SOP Number: ADM 21
SOP NAME: Regulatory Document Maintenance and Storage
Effective Date: 25-February-2015 (rev 10-Aug-2023)

1. PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe regulatory document collection and maintenance procedures for StrokeNet clinical trials utilizing the WebDCU™ Regulatory Document Module. International Conference on Harmonization's Good Clinical Practice Guidelines (ICH-GCP) has defined the essential documents needed during the conduct of a clinical investigation. These essential documents are required to:

- demonstrate the compliance of the investigator, sponsor, and the monitor with all applicable regulatory requirements and GCP
- assist in the successful management of the study by the investigator, sponsor, and monitor
- confirm the validity of the conduct of the clinical investigation and the integrity of the data collected

The FDA has adopted this ICH-GCP guidance, in addition to its own regulatory document requirements, for studies conducted under its jurisdiction.

2. DEFINITIONS AND ACRONYMS

CFR	Code of Federal Regulations
CIRB	Central Institutional Review Board
FDA	Food and Drug Administration
ICH-GCP	International Conference on Harmonization's Good Clinical Practice Guidelines
IND	Investigational New Drug Application
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at the Medical University of South Carolina.
SOP	Standard Operating Procedure
TMF	Trial Master File
US	United States
WebDCU ™	Web-based central trial management system developed by NDMC

3. SCOPE

This SOP applies to all personnel involved with monitoring, including the National Data Management Center (NDMC) investigators/staff, site investigators/staff, biostatisticians, and contract monitors, for StrokeNet studies in which NDMC is responsible for trial monitoring.

4. PROCEDURES

A. Regulatory Document Collection

1. The Trial Master File (TMF) of essential regulatory documents will be maintained in WebDCU™. Trial documents needed by StrokeNet project managers that cannot be stored in WebDCU™ will be maintained in an additional secure database, e.g., SharePoint. Sites may not be required to keep duplicate documents locally, as they will have access to all regulatory documents submitted into WebDCU™. Verification of the local requirements is necessary.
2. Sites must retain regulatory documents which are not required to be submitted to WebDCU™ (such as correspondence with the Institutional Review Board, trial correspondence, notes to file/memorandums) in their local investigator's site file.
3. Prior to collection of regulatory documents, the Regulatory Document Manager (usually the Project Manager at the National Coordinating Center (NCC)) will provide NDMC with a list of required documents based upon ICH-GCP and Food and Drug Administration (FDA) Code of Federal Regulations (CFR) and the specific protocol requirements. The central IRB approval letter and approved informed consent should be in the list of regulatory documents. NDMC will customize WebDCU™ Regulatory Documents Module accordingly.
4. The Regulatory Document/Project Manager will notify sites which documents are required to be collected for the study, and of those, which should be submitted to WebDCU™ verses retained at the site. Additionally, a Regulatory Documents Parameters guide will be provided to sites detailing the specific requirements of each document.
5. Sites are required to post evidence or acknowledgement in the WebDCU™ regulatory module that the Reliant IRB has been notified of their participation in a StrokeNet trial**.**
6. Study team members at the participating sites or the Regulatory Document Manager/Project Manager will upload PDFs of the required documents into WebDCU™.
7. The Regulatory Document/Project Manager will review and either approve or reject each regulatory document as it is submitted into WebDCU™.
8. After all regulatory document requirements have been met a site will be released to enroll subