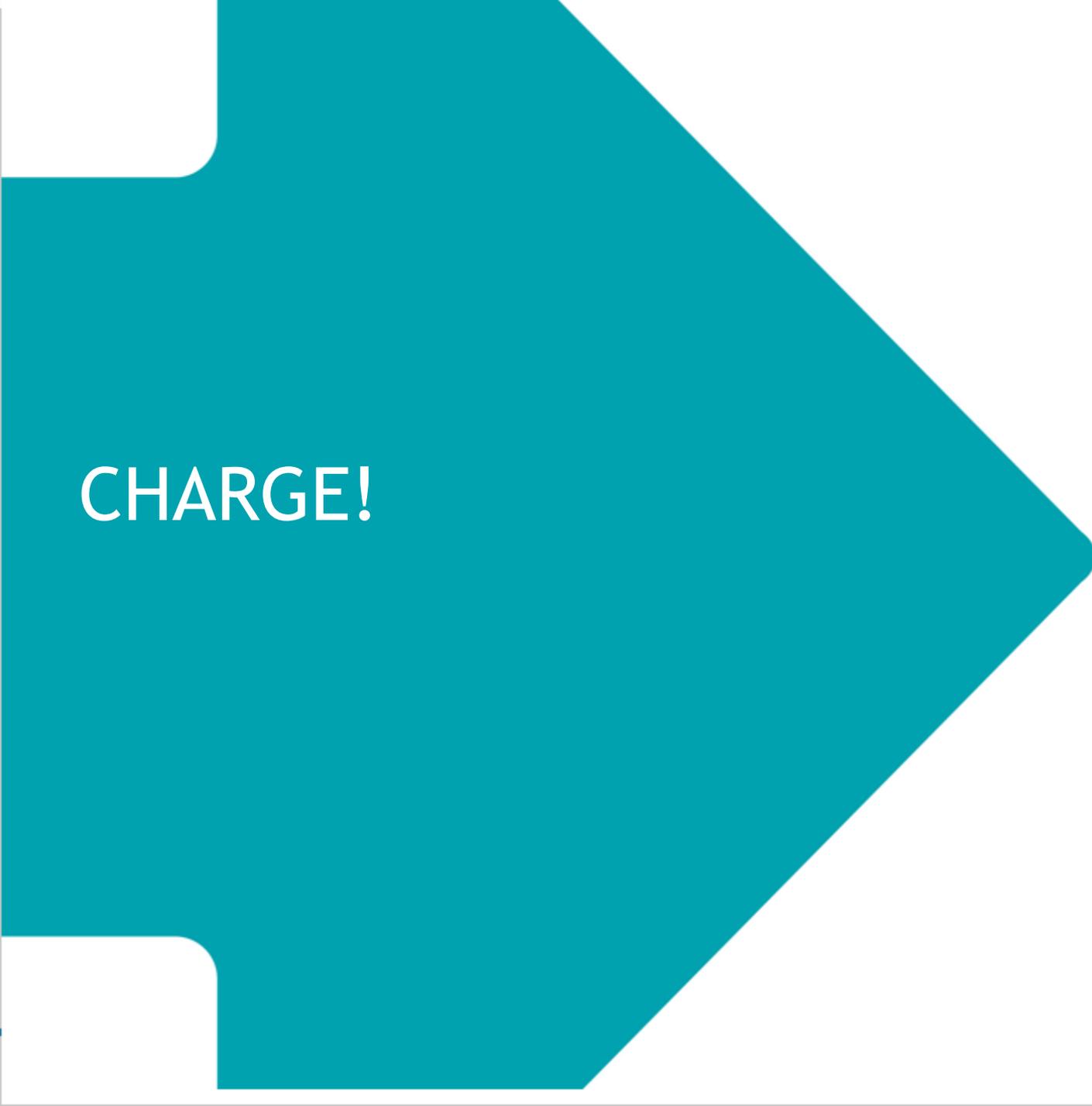
Mike Linke, PhD, CIP  
Chair, NIH StrokeNet Central IRB  
Adjunct Professor of Internal Medicine  
University of Cincinnati

# Membership

- Stacey Goretzka, Ambassador + Medical University of South Carolina
- Mike Linke, StrokeNet CIRB + University of Cincinnati
- Nichelle Cobb, SMART IRB + University of Wisconsin-Madison
- David Forster, WIRB + Copernicus
- Polly Goodman, Dana-Farber Cancer Institute
- Kathy Lawry, Ambassador + AAHRPP
- Ada Sue Selwitz, Ambassador + University of Kentucky
- Kim Summers, Ambassador + University of Texas Health Sciences Center at San Antonio
- Paula Tebeau, Harvard Pilgrim Health Care Institute

# Started and Finished

- First Meeting: February 14, 2019
- Last Meeting: June 27, 2019
- Met approximately twice a month

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**CHARGE!**

# Problem

- Changes in study personnel are common study amendments
- Single IRBs overseeing large multi-site studies can be overwhelmed by such amendments
- The use of external IRBs eliminates the local knowledge of study personnel
- NIH StrokeNet experience

# Charge to the Work Group

Identify, simplify, and harmonize reporting mechanisms to address changes in personnel for the duration of multi-site studies.

# First things first...

## **Revise the charge!**

Expand the scope of the charge to include review of PI and non PI personnel at initial review as well as with changes for the duration of multi-site studies.

# Committee Discussion



# Where To Begin?

- Reviewed federal regulations and guidance
- Compared policies/processes of our own HRPPs
- Received information from TIN IRBs
- Reviewed AAHRPP standards

# Discussion Items

- Which Study Personnel require IRB approval?
- Who is responsible for assessing qualifications?
- What are the IRB responsibilities in approving study personnel?
- How to evaluate and manage conflicts of interest?
- Are study personnel decision different for SBER protocols?

# Challenges

- Regulations and guidance do not provide clear instructions
- Variability among institutions
- Identifying responsibilities

# Challenges

- Not making the process too complicated!

# Recommendations



# Work Group Recommendations

1. Relying Institutions and investigators assume the primary responsibility to assess study personnel training and qualifications
2. Relying institutions develop mechanisms to identify and communicate relevant COIs and proposed management plans to the Reviewing IRB

# Responsibilities Guidance Document

- Documenting and Communicating Roles & Responsibilities Related to Personnel Review and Oversight
  - Division of responsibilities should be formally outlined in a reliance agreement
  - SMART IRB Master Agreement
  - SMART IRB Communication plan

# Responsibilities Guidance Document

- Responsibilities of Reviewing IRBs
  - Implement processes to ensure that study personnel are adequately trained and qualified to conduct the research and to obtain information about relevant COIs
  - Ensure Relying Institutions are aware of their obligations
  - Obtain information for any Overall Lead PI, Relying Site PIs, and a study team Point of Contact (POC) for each of the relying site,
  - Have policies and procedures to collect information about COIs from Relying Institutions in sufficient detail to be able to make the assessments recommended by HHS

# Responsibilities Guidance Document

- Responsibilities of Relying Institutions
  - Study personnel are trained and qualified to conduct the proposed research study.
  - Study personnel meet institutional requirements
  - Monitoring for and communicating COI determinations, prohibitions, and management plans to the Reviewing IRB
  - Ensuring compliance with the requirements of Reviewing IRB

# Responsibilities Guidance Document

- Relying Institutions may meet these obligations in a variety of ways:
  - Delegate responsibilities to a coordinating center
  - Require local site PIs to track personnel
  - Leverage credentialing or human resources processes

# Responsibilities Guidance Document

- Responsibilities of Study Teams/PIs
  - Research personnel are appropriately trained including study-specific/study procedure training
  - Assessing research workload to ensure adequate time and resources to decrease risks to subjects
  - Providing information regarding possible COIs to the Institution and reviewing IRB
  - Comply with institutional requirements regarding oversight of personnel

# Responsibilities Guidance Document

- Other Factors to Consider About Responsibilities
  - Relying sites that have little or no research infrastructure
  - Reviewing IRBs may need to take on responsibilities normally assigned to Relying Institutions and Study Teams

# Appendix

- Responsibilities Table
  - Easy and quick; visual reference guide
  - Can be turned into a checklist

# APPENDIX

The table below outlines responsibilities of Reviewing IRBs, Relying Institutions, and Investigators regarding research personnel.

Responsibility	Relying Institutions	Study Teams	Reviewing IRBs
Verify site Principal Investigator (PI) Qualifications	X		X
Set basic human subjects institutional training requirements for research personnel	X		
Define key study personnel that must be included on a study	X		
Verify study personnel have completed human subjects protection training	X		
Verify study personnel have completed additional training required for study (e.g. GCP)	X	X	
Verify Study personnel have completed study-specific training		X	
Ensure compliance with relying institution's policies and requirements for participating in human subjects research	X		
Approve site PI changes during a study			X
Notify study personnel their responsibilities related to information that should be provided to Reviewing IRBs and others to fulfill oversight obligations.	X		
Comply with institutional requirements regarding oversight of personnel (e.g. tracking study personnel, ensuring personnel are appropriately trained, communicating personnel changes to the local human research protection program for assessment		X	
Obtain information about and assess relevant financial conflicts of interest (COIs) for their potential impact on the research in order to ensure risks to subjects are minimized and disclosed to subjects when appropriate	X		X
Provide information on COI relevant to the research for all engaged protocol personnel via the appropriate channels so that institutions (or designees) and Reviewing IRBs can make appropriate assessment and determinations		X	
Monitor for and communicate COI determinations, prohibitions, and management plans to Reviewing IRBs throughout the life of a study	X		
Comply with the requirements of Reviewing IRBs		X	
Ensure compliance with the requirements of Reviewing IRBs	X		

# StrokeNet Implementation of Guidance

*Per the StrokeNet Central IRB (cIRB) Reliance Agreement, your institution ensures that investigators and staff are qualified to work on studies and that financial conflicts of interest (fCOI) are identified and managed. The cIRB currently verifies this information during their reviews. Beginning on September 1st, 2019 the cIRB will only perform these verifications for Principal Investigators.*

*Principal Investigators will continue to submit documentation of training and the StrokeNet study-specific fCOI forms with the initial submissions, PI change modifications, and at the time of continuing reviews.*

*Any fCOIs identified by your institution for other investigators or staff must be submitted to the cIRB along with the approved management plans. The fCOI cIRB review process is described in the attached StrokeNet SOP ADM 02 Reporting Conflict of Interest and Financial Disclosures*

*Please direct questions to your StrokeNet Project Manager.*

*Please share this information with your local human research protection programs and COI offices.*

A teal-colored header bar with a white network diagram of interconnected nodes and lines. The text "Thank you!" is written in white on the left side.

Thank you!

**Yes, we anticipate many questions and comments!**