SOP Number: ADM 10
SOP NAME: Inclusion of New Satellite Sites and Performance Sites
Effective Date: 3-Jun-2014 (rev 31-May-2023)

1. POLICY

This policy will define the recommended process for the addition of new satellite sites (SS) and performance sites (PS) to the StrokeNet Network. The Principal Investigator (PI) of the Regional Coordinating Center (RCC) ultimately has decision making authority about initial inclusion of a SS and removal of a SS from the RCC because of failure to meet expectations of recruitment and trial conduct. It is not required that a new site be in close geographic proximity to the RCC, however network leadership encourages RCCs to choose SS geographically close to maintain the Regional Network concept and to facilitate the supervision of that site.

2. DEFINITIONS AND ABBREVIATIONS

COI   Conflict of interest also known as financial conflict of interest. A significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research (42 CRF 50).

CTA   A clinical trial agreement is legally binding contract between a sponsor, site, and researcher, and outlines each party's responsibilities and obligations for the clinical trial.

GCP   Good clinical practice is an international set of guidelines that helps make sure that the results of a clinical trial are reliable and that the patients are protected.

IRB   Institutional Review Board

NCC   National Coordinating Center at the University of Cincinnati

NIH   National Institutes of Health

NINDS   National Institute of Neurological Disorders and Stroke

PS   Performance sites are institutions that are not legally affiliated with the awarded RCC but which have agreed to serve as a network trial recruitment site for an awarded RCC network.

RA   The reliance agreement is a formal, written document that provides a mechanism for an institution engaged in research to delegate institutional review board (IRB) oversight to the central IRB.

RCC   A Regional Coordinating Centers is an institution designed and directly funded by NINDS/NIH to provide leadership for the Stroke Network on a regional level.

SS   Satellite sites are institutions named by an RCC as a part of its regional network that are not legally affiliated with the RCC.

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3. SCOPE

This policy applies to all Regional Coordinating Centers with infrastructure awards from the NIH.

4. PROCEDURES

A.   Review criteria for adding sites:
  1.   It is the policy of the NIH StrokeNet that a SS and PS can only be aligned with one network RCC.
  2.   It is recommended that RCCs accept potential sites that have a demonstrated ability to recruit into stroke trials.
  3.   New potential sites should have clearly defined leadership and delegation of authority within the SS or PS that is responsible for meeting the requirements of a site participating in the NIH StrokeNet with regards to CTAs, Reliance Agreements (RAs), and clinical research requirements for participating investigators, including conflict of interest (COI) reporting.

B.   Process for adding to the Network:
  1.   RCC establishes relationship with potential SS or PS. The process may be initiated by the RCC or the potential SS/PS.
  2.   The RCC notifies the NCC of their interest in adding a new satellite to their RCC.
  3.   The NCC verifies that the SS or PS is not currently linked with another RCC.
  4.   NCC executes CTAs for each trial and the Institutional Review Board (IRB) of record executes an RA as appropriate.

C.   Responsibilities of RCC Leadership:
  1.   Ultimate responsibility for the quality of trial data at all RCC sites, as well as compliance of SS and PS with Good Clinical Practice (GCP) and COI reporting – even if this task is delegated to the SS.
  2.   Communication to SS and PS of all RCC activities.
  3.   Training required of SS and PS staff may include:
     i.   Trial specific protocol training
     ii. Trial initiation and mock subject enrollment
     iii. Trial close-out process
     iv. Develop plan for screening and recruiting trial subjects
     v.   Investigational pharmacy education
     vi. Obtaining informed consent
     vii. Safety reporting
  4.   Act as a resource for any local questions regarding ongoing NIH StrokeNet trials within the RCC.
  5.   Visit the SS or PS to understand the infrastructure and processes that are in place.

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6.   Monitor documentation of COIs and GCP training provided by the responsible SS or PS leadership.

7.   Conduct regular regional meetings, either in person or by teleconference, to discuss staffing, recruitment, resources, and training.

8.   Ensure compliance of the SS and PS for trial feasibility assessments, StrokeNet Annual Surveys, and the scope of work defined by each StrokeNet trial's CTA.

D.   Responsibilities of new SS:

1.   Current registration in SAM.gov, the entity name associated with the Unique Entity Identifier (UEID) must match the entity name on the Internal Revenue Service Form W-9.

2.   Recruit into the NIH StrokeNet Trials under trial-specific fully executed CTAs.

3.   Provide excellent quality data, documentation of COI and GCP training for participating investigators.

4.   Travel to RCC meetings or NIH StrokeNet meetings must be paid for by the RCC unless covered by a specific trial for recruitment sites. Any other coverage of travel expenses would be at the discretion of the RCC PI.

5.   Complete documentation of trial enrollment and required tasks prior to receiving payment by the NCC.

6.   Provide accurate and complete contact information for key personnel to the RCC and communicate staffing changes in a timely manner to the RCC and national trial teams.

E.   Responsibilities of new PS:

1.   Recruit into the NIH StrokeNet Trials under trial-specific fully executed CTAs.

2.   Provide excellent quality data, documentation of COI and GCP training for participating investigators.

3.   Travel to RCC meetings or NIH StrokeNet meetings must be paid by the RCC unless covered by a specific trial for recruitment sites. Any other coverage of travel expenses would be at discretion of the RCC PI.

4.   Complete documentation of trial enrollment and required tasks prior to receiving payment by the entity listed on the CTA.

5.   Provide accurate and complete contact information for key personnel to the RCC and communicate staffing changes in a timely manner to the RCC and national trial teams.

F.   Responsibilities of the NCC:

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1. Execution of CTA and facilitate RA execution between the SS or PS and IRB of record.
2. Communication of NIH StrokeNet activities including ongoing trials with all SS/PS.
3. Provide payment to each SS or PS for trial activities as defined in CTAs Such payments may be withheld if there are major issues with data completion and quality until these issues are addressed by the RCC, SS, and PS.
4. Compensate for travel for investigators as needed for a given clinical trial run through the NIH StrokeNet.
5. Assess the SS/PS performance as part of the larger RCC performance measurement.
6. Credit the RCC for all recruitment at their SS/PS.

5. APPLICABLE REGULATIONS

42 CFR 50.604	Responsibilities of Institutions regarding Investigator financial conflicts of interest
45 CFR Part 94	Responsible Prospective Contractors
45 CFR 56	Federal Policy for the Protection of Human Subjects ("The Common Rule")
NIH/NINDS	RCC Notice of Award, Cooperative Clinical Research Agreement

6. REFERENCES TO OTHER APPLICABLE SOPs

ADM 06 Network Process for Documenting Essential Financial and Federal Compliance
ADM 15 Network Communication

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	3-Jun-2014	3-Jun-2014	3-Jun-2014
1.1	Biannual review with minor administrative changes	19-Sep-2016		
2.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
3.0	Review with process updates	31-May-2023	09-June-2023	09-June-2023

NIH StrokeNet Network

Standard Operating Procedure (SOP)

Inclusion of New Satellite Sites and Performance Sites

Standard Operation Procedures

Version 3.0

ADM #10

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