NIH StrokeNet Network
Standard Operating Procedure

SOP Number [insert number]
SOP NAME: Regional Coordinating Center Management of Satellite and Performance Sites
Effective Date [insert date]

1. **POLICY**
   The purpose of this standard operating procedure (SOP) is to define the relationship between the StrokeNet Regional Coordinating Center (RCC) and its Satellite Sites (SS) and Performance Sites (PS).

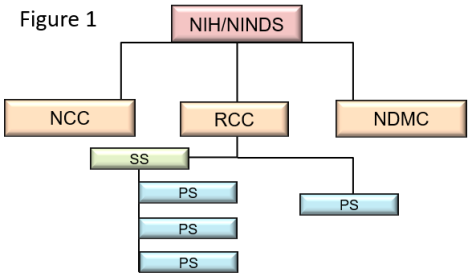
2. **DEFINITIONS AND ABBREVIATIONS**

CTA	**Clinical Trial Agreement**
GCP	**Good Clinical Practice**
HSP	**Human Subject Protection**
NCC	**National Coordinating Center** at the University of Cincinnati – an institution awarded NINDS/NIH funding to provide leadership for the StrokeNet infrastructure to facilitate rapid development and implementation of NINDS funded stroke trials
NDMC	**National Data Management Center** at the Medical University of South Carolina – an institution that receives NINDS/NIH funding to provide protocol data management, ensure data quality control, data monitoring, interim monitoring, analysis, and reporting for the NCC, the NINDS, and Data and Safety Monitoring Boards (DSMBs)
NINDS	**National Institute of Neurological Disorders and Stroke**
PI	**Principal Investigator**
PS	**Performance Site** – a clinical location that is engaged in research for a clinical trial
SOP	**Standard Operating Procedure**
RCC	**Regional Coordinating Center** – an institution awarded NINDS/NIH funding to provide scientific leadership, regular communication, and support to their regional consortium of sites that participate in StrokeNet trials
SAE	**Serious Adverse Event**
SS	**Satellite Site** – an institution not legally affiliated with the awarded RCC but named by an RCC as a branch of its regional network. SS may or may not be a site for a clinical trial for StrokeNet affiliated studies.
UAE/UAP	**Unanticipated Event** (StrokeNet CIRB)**/ Unanticipated Problem** (Advarra)
WebDCU™	Comprehensive clinical trials management system operated by NDMC

3. **SCOPE**
   The information provided in this document is applicable to SS and PS operating under the RCC and outlines roles, responsibilities, and operational expectations of the RCC to others in the StrokeNet network.

4. **STRUCTURE** – The RCC is the regional academic medical center that includes geographically or organizationally linked SS and PS that are committed to randomizing patients in NINDS-funded

Figure 1



NIH StrokeNet clinical studies (Figure 1). The RCC provides research support for its SS and PS. The NCC manages ongoing operational issues, such as regulatory assistance, subcontracts for capitated payments, and protocol-specific site training. The NDMC manages data and site monitoring. The productivity of the SS and PS will be considered part of the RCCs contribution to the NIH StrokeNet.

5. **ROLES AND RESPONSIBILIIES**
   A. The **RCC** will provide scientific leadership, regular communication regarding protocols and study progress, administrative and technical support for protocol implementation and conduct at SS and PS, additional site monitoring if deemed necessary, and technical assistance for the development of compelling clinical research applications from SS and PS. Responsibilities include, but are not limited to:
      1. Ensure that all participating sites demonstrate their intent and capability of complying with federal regulations, GCP, HSP, and NIH StrokeNet SOPs
      2. Provide frequent communication to SS and PS regarding protocols, study progress, and administrative or technical support.
      3. Ensure that the PIs, study team members, and participating institutions are qualified and appropriately resourced to conduct the protocol.
      4. Ensure that each participating investigator and study team member receives adequate StrokeNet procedure and protocol training prior to enrolling participants and facilitate training if need be.
      5. Monitor progress and overall conduct of the study at all participating sites.
      6. Review data and maintain timely submission of data for study analysis.
      7. Ensure all participating sites submit SAEs and UAE/UAPs in accordance with CIRB policy.
      8. Distribute, collect, and enter data for StrokeNet trial feasibility surveys and annual surveys for your SS and PS.
      9. Ensure RCC contact information entered in [Regional Coordinating Center] tab is current in the WebDCU™ on a yearly basis or within 30 days of a change.

   B. Enrolling **SS** and **PS** will be directly involved in establishing infrastructure and personnel for clinical trial performance activities including training and trial initiation, trial execution, and trial closeout. Responsibilities include but are not limited to:
      1. Maintain current registration in SAM.gov and executed reliance agreement with the StrokeNet Central Institutional Review Board (CIRB) and/or Advarra.
      2. SS will recruit participants into StrokeNet trials under their own clinical trial agreement (CTA) with the NCC at the University of Cincinnati. PS will recruit participants into StrokeNet trials under the same CTA as their RCC or SS.

3. Provide quality data, documentation of conflict of interests, GCP, HSP, and protocol training for participating investigators and study staff.
4. Comply with all local and federal requirements for the initiation and ongoing performance of a clinical trial per the principles of GCP as defined in ICH Consolidated Guidance (ICH E6) and Title 45 and part 46 Federal Policy for the Protections of Human Subjects "Common Rule".
5. Comply with the trial investigational plan as defined in the protocol and approved by the CIRB of record and the NINDS appointed DSMB.
6. Obtain appropriate CIRB approval and local IRB acknowledgement.
7. Report SAEs and UAE/UAP through WebDCU™ or CIRBI for timely submission to CIRB of record.
8. Complete internal logistics necessary to execute the trial.
9. Assure that the expenses for research related procedures are not billed to the participant.
10. Receipt, storage, and accountability of study provided supplies in compliance with defined procedures.
11. Handling and administration of study supplies to participants in compliance with defined procedures.
12. Assure access to participant medical records for site monitoring visits per institutional and trial procedures.
13. Enter collected data into WebDCU™ in a time frame consistent with defined procedures.

6. REGIONAL NETWORK OPERATIONS

A. Communication Plan

1. Regional Meetings

- *Define that RCC team and the PS and SS teams that will meet (PIs, coordinators, pharmacy, sub-Is etc.).*
- *Define frequency of meetings and method of meetings (in-person, virtual).*
- *Define purpose of meetings, discussion items, training topics, etc.*
- *Define other regular meetings, virtual conferences, phone calls, and resources provided to SS and PS team (office hours, StrokeNet resources, trial resources, etc.).*

2. Contact Lists and Changes in Personnel

- *Define whom from the SS and PS will provide contact information to whom at the RCC.*
- *Define the contact information that SS and PS will provide the RCC.*
- *Define frequency that contact information should be reviewed/updated and the timeline after a personnel change that the RCC must be notified.*

3. New Personnel Onboarding

- *Define whom from the RCC will provide StrokeNet orientation to whom at the SS and PS.*
- *Please reference the NIH StrokeNet Coordinator Training Guidance. All RCC managers are expected to review this guidance during the onboarding process for all new coordinators at SS and PS.*

4. Other Communication

- *Ex: who to contact for regulatory questions, how to manage communication issues with SS or PS that arise from NCC or National Trial Team*

B. **Competing Trials at SS and PS**

- *Describe processes the help SS and PS to manage enrollment in competing non-NIH StrokeNet trial that may compete for participants or conflict with resources.*
- *Consider referencing Competing Trials in StrokeNet Guidance document.*

C. **Addition of New SS or PS**

- *Describe specific considerations or processes of the RCC when initiating or receiving inquiries for additional SS or PS.*
- *Describe communication and approval for this process.*
- *Reference the annual survey that all new SS and PS must complete to become a StrokeNet participating site.*

D. **Feasibility and Site Selection Surveys**–

- *Describe RCC process for selecting the sites it distributes feasibility and site selection surveys to.*
- *Describe communication, expectations and timelines for SS and PS when completing the surveys.*
- *Describe who is responsible for completing and submitting surveys.*

E. **Activating New NIH StrokeNet Trials**

- *Describe whom at RCC will support whom at SS or PS during site start-up.*
- *Describe the communication, support, and resources the RCC will provide to SS or PS during site start-up (regulatory support, budgeting, coverage analysis, education, staffing structure, order set management, instruction sheets, mock enrollments etc.).*

F. **Performance Review and Termination of SS or PS**

- *Describe whom at RCC will conduct performance reviews with whom at SS or PS.*
- *Describe frequency of performance reviews.*
- *Describe the metrics used for conducting reviews (recruitment, retention, data quality, protocol compliance, regulatory compliance, infrastructure etc.).*
- *Describe specific RCC standards or thresholds that may result in probation or termination from RCC.*
- *Describe plan to communicate inadequate performance or serious issues discovered at SS or PS to NCC, National Trial PI and NINDS.*

7. APPLICABLE REGULATIONS

21 CRF 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
RCC NOA	RCC Notice of Grant Awards (2023)
45 CFR Part 46	Protection of Human Subjects
21 CFR Parts 50	FDA Policy and Regulations
21 CFR 312	FDA Policy and Regulations

8. REFERENCES TO OTHER APPLICABLE SOPs

ADM 06	Process for Documenting Essential Financial and Federal Compliance
ADM 07	Per Subject Payments and Development of Clinical Trial Budgets
ADM 09	RCC Management of Satellites and Performance Sites
ADM 10	Process for Inclusion of New Satellite Sites for RCC
ADM 11	Process for CIRB Reliance and Approvals
ADM 12	Process for CIRB Reporting
ADM 13	Safety Monitoring and Reporting
ADM 15	Network Communications
ADM 16	Process for Trial Master and Site Regulatory File Management
ADM 17	NIH StrokeNet Organization and Governance

9. DOCUMENT HISTORY

Version	Description of Modification	Justification for Modification	Completion Date	Issue Date	Effective Date