

**NIH StrokeNet Network
Standard Operating Procedure**

SOP Number: ADM 01
SOP NAME: Developing StrokeNet Standard Operation Procedures
Effective Date: 3-Jun-2014 (rev 20-Jan-2023)

1. POLICY

The purpose of this Standard Operating Procedure (SOP) is to describe the process of creating, editing, controlling and distributing SOPs for the NIH StrokeNet Network (StrokeNet).

2. DEFINITIONS AND ABBREVIATIONS

Abbreviations:

GCP	Good Clinical Practice
ICH	International Conference on Harmonization
IRB	Institutional Review Board
cIRB	central Institutional Review Board
MPIs	Multiple Principal Investigators
MTA	Master Trial Agreement
NCC	National Coordinating Center, University of Cincinnati
NDMC	National Data Management Center, Medical University of South Carolina
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
PS	Regional Coordinating Center Performance Site also known as Clinical Trial Performance Site
RA	Reliance Agreement
RCC	Regional Coordinating Center
SS	Regional Coordinating Center Satellite Sites
SOP	Standard Operating Procedure
StrokeNet	NIH StrokeNet Network

Definitions:

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Approval: Indicates the last step of the designated approval chain. The approval chain will be defined at the beginning of the document creation process. The approval process may vary between different types of documents.

Controller: Author of the document, responsible for the draft, revision and final document content.

Critical Documents: Any document that will be provided to the Regional Coordinating Centers (RCCs), RCC-SS, RCC-PS or Non-Network Protocol Center for regulatory purposes such as IRB submissions, including clinical trial protocols, protocol amendments, and sponsor progress reports. This includes any document that describes or guides network activities including SOPs, processes, and any document under development or revision by a collaborative effort of a StrokeNet committee or working group.

Draft: Document created by the controller of the document. Documents remain drafts until all revisions and edits are completed and the document is approved.

Final: A document that has been approved for use and distribution, no further edits or revisions are considered on finalized documents.

National Coordinating Center (NCC): An institution designed and directly funded by the NINDS/NIH to provide leadership and overall network coordination to harness the clinical science excellence and specialized expertise in stroke management of the RCCs to facilitate recruitment of stroke patients in multiple ongoing stroke trials and studies.

National Data Management Center (NDMC): An institution designed and directly funded by the NINDS/NIH to centralize, harmonize, and coordinate all aspects of data collection for studies conducted in the network.

Prime Award Site: The institution that was awarded the grant to oversee the study protocol.

Penultimate: Next to last draft before final approval.

Policy: Defines the purpose and general area that the SOP addresses.

Procedures: Provides detailed step-by-step instructions, including any additional notes that may assist in the completion of the SOP.

Revision: Document created by a collaborator by modifying a draft using the track changes feature.

Regional Coordinating Center (RCC): An institution designed and directly funded by the NINDS/NIH to provide leadership for the StrokeNet on a regional level.

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RCC Performance Sites (PS): Regional Coordinating Center Performance Sites- an institution that is not legally affiliated with the awarded RCC which has agreed with the RCC to serve as a PS for StrokeNet affiliated studies. An RCC-PS institution does not have a MTA with the NCC to participate in StrokeNet trials/activities but functions under the direct leadership of the RCC or SS.

RCC Satellite Site (SS): Regional Coordinating Center Satellites Site -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 performance site for a clinical trial for StrokeNet affiliated studies.

SCOPE: Defines to whom the SOP applies.

Standard Operating Procedure: Detailed written instruction to achieve uniformity in the performance of a specific function.

3. SCOPE

This Standard Operating Procedure (SOP) applies to any and all SOPs created to define procedures for use within StrokeNet. This SOP applies to the National Coordinating Center (NCC), the National Data Management Center (NDMC), and to all StrokeNet investigators, staff, subcontractors, or other entities associated with the StrokeNet who manage, oversee, and conduct research within the network.

4. PROCEDURES

A. SOP Creation

1. Any member of a StrokeNet entity performing StrokeNet related activities may submit a request for the creation and implementation of a SOP. Requests should be submitted to the StrokeNet Administrative Co-Director for consideration. The request should include the activity and reason to be considered for the creation of the SOP.
2. If needed, the StrokeNet Administrative Co-Director will forward the request for creation to the StrokeNet Coordinating Center MPIs for review and approval of the request.
3. The Administrative Co-Director or designee will be considered the controller of the document as described in the StrokeNet version control SOP.
4. A draft version will be circulated among the applicable StrokeNet NCC, NDMC and NINDS members for comment.
5. Edits and revisions to the draft document will be made by the review members using track changes and returned to the controller of the documents.
6. The controller, using document review procedures, will incorporate all comments and prepare the document for final review.

