SOP Number: GCP 04
SOP NAME: Safety Reporting
Effective Date: 4-Jan-2016 (rev 31-Oct-2023)

1. Policy

Adverse events will be monitored for all studies conducted by the NIH StrokeNet Network, in compliance with Federal regulations, Good Clinical Practice (GCP), and Central Institutional Review Board (CIRB) regulations. The purpose of this SOP is to provide guidelines for timely and accurate reporting of adverse events that occur during the conduct of NIH StrokeNet clinical trials.

2. Definitions and Abbreviations

AE	Adverse Event
CIRB	Central Institutional Review Board
DCR	Data Clarification Request
eCRF	Electronic Case Report Form
ICH	International Conference on Harmonization
MSM	Medical Safety Monitor
NCC	National Coordinating Center – located at University of Cincinnati
NDMC	National Data Management Center – located at Medical University of South Carolina
PHI	Protected Health Information
PPI	Protocol Principal Investigator
PS	Performance Site
PS PI	Performance Site Principal Investigator
PS SC	Performance Site Study Coordinator
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
UADE	Unanticipated Adverse Device Effect
UPIRSO	Unanticipated Problems Involving Risks to Subjects or Others
US	United States
WebDCU™	Clinical trial management system developed and utilized at the NDMC

3. Scope

This SOP has been developed to ensure compliance with United States (US) Federal regulations and Good Clinical Practice, as set forth in the International Conference on Harmonization E6 Consolidated Guidance Manual (2016). The policies and procedures described in this standard operation procedure (SOP) apply to the NIH StrokeNet Performance Sites (PS), the National Coordinating Center (NCC) and the National Data Management Center (NDMC) within the context of their oversight and advisory roles for the NIH StrokeNet Network, and to all investigators, staff, subcontractors, and other entities associated with the NIH StrokeNet who manage, oversee, and conduct research regulated by the FDA and/or applicable review committees.

4. **Procedures**

The Performance Site (PS) is responsible for ensuring that complete and accurate information regarding Unanticipated Adverse Device Effect (UADEs), Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), Adverse Events (AEs) and Serious Adverse Events (SAEs) is submitted in WebDCU within the required time frame per specific protocol requirements. For a complete description of this process, please see ADM SOP 12, Central Institutional Review Board Reporting. The Performance Site Principal Investigator (PS PI) or designate is responsible for following CTCAE guidelines for grading the intensity of the event, completing the appropriate sections of the Adverse Event Electronic Case Report Form (eCRF), and submitting the eCRF through the electronic data entry system (WebDCU™). Study-specific adverse event reporting instructions for completing and submitting the AE eCRF can be found in each trial's 'Data Collection Guidelines' document that is located in the associated trial's Toolbox > Project Documents.

The PS PI participating in NIH StrokeNet trial is responsible for assuring the AEs and SAEs are properly recorded in the study records and entered in WebDCU™ in a timely manner.

Research personnel selected by the Protocol Principal Investigator (PPI), typically the NCC Project Manager, is responsible for assuring all UADEs, UPIRSOs, AEs and SAEs are properly reported to the CIRB of record, the PPI, and the sponsor of the study as applicable and required by the protocol.

For AEs of interest per the protocol or SAEs submitted in WebDCU™, the NCC Project Manager will review the eCRF to ensure it contains no protected health information (PHI), is blinded, and is complete prior to forwarding the eCRF within WebDCU™ to the Medical Safety Monitor (MSM) for review. If not, the NCC Project Manager will send a data clarification request (DCR) to the PS to update the eCRF. The NCC Project Manager can rely on the MSM or the PPI (depending on the type of event) to provide clinical expertise to ensure the eCRF is complete. Should an AE be deemed serious, unexpected, and study related by the MSM, WebDCU™ will generate an automated notification for the NCC Manager to submit a safety report to the CIRB within 10 days.

5. References to Other Applicable SOPs

SOP ADM 12 Central Institutional Review Board (CIRB) Reporting

6. Document History

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	21-Dec-2015	21-Dec-2015	4-Jan-2016
2.0	Review with minor administrative changes	27-Jan-2023	14-Feb-2023	14-Feb-2023
3.0	Additional information on SAE process	31-Oct-2023	06-Nov-2023	06-Nov-2023
