SOP Number: ADM 13
SOP NAME: Safety Monitoring and Reporting
Effective Date: 22-Jun-15 (rev 27-Jan-2023)

1. PURPOSE

The purpose of this SOP is to describe the safety monitoring procedures for StrokeNet clinical trials.

2. DEFINITIONS AND ACRONYMS

National Coordinating Center (NCC): An institution designed and directly funded by NINDS/NIH to oversee project management for StrokeNet research protocols. The NCC for StrokeNet is at the University of Cincinnati.

National Data Management Center (NDMC): An institution designed and directly funded by NINDS/NIH to oversee all aspects of data collection and management for StrokeNet research protocols. The NDMC for StrokeNet is at the Medical University of South Carolina.

Medical Dictionary for Regulatory Activities (MedDRA): A clinically validated international medical terminology dictionary

WebDCU™: An integrated web-based central trial management system developed by NDMC for clinical trial data management and full scope trial operation management.

3. SCOPE

This standard operating procedure applies to all personnel involved with safety monitoring and/or reporting for StrokeNet studies, including the NCC investigators/staff, NDMC investigators/staff, protocol principal investigators/staff, site investigators/staff, and study biostatisticians. Overall monitoring plans might vary by trial.

4. PROCEDURES

A. Management of Adverse Events
   1. Adverse Events and Serious Adverse Events will be entered by the clinical sites into WebDCU™ and centrally coded using MedDRA.
   2. When applicable, results from contemporaneous review by the trial appointed medical safety monitor(s) will be entered and managed in WebDCU™.
   3. When applicable, safety reports will be generated in WebDCU™.
   4. When applicable, the central Institutional Review Board will be notified of trial designated adverse and unanticipated events reported in WebDCU™.

B. Safety Data Monitoring and Reporting
   1. A trial specific Safety Monitoring Plan will be developed for each StrokeNet study.
   2. The safety monitoring plan will specify the parties responsible for safety reporting to the applicable oversight bodies.
   3. Oversight bodies may include, but are not limited to, the U.S. Food and Drug Administration, the study's Data and Safety Monitoring Board, and Institutional Review Boards (local and central).

C. StrokeNet studies will comply with the following procedures/guidance/regulations for safety monitoring and reporting, as applicable.
   1. ICH harmonised tripartite guideline: Guideline for good clinical practice.
   2. ICH harmonised tripartite guideline: Clinical Safety Data Management: Definitions and standards for expedited reporting, E2A.
   3. Guidance for Industry and Investigators: Safety Reporting Requirements for INDs and BA/BE Studies.
   4. NINDS Guidelines for Data and Safety Monitoring in Clinical Trials for monitoring of safety data.
   5. US Food and Drug Administration. 21 C.F.R. § 312.
   6. US Food and Drug Administration. 21 C.F.R. § 812.

5. APPLICABLE REGULATIONS AND GUIDELINES

International Conference on Harmonisation (1994). ICH harmonised tripartite guideline: Clinical Safety Data Management: Definitions and standards for expedited reporting, E2A. Retrieved from: http://fercsl.lk/wp/wp-content/uploads/2019/04/Clinical-Safety-Data-Management-Definitions-Standards-for-Expedited-Reporting-ICH-Harmonised-Tripartite-Guideline-1994.pdf

International Conference on Harmonisation (2001). ICH harmonised tripartite guideline: Guideline for good clinical practice. *Journal of Postgraduate Medicine, 47*(3), 199-203.

National Institute of Neurological Disorders and Stroke (2023). NINDS Guidelines for Data and Safety Monitoring in Clinical Trials for monitoring of safety data. Retrieved from: https://www.ninds.nih.gov/current-research/research-funded-ninds/clinical-research/ninds-guidelines-monitoring-clinical-trials

US Food and Drug Administration (2012). Guidance for industry. Safety Reporting Requirements for INDs and BA/BE Studies. Retrieved from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf

US Food and Drug Administration (2022). Food & Drugs, 21 C.F.R. § 312. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312

US Food and Drug Administration (2022). Food & Drugs, 21 C.F.R. § 812. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812

6. References to Other Applicable SOPs

ADM SOP 11 CIRB Reliance

ADM SOP 12 CIRB Reporting

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	10-Dec-2014	22-Jun-2015	22-Jun-2015
1.1	Biannual review with minor administrative changes	19-Sep-2016		
2.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
3.0	Review with minor administrative changes	27-Jan-2023	14-Feb-2023	14-Feb-2023

NIH StrokeNet Network

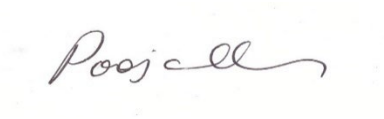
Standard Operating Procedure (SOP)

Safety Monitoring and Reporting

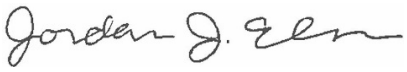
Version 3.0

ADM #13

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)