**NIH StrokeNet Network
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7. After final review designees from the NCC, NDMC, NINDS, along with the controller of the document, will sign off on the SOP.
8. An email that includes the approved SOP and a link to the website will be sent to members of the StrokeNet entities. All StrokeNet SOPs will be posted on the StrokeNet website (www.nihstrokenet.org).
9. The SOP is effective immediately after the final date of signatures by the approving members.

B. SOP Format

1. The title of the SOP document should be brief and descriptive.
2. SOP documents are described with sequential numbers. Whole numbers indicate the version of the resulting **final** document. Incremental numbers (e.g. 0.1, 0.2) indicate the sequential **drafts** that precede a final document. New documents are given the number 1.0 when first created. For Example, the first draft will be DRAFT 0.1, the second draft will be DRAFT 0.2 and the version used for final approval will be labeled PENULTIMATE. The approved final document will be FINAL 1.0 and future revisions of an approved document will be DRAFT 1.1 and so on.
3. The status of the document will be noted in the footer (i.e. draft, revision, final).
4. The controller will circulate the draft and incorporate comments/suggestions from the reviewers.
5. The controller will circulate the revised document to all signatories and request signature to indicate the approval of the final draft.
6. Incorporated changes to a document will be recorded in the **Document History** section.
7. Each SOP will contain the following sections. Additional sections can be added as necessary:
 - a. **Policy:** defines the purpose and general area that the SOP addresses
 - b. **Definitions and abbreviations:** defines words/abbreviations that are used in the SOP
 - c. **Scope:** defines who the SOP applies
 - d. **Procedures:** provides a detailed list and/or flow diagram of step-by-step instructions, including any additional notes that may assist in completion of the SOP
 - e. **Applicable Regulations:** List of references to specific policies and guidance documents from which the activity of function
 - f. **References to Other Applicable SOPs**
 - g. **Attachments:** List of forms or other documents that may be used in conjunction with the SOP
 - h. **Document History:** Record of SOP development, revisions and approvals.

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C. Revision of an Existing SOP

1. Any member of a StrokeNet entity performing StrokeNet related activities may submit a request for the revision of a SOP. Requests should be submitted to the StrokeNet Administrative Co-Director for consideration.
2. The StrokeNet Administrative Co-Director will forward the request to the StrokeNet Executive Committee for review and approval, if needed.
3. If approved, the revision process will follow the steps outlined in Section A of this Document.

D. SOP Review and Maintenance of SOPs

1. All SOPs will be reviewed by the NCC as needed and/or by the Executive Committee at least once every 5 years to ensure compliance with applicable regulations, policies and procedures. These reviews will be documented in the SOP document history.
2. The NCC will maintain all current SOPs in an electronic format on the StrokeNet website.
3. The NCC will archive all revised and/or retired SOPs.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 312.57	Recordkeeping and Record Retention
ICH E6, 2.13	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.5	Trial Management, Data Handling and Recordkeeping

6. REFERENCES TO OTHER APPLICABLE SOPS

This SOP applies to all NSN Network SOPs

7. ATTACHMENTS AND REFERENCES

SOP Template

SOP Approval Signature Page

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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	23-Aug-2016		
2.0	Final	15-Sep-2016	15-Sep-2016	15-Sep-2016
3.0	Review with minor administrative changes	8-Dec-22	20-Jan-2023	20-Jan-2023

*additional rows can be added as needed

NIH StrokeNet Network
Standard Operating Procedure

SOP Number TBD
SOP NAME
Effective Date [insert date]

- 1. POLICY
- 2. DEFINITIONS AND ABBREVIATIONS
- 3. SCOPE
- 4. PROCEDURES
- 5. APPLICABLE REGULATIONS AND GUIDELINES
- 6. REFERENCES TO OTHER APPLICABLE SOPS
- 7. ATTACHMENTS AND REFERENCES
- 8. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
				Upon date of last signature



NIH StrokeNet Network

Standard Operating Procedure (SOP)

XXXXXXX

Version 1

ADM #1

Originators: StrokeNet National Coordinating Center Personnel

Reviewed and Approved by:

(StrokeNet NCC Principal Investigator)

(StrokeNet NDMC Principal Investigator)

(NINDS Representative)

NCC Administrative Co-Director, Document Author/Controller



NIH StrokeNet Network

Standard Operating Procedure (SOP)

Developing StrokeNet

Standard Operation Procedures

Version 3.0

ADM #1

Reviewed and Approved by:

A handwritten signature in black ink that reads "Pooja Khatri".

Pooja Khatri, MD, (StrokeNet NCC Principal Investigator)

A handwritten signature in black ink that reads "Jordan J. Elm".

Jordan Elm, PhD, (StrokeNet NDMC Principal Investigator)

A handwritten signature in black ink that reads "Scott Janis".

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