SOP Number: ADM 08
SOP NAME: Network Process for RCC Performance Review
Effective Date 3-Jun-2014 (rev 15-Jun-2023)

1. POLICY

The NIH StrokeNet Network (StrokeNet) National Coordinating Center (NCC), National Data Management Center (NDMC), and the RCCs will work together to determine each Regional Coordinating Center's (RCC) performance as needed. Reviews will include overall recruitment performance and quality of trial performance. Recruitment or quality issues identified by the review will be discussed with the RCC to analyze the root cause of the issue, develop a corrective action and preventive action (CAPA) plan and monitor implementation of the plan.

Cumulative data from the clinical trial management system, WebDCU™, will be used to promote recruitment into the NIH funded clinical trials and to maximize efficiencies of individual trials and the trial network.

2. DEFINITIONS AND ABBREVIATIONS

CAPA	Corrective Action and Preventive Action
CTA	Clinical Trial Agreement
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
NCC	National Coordinating Center
NDMC	National Data Management Center
NIH	The National Institutes of Health
NINDS	The National Institute of Neurological Disorders and Stroke
NOA	Notice of Award
PPI	Protocol Specific Principal Investigator
PS	Performance Sites
RCC	Regional Coordinating Center
SOP	Standard Operating Procedure
SS	Satellites Sites
StrokeNet	NIH StrokeNet Network

3. SCOPE

This SOP applies to all parts of Regional Coordinating Centers including their respective SS and PS, the NCC and the NDMC of the NIH StrokeNet.

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4. PROCEDURES

A. The RCC is responsible for overseeing site performance for their SS and PS.

B. The NDMC maintains the WebDCU™ Dashboard which includes enrollment metrics by RCC for completed and current trials. The Dashboard will be used to view sites' metrics.

C. Metrics to be reviewed overall and by trial include but are not limited to:
   1. Enrollment-Number of subjects enrolled
   2. Retention-Percent of participants not retained
   3. Regulatory Document Collection-percent of outstanding documents
   4. Case Report Collection- percent of outstanding documents
   5. CIRB Submission- time from receiving the CIRB packet to submission is less than 90 days
   6. CTA Execution-time from receiving the CTA to execution is less than 90 days

D. The NCC will provide a list of StrokeNet activities quarterly. These lists can assist the RCCs with the annual RPPR required by the NIH.

Regional Coordinating Center Performance Metrics (NIH StrokeNet Operation Progress Dashboard)
WebDCU™ StrokeNet Trial-Specific Database (Site Management/Site Startup Progress)

Metric Category	Criteria
Subject Enrollment by RCC	Total number of subjects enrolled
Project Enrollment Summary by RCC	Number of enrollments into each trial
RCC Project Operation Summary	Summary of site participation, subject enrollment, demographics, and case report form data entry
Site Startup Progress	Site metrics available in trial-specific databases and available by request

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CRF 312.50	General Responsibilities of Sponsors
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	Regional Coordinating Center Notice of Award

6. REFERENCES TO OTHER APPLICABLE SOPS

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SOP NAME: Network Process for RCC Performance Review
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ADM 09 Network Process for RCC Management of Satellites and Performance Sites

7. ATTACHMENTS AND REFERENCES

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	15-Sep-2016	15-Sep-2016	15-Sep-2016
2.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
3.0	Further define RCC metrics data to be assessed	25-Sep-2018	4-Oct-2018	4-Oct-2018
4.0	Quarterly Activity Reports discontinued	01-Oct-2019	13-Jan-2020	13-Jan-2020
5.0	Updates to reflect current process	15-Jun-2023	28-Jun-2023	28-Jun-2023

NIH StrokeNet Network

Standard Operating Procedure (SOP)

Network Process for RCC Performance Review

Standard Operation Procedures

Version 5.0

ADM #8

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