SOP Number: ADM 10
SOP NAME: Inclusion of New Satellite and Clinical Performance Sites
Effective Date: 3-Jun-2014

1. POLICY

This policy will define the recommended process for the addition of new satellite sites. The Principal Investigator (PI) of the Regional Coordinating Center (RCC) ultimately has decision making authority about initial inclusion of a satellite site (SS) and whether a satellite site should be removed from the RCC because of failure to meet expectations of recruitment and trial conduct. An RCC should initially focus on integration of its satellite sites included in the initial submission before adding new sites. An RCC can accept a new satellite site that was not part of an original submission. An RCC is not required to accept a satellite site that was not part of original submission. It is not required that a new site be in close geographic proximity to the RCC, however network leadership encourages RCCs to choose satellites geographically close to maintain the Regional Network concept and to facilitate the supervision of that site during clinical trial enrollments.

2. DEFINITIONS AND ABBREVIATIONS

RCC Regional Coordinating Centers-Institutions 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

PS A performance site is an institution that is not legally affiliated with the awarded RCC but which has agreed to serve as a network trial recruitment site for an awarded RCC network.

NCC National Coordinating Center at the University of Cincinnati

NIH National Institutes of Health

MTA NIH StrokeNet Master Trial Agreement is a bilateral agreement between the NCC and the RCC or SS similar to a memorandum of understanding. This agreement expresses a convergence of will between the parties, indicating an intended common line of action.

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) review to the central IRB

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)

GCP Good Clinical Practice –per International Conference on Harmonization

3. SCOPE

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

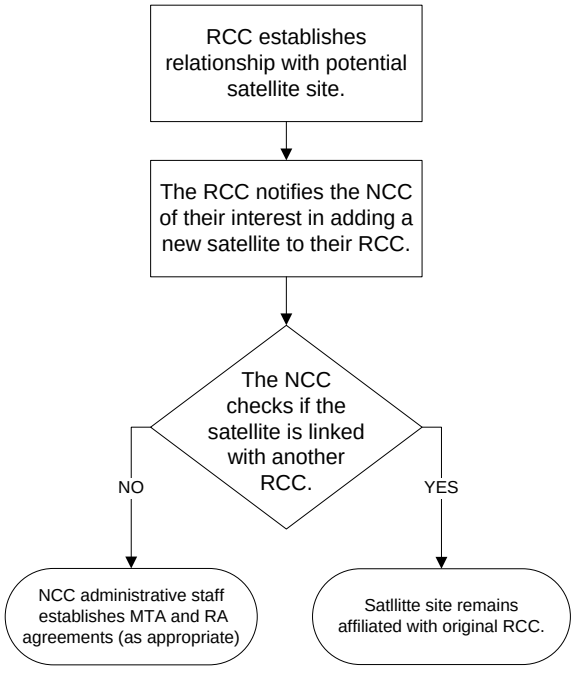
4. PROCEDURES

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 satellites should have clearly defined leadership and delegation of authority within the satellite site that is responsible for meeting the requirements of a satellite site in the NIH StrokeNet with regards to MTA, RA, and clinical research requirements for participating investigators, including Conflict of Interest (COI) reporting.

B. Process for adding to Network

1. RCC establishes relationship with potential satellite site. The process may be initiated by the RCC or vice versa.
2. The RCC notifies the NCC of their interest in adding a new satellite to their RCC.
3. The NCC verifies that the satellite is not currently linked with another RCC.
4. NCC establishes MTA and 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 and Conflict of Interest Reporting – even if this task is delegated to the SS.
2. Communicating of all RCC activities to SS including regional meetings.
3. Acting as a resource for any local questions regarding ongoing NIH StrokeNet trials within the RCC.

4. Visiting the SS to understand the infrastructure and processes that are in place.
5. Monitoring the SS documentation of COIs, GCP provided by the responsible SS leadership.

D. Responsibilities of new SS:

1. Current registration in SAM.gov
2. Recruit into the NIH StrokeNet Trials under the same Protocol Trial Agreements as the participating RCC site.
3. Provide excellent quality data, documentation of Conflict of Interests and Good Clinical Practice training for participating investigators.
4. Travel to RCC meetings or NIH StrokeNet meetings must be paid for by the RCC except as covered for travel related to trials as a recruitment site. Any other coverage of travel expenses would be at the discretion of the RCC PI.
5. Completing documentation of trial enrollment and accomplished tasks prior to receiving payment by the NCC.

E. Responsibilities of new RCC-PS:

1. Recruit into the NIH StrokeNet Trials under the RCC Protocol Trial Agreements.
2. Provide excellent quality data, documentation of Conflict of Interests and Good Clinical Practice training for participating investigators.
3. Travel to RCC meetings or NIH StrokeNet meetings must be paid by the RCC except as covered for travel related to trials as a recruitment site. Any other coverage of travel expenses would be at discretion of the RCC PI.
4. Completing documentation of trial enrollment and accomplished tasks prior to receiving payment by the RCC.

F. Responsibilities of the NCC:

1. Execution of MTA and RA agreements with the SS.
2. Communicating NIH StrokeNet activities including ongoing trials with all SS.
3. Providing payment to each SS for trial activities as defined in MTA and Protocol Trial Agreements trial budgets including overhead. Such payments may be withheld if there are major issues with data completion and quality until these issues are addressed by the RCC and the SS.
4. Compensating for travel for investigators as needed for a given clinical trial run through the NIH StrokeNet.
5. Assessing the SS performance as part of the larger RCC performance measurement.
6. Crediting the RCC for all recruitment at the SS included in the RCC.

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")
RCC Notice of Award,	Cooperative Clinical Research Agreement, Section IV- NS Special Terms and Conditions and Terms of Award sections

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

Attachment A- MTA Template available on www.nihstrokeNet.org
Attachment B- RA template on available on www.nihstrokeNet.org

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

NIH StrokeNet
PREVENTION | TREATMENT | RECOVERY

NIH StrokeNet Network

Standard Operating Procedure (SOP)

Inclusion of New Satellite and Clinical Performance Sites

Version 1

ADM #10

Originators: NIH StrokeNet NCC Personnel

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6/3/14

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3 June 2014

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