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 US Food and Drug Administration, the study’s Data 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.
   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.

5. APPLICABLE REGULATIONS AND GUIDELINES


6. References to Other Applicable SOPs

ADM SOP 11 CIRB Reliance
7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

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<th>Issue Date</th>
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NIH StrokeNet Network

Standard Operating Procedure (SOP)

Safety Monitoring and Reporting

Version 1

ADM #13

Originators: StrokeNet National Data Management Center Personnel

Reviewed and Approved by:

Joseph P. Broderick, MD (StrokeNet NCC Principal Investigator) (Date)

Yuko Palesch PhD (StrokeNet NDMC Principle Investigator), (Date)

NIH/NINDS Representative, (Date)

Judith Spilker RN/BSN, NCC Administrative Director (Date)

Catherine Dillon CCRP, NDMC Trials Operations Manager, Document Author/Controller (Date)