SOP Number: GCP 04
SOP NAME: Safety Reporting
Effective Date: 4-Jan-2016 (rev 27-Jan-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
CTPS	Clinical Trial Performance Site
CTPS-SC	Clinical Trial Performance Site Study Coordinator
CTPS-PI	Clinical Trial Performance Site Principal Investigator
eCRF	Electronic Case Report Form
NCC	National Coordinating Center – located at University of Cincinnati
NDMC	National Data Management Center – located at Medical University of South Carolina
PPI	Protocol Principal Investigator
SAE	Serious Adverse Event
UADE	Unanticipated Adverse Device Effect
UPIRSO	Unanticipated Problems Involving Risks to Subjects or Others
WebDCU™	Clinical trial management system developed and utilized at the NDMC

3. Scope

This SOP has been developed to ensure compliance with Federal regulations and Good Clinical Practice, as set forth in the ICH E6 Consolidated Guidance Manual (2016). The policies and procedures described in this SOP apply to the NIH StrokeNet Clinical Performance Sites (CTPS), 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 Clinical Trial Performance Site (CTPS) is responsible for ensuring that complete and accurate information regarding UADEs, UPIRSOs, AEs and SAEs is submitted to the NDMC within the required time frame per specific protocol requirements (see NIH StrokeNet Network ADM SOP 12, Central Institutional Review Board Reporting for additional information). The Clinical Performance Site Principal Investigator (CTPS-PI) or designate is responsible for following NDMC 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 will be created for each NIH StrokeNet Network study.

Research personnel participating in NIH StrokeNet research studies will be responsible for assuring the AEs and SAEs are properly recorded in the study records and entered in the WebDCU™ in a timely manner.

Additionally, research personnel participating in NIH StrokeNet research studies will be responsible for assuring all UADEs, UPIRSOs, AEs and SAEs are properly reported to the CIRB or the IRB of record, the NIH StrokeNet PPI and the sponsor of the study as applicable and required by the protocol.

5. Applicable Regulations and Guidelines

45 CFR 46
21 CFR 50
21 CFR 56
ICH E6

6. References to Other Applicable SOPs

SOP ADM 12 Central Institutional Review Board (CIRB) Reporting

7. 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