SOP Number: ADM 16
SOP NAME: Network Process for Trial "Master" and "Site" Regulatory File Management
Effective Date: 3-Mar-2016 (rev 26-Jan-2023)

1. Policy

Federal regulations require documentation of all clinical trial-related activities. Maintenance and retention of complete, accurate, and readily retrievable records are integral to the research process. The regulatory binder (paper or electronic) serves as documentation of compliance with the regulations governing human subject research, and provides verification that the study was conducted according to the approved protocol, the data are authentic and accurate, and the findings can be verified and are accurately represented.

This Standard Operating Procedure (SOP) provides guidance for collecting, filing, and storing study-related documents and records, including essential documents, professional licenses, curricula vitae (CV) and resumes, and laboratory certifications and normal range values.

Documents and records must be maintained in an organized, complete, and accurate manner that assure a complete, readily retrievable history of regulatory activities. Records must be accessible for inspection by authorized representatives of the National Institute of Neurological Disorders and Stroke (NINDS), National Data Management Center (NDMC), National Coordinating Center (NCC), Food and Drug Administration (FDA) or other governmental agency, sponsors/sponsor agents or funding entities.

2. Definitions and Abbreviations

FDA	Food and Drug Administration
GCP	Good Clinical Practice
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at the Medical University of South Carolina
PS	Performance Site

3. Scope

This SOP has been developed to ensure compliance with federal regulations and Good Clinical Practice, as set forth in the 2016 ICH E6 Consolidated Guidance manual. The policies and procedures described in this SOP apply to Performance Sites (PS) that have been approved by the National Institute of Neurological Disorders and Stroke (NINDS) for participation in an approved NIH StrokeNet Network research protocol. This SOP applies to the activities involved in maintaining and retaining the regulatory files for all NIH StrokeNet studies at each selected PS.

4. Procedures

The ICH GCP Guidelines define essential documents as those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of data produced. These documents serve to demonstrate compliance with standards of Good Clinical Practice and with all applicable regulatory requirements. Filing essential documents in a timely manner can greatly assist in the successful management of a clinical trial. The regulatory binder (paper or electronic)

should be organized into functional sections.

All RCCs and PSs are expected to comply with their own institutional requirements for file management as well as those identified above.

5. Applicable Regulations and Guidelines

- 21 CFR 312.60 General responsibilities of investigators
- 21 CFR 312.62 Investigator recordkeeping and record retention
- 21 CFR 312.68 Inspection of investigator's records and reports
- ICH GCP guideline, section 8 titled "Essential Documents for the Conduct of a Clinical Trial"
- ICH GCP guideline, section 4.1.1
- FDA Information Sheet, October 1995: Recordkeeping in Clinical Investigations
- 21 CFR Parts 50 and 312

6. References to Other Applicable SOPs

ADM SOP 20	Data Quality Assurance and Control
ADM SOP 21	Regulatory and Clinical Data Maintenance and Data Storage

7. Attachments and References

8. Specific Procedures

See NIH StrokeNet GCP SOP 12

9. Document History

Version	Description of Modification Justification for Modification	Completion Date	Issue Date	Effective Date
1.0	Final	3-Mar-2016	3-Mar-2016	3-Mar-2016
1.1	Biannual review with minor administrative changes	28-Oct-2016		
2.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
3.0	Biannual review with minor administrative changes	26-Jan-2023	14-Feb-2023	14-Feb-2023

NIH StrokeNet Network

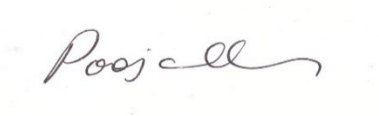
Standard Operating Procedure (SOP)

Network Process for Trial "Master" and "Site" Regulatory File Management

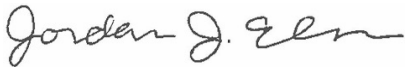
Version 3.0

ADM #16

Reviewed and Approved by:



Pooja Khatri, MD, (StrokeNet NCC Principal Investigator)



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