

# NIH StrokeNet Network Standard Operating Procedure

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

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## 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 (RCC-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 RCC's 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

<b>RCC</b>	Regional Coordinating Centers-Institutions designed and directly funded by NINDS/NIH to provide leadership for the Stroke Network on a regional level
<b>RCC-SS</b>	Satellite sites are institutions named by an RCC as a part of its regional network that are not legally affiliated with the RCC
<b>RCC-CPS</b>	A clinical 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.
<b>NCC</b>	National Coordinating Center, University of Cincinnati
<b>NIH</b>	National Institutes of Health
<b>MTA</b>	NIH StrokeNet Master Trial Agreement is a bilateral agreement between the NCC and the RCC or RCC-SS similar to a memorandum of understanding. This agreement expresses a convergence of will between the parties, indicating an intended common line of action.
<b>RA</b>	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

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| <b>COI</b> | 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 CFR 50) |
| <b>GCP</b> | 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-

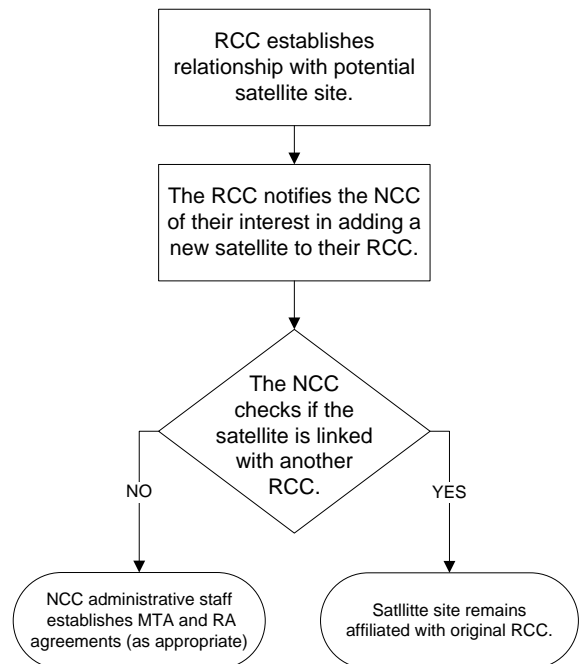
- a. It is the policy of the NIH StrokeNet that an RCC-SS and RCC-CPS can only be aligned with one network RCC.
- b. It is recommended that RCCs accept potential sites that have a demonstrated ability to recruit into stroke trials
- c. New potential satellites should have clearly defined leadership and 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

- a. RCC establishes relationship with potential satellite site. The process may be initiated by the RCC or vice versa.
- b. The RCC notifies the NCC of their interest in adding a new satellite to their RCC.
- c. The NCC verifies that the satellite is not currently linked with another RCC.
- d. NCC establishes MTA and RA as appropriate.

#### C. Responsibilities of RCC Leadership:

- a. Ultimate responsibility for the quality of trial data at all RCC sites, as well as compliance of RCC-SS and RCC-CPS with Good Clinical Practice



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- b.        and Conflict of Interest Reporting – even if this task is delegated to the RCC-SS. Communicating of all RCC activities to RCC-SS including regional meetings.
  - c.        Acting as a resource for any local questions regarding ongoing NIH StrokeNet trials within the RCC.
  - d.        Visiting the RCC-SS to understand the infrastructure and processes that are in place.
  - e.        Monitoring the RCC-SSs documentation of COIs, GCP provided by the responsible RCC-SS leadership.
- D.        Responsibilities of new RCC-SS:
- a.        Current registration in SAM.gov
  - b.        Recruit into the NIH StrokeNet Trials under the same Protocol Trial Agreements as the participating RCC site.
  - c.        Provide excellent quality data, documentation of Conflict of Interests and Good Clinical Practice training for participating investigators.
  - d.        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.
  - e.        Completing documentation of trial enrollment and accomplished tasks prior to receiving payment by the NCC.
- E.        Responsibilities of new RCC-CPS:
- a.        Recruit into the NIH StrokeNet Trials under the RCC Protocol Trial Agreements.
  - b.        Provide excellent quality data, documentation of Conflict of Interests and Good Clinical Practice training for participating investigators.
  - c.        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.
  - d.        Completing documentation of trial enrollment and accomplished tasks prior to receiving payment by the RCC.
- F.        Responsibilities of the NCC:
- a.        Execution of MTA and RA agreements with the Satellite Site.
  - b.        Communicating NIH StrokeNet activities including ongoing trials with all RCC-SS.
  - c.        Providing payment to each Satellite Site 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 RCC-SS.

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- d.        Compensating for travel for investigators as needed for a given clinical trial run through the NIH StrokeNet.
- e.        Assessing the RCC-SS performance as part of the larger RCC performance measurement.
- f.        Crediting the RCC for all recruitment at the RCC-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 #6 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](http://www.nihstrokeNet.org)  
Attachment B- RA template on available on [www.nihstrokeNet.org](http://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



## NIH StrokeNet Network

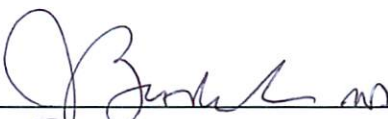
# Standard Operating Procedure (SOP) Inclusion of New Satellite and Clinical Performance Sites

Version 1

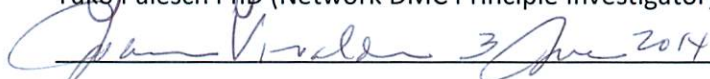
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Originators: NIH StrokeNet NCC Personnel

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