SOP Number: ADM 15
SOP NAME: Network Communications
Effective Date: 3-Jun-2014 (rev 18-Aug-2023)

1. POLICY

Effective communication within the NIH StrokeNet Network (StrokeNet), including those between the National Institute of Neurological Disorders and Stroke (NINDS), the National Coordinating Center (NCC), the National Data Management Center (NDMC), Regional Coordinating Centers (RCCs), Satellites Sites (SS), Performance Sites (PS), the Protocol Principal Investigators (PPIs), and all other relevant entities is essential to ensure the integrity of all StrokeNet activities. To maximize the efficiency of StrokeNet communication, maintaining accurate contact information is critical. This SOP aims to facilitate the collection and maintenance of current contact information and standardize communications within StrokeNet.

2. DEFINITIONS AND ABBREVIATIONS

NCC   National Coordinating Center at the University of Cincinnati

NDMC   National Data Management Center at the University of South Carolina

NINDS   National Institute of Neurological Disorders and Stroke

PPI   Protocol Principal Investigator

PS   Performance Sites

RCC   Regional Coordinating Centers

SS   Satellites Sites

SOP   Standard Operating Procedure

StrokeNet   NIH StrokeNet Network

3. SCOPE

This Standard Operating Procedure (SOP) applies to any and all activities involving the StrokeNet. This SOP applies to the NCC, the NDMC, and to all StrokeNet investigators, staff, or other entities associated with the StrokeNet who manage, oversee, and conduct research within the Network.

4. PROCEDURES

   A.   **RCC Contact Information**

   1.   Each RCC will have their contact information stored electronically in the WebDCU™ clinical trials management system under the StrokeNet tile. Instructions on how to enter information is located

SOP Number: ADM 15
SOP NAME: Network Communications
Effective Date: 3-Jun-2014 (rev 18-Aug-2023)

in the WebDCU User Guide. Information to be included are the RCC's full address, and name, email address and phone number for the following individuals:

> a. Contact Principal Investigator*
> b. Co-Principal Investigator
> c. Fellow
> d. Primary Study Coordinator
> e. Secondary Study Coordinator(s)
> f. Contract Administrator
> g. IRB Representative
> h. Institutional Authority

2. The RCC contact list must be updated in the WebDCU™ by the RCC's designated network contact person within 30 days of a change or annually each January.
3. Each RCC is responsible for providing their institution's process for reporting changes in key personnel to NIH/NINDS in their RCC management SOP.

*A change in the Principal Investigator or key personnel at the awardee RCC requires the prior approval of the NINDS Program Director. The NINDS must be sent the curricular vitae (CV) of the new investigator or key personnel 30 days prior to the anticipated change date along with confirmation that s/he has completed current NIH-required human subjects protection and good clinical practice training.

B.   General Correspondence with NCC/NDMC

RCCs, their SS and PS are encouraged to ask questions as often as necessary. In an effort to maximize efficiency and facilitate correspondence archival, the NCC and NDMC request that all email correspondences include in the subject/topic line the RCC or site number and name and the topic of the email. Additionally, communications of a confidential nature will be flagged.

C.   Internal Network Communications and Meetings

1. The StrokeNet website www.NIHStrokeNet.org/ lists ongoing educational activities as well as StrokeNet meetings, agendas and minutes in the StrokeNet event calendar and in the meeting minutes folder. Links to archived webinars are also on that website. These resources are available to anyone with access to the RCC essential documents files, located in a secure password protected section of the website. RCCs will only be able to view its own or its SS or PS documents. Access is granted by the NCC administrator.

2. Monthly StrokeNet updates will be sent via email to all participating RCC personnel. These updates will include upcoming StrokeNet meeting details (in person and by videoconference), information about new StrokeNet documents, website updates, approaching deadlines,

SOP Number: ADM 15
SOP NAME: Network Communications
Effective Date: 3-Jun-2014 (rev 18-Aug-2023)

upcoming educational offerings, and links to recently archived educational offerings. The "topic" line of these emails will be flagged as "**NIH StrokeNet First Friday Update**". Every attempt will be made to include non-urgent requests and contents in these monthly emails.

3. Urgent network messages will be sent via email to all participating RCC personnel. The topics of these emails will address non-routine content such as last minute changes to meetings/agendas, StrokeNet wide educational offerings, or a trial-wide announcement**.** The topic line of these emails will be flagged as **"Urgent Network Updates".**

4. Regular meetings are necessary to facilitate the work of StrokeNet. The framework and basic purpose for these meetings are below. Educational offerings, study trainings or other leadership meetings will be flagged on the StrokeNet network calendar as mandatory with clarification for whom attendance is required.

    a. General Network Meetings include face to face or videoconference meetings that require or request representation from the entire StrokeNet community.
    b. Study Specific Investigator Meetings include face to face or videoconference meetings that require or request representation from all PSs participating in the trial, and NDMC/NCC/NINDS leadership. A study-specific communication plan will be developed with the PPI, the NDMC, and NCC that describes the study's communications strategy details.
    c. Network Committee Meetings:
        1. Executive Committee (bi-monthly)
        2. Steering Committee (monthly)
        3. Operations Committee (weekly)
        4. Educational Committee (frequency to be determined by group leadership)
        5. Imaging Core (frequency to be determined by group leadership)
    d. Working Groups Meetings
        1. Acute Stroke (frequency to be determined by group leadership)
        2. Primary and Secondary Prevention (frequency to be determined by group leadership)
        3. Recovery and Rehabilitation (frequency to be determined by group leadership)
        4. Coordinator Calls (monthly)

D.   **External Communication**

SOP Number: ADM 15
SOP NAME: Network Communications
Effective Date: 3-Jun-2014 (rev 18-Aug-2023)

External Communications include information on the public access portion of the www.NIHStrokeNet.org/ website; scheduled meetings with non-US network leadership such as during the International Stroke Conference, European Stroke Organisation Conference, and World Stroke Organization; and ongoing conference calls and in person meetings with other U.S. neurology/neurosciences networks including the Strategies to Innovate Emergency Care Clinical Trials Network (SIREN) and the Network of Excellence in Neuroscience Clinical Trials (NeuroNEXT).

5. APPLICABLE REGULATIONS AND GUIDELINES

NINDS Terms of Award for Clinical Research, https://www.ninds.nih.gov/funding/manage-your-award/pre-award/notice-award

6. REFERENCES TO OTHER APPLICABLE SOPS

ADM 06   Network Process for Documenting Essential Financial and Federal Compliance

7. ATTACHMENTS AND REFERENCES

Study Site Information Confirmation Sheet and Ongoing Contact List

8. DOCUMENT HISTORY

Version	Description of Modification Justification for 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	29-Sep-2016		
2.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
3.0	Current process updates	30-May-2023	30-May-2023	30-May-2023
4.0	NDMC Edits included	18-Aug-2023	18-Aug-2023	18-Aug-2023

NIH StrokeNet Network

Standard Operating Procedure (SOP)

Network Communications

Standard Operation Procedures

Version 4.0

ADM #15

Reviewed and Approved by:

Pooja Khatri, MD, (StrokeNet NCC Principal Investigator)

Jordan Elm, PhD, (StrokeNet NDMC Principal Investigator)

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