

**NIH StrokeNet Network
Standard Operating Procedure**

SOP Number: ADM 18

SOP NAME: NIH StrokeNet and Conduct of Shared Trials

Effective Date: 22-February-2016 (rev 30-May-2023)

1. POLICY

The purpose of this Standard Operating Procedure (SOP) is to describe the processes by which the NIH StrokeNet and another network will operate given the opportunity to collaborate via sharing of sites in the execution of a NIH-funded clinical trial. This document will provide detail on the method by which these two or more networks will jointly execute educational, financial, and general collaborative activities when a trial is funded by NIH and shared between these networks.

2. DEFINITIONS AND ABBREVIATIONS

Abbreviations:

CIRB	Central Institutional Review Board
CTA	Clinical Trial Agreement
F&A	Facilities and Administrative Costs (also known as Indirect Costs)
FOA	Funding Opportunity Announcement
MPI	Multiple Principal Investigator
MUSC	Medical University of South Carolina
StrokeNet	NIH StrokeNet Network
NCC	NIH StrokeNet National Coordinating Center at the University of Cincinnati
NDMC	NIH StrokeNet National Data Management Center at the Medical University of South Carolina
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
PI	Principal Investigator
PPI	Protocol Principal Investigator
PS	Performance Sites

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RA	Reliance Agreement
RCC	NIH StrokeNet Regional Coordinating Centers
SS	Satellite Sites

Definitions:

Funding Opportunity Announcement (FOA): A notice in grants.gov of a federal grant funding opportunity.

Lead Network: The network sponsoring the network specific FOA to which a funded grant was submitted in response.

Clinical Trial Agreement: A contract documenting planned institutional participation in a funded trial by NIH StrokeNet-affiliated entities.

Regional Coordinating Center (RCC): One of 24 institutions receiving regional network infrastructural support funds from the NIH to provide leadership and network coordination of associated satellites and/or performance sites within the NIH StrokeNet on a regional level.

Performance Sites (PS): An institution that may or may not be legally affiliated with the awarded RCC which has agreed with the RCC to serve as a clinical performance site for NIH StrokeNet affiliated studies.

Satellite Site (SS): An institution that is not legally affiliated with the awarded RCC but named by an RCC as a branch of its regional network. An RCC-SS may or may not be a PS for a clinical trial for NIH StrokeNet affiliated studies.

3. SCOPE

This Standard Operating Procedure (SOP) applies to administrative leadership at the NIH StrokeNet NCC, the NIH StrokeNet NDMC, another trial-sharing network leadership, including investigators, staff, participating institutions, or other entities associated with the NIH StrokeNet who have a role in proposal preparation, award management, oversight, and execution of NIH-funded trials that utilize entities affiliated with each network.

4. PROCEDURES

- A. Pre-Award (Application Stage) for stroke specific applications via the NIH StrokeNet Funding Opportunity Announcement (FOA), uses current PAR-XX-XXX**

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1. The opportunity for trial execution enhancement through incorporation of other network performance sites (PS) and NIH StrokeNet RCCs, SS, and CPS is identified, discussed, justified, and endorsed by the NIH StrokeNet NCC and NDMC, the other network leadership, and the PPI leadership.
 2. Degree of another network involvement in a trial is determined.
 - a. Fully involved - a decision/plan will be made specific for each potential proposal in regard to overall management of the trial and the sharing of the management duties will be planned.
 - b. Not fully involved (i.e., a portion of another network performance sites are desired), participating other network institutions will operate under leadership of the NIH StrokeNet NCC and financial considerations specific to the NIH StrokeNet.
 3. The PPI will submit a proposal in response to a NINDS issued funding opportunity announcement.
 4. Endorsement of the application will be documented in the form of NIH StrokeNet and/or another network support via letters of support from non-lead network PI and leadership.
 5. Letters of support demonstrating NIH StrokeNet and/or another network involvement and leadership shall clearly delineate adherence to the F&A collection policies of all networks in place at the time of submission of the proposal.
- B. Post-Award (Trial Implementation and Execution Stage) for conduct of shared trials**
1. NIH StrokeNet sites will utilize the NIH StrokeNet CIRB or approved commercial CIRB for trial protocol review, approval, and regulatory oversight.
 2. The other network CPS must execute a Reliance Agreement (RA) to utilize the NIH StrokeNet approved CIRB for regulatory oversight of a funded trial through the NIH StrokeNet network. For networks in other countries, human subjects' protection, and good clinical practice requirements will be through the respective pathways utilized within the specific country and at specific recruitment centers for a given trial.
 3. Statistical and data management will take place at the NIH StrokeNet NDMC for all sites participating in trials involving both non-NIH StrokeNet and NIH StrokeNet institutions. Data management services of the NDMC are inclusive of monitoring for all trials run through the NIH StrokeNet in the United States (U.S.). Networks outside of the U.S. would utilize contracted monitoring and management services as per the needs of a given trial but require approval of the NIH StrokeNet NCC and NDMC.
 4. Trials utilizing neuroimaging techniques must utilize a neuroimaging repository designated by the NIH StrokeNet NDMC as the imaging central repository and

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for processing of central imaging review if neuroimaging data from image analysis is part of the data collection of a trial.

C. Financial Considerations for inter-network collaboration on a shared trial

1. Each network will operate under the financial requirements and general considerations as stipulated by each network's Notice of Award.

D. Educational tasks and designation for inter-network collaboration on a shared trial

1. Upon funding of a shared trial, educational tasks and activities will be coordinated between the networks to avoid duplication of efforts. The goal will be to efficiently educate all members of the networks and deliver training of trial-specific procedures, and to provide and maintain web-based locations where reference material and educational resources can be accessed at any time by trial personnel.
2. The networks' educational coordinators will actively collaborate and share in the production/coordination of educational webinars, publishing of study educational material, and coordinate any other educational needs as they arise related to the shared trial.

E. Ongoing communication between NIH StrokeNet and Other Networks

1. For the purpose of collaborative protocol development, outside network representatives need to work with the NIH StrokeNet PIs and the appropriate NIH StrokeNet working group during the development of the grant.
2. NIH StrokeNet NCC and NDMC multiple PIs (MPIs) or designate participate on the other network videoconferences as needed.
3. There will be annual in-person meetings alternated with annual videoconferences with mutually agreeable times to be determined by the NIH StrokeNet and the other network leadership, as well as NINDS representatives. Meeting related expenses for the in-person events can be shared equally among the networks.

5. APPLICABLE REGULATIONS AND GUIDELINES

6. REFERENCES TO OTHER APPLICABLE SOPS

ADM 01 Developing StrokeNet Standard Operating Procedures

ADM 09 RCC Management of Satellites and Clinical Performance Sites

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

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Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	22-Feb-2016	22-Feb-2016	22-Feb-2016
1.1	Biannual review with minor administrative changes	13-Dec-2016		
2.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
3.0	Review with administrative changes	30-May-2023	30-May-2023	30-May-2023



NIH StrokeNet Network

Standard Operating Procedure (SOP)

NIH StrokeNet and Conduct of Shared Trials

Version 3.0

ADM #18

Reviewed and Approved by:

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Scott Janis, PhD, (NIH/NINDS Program Director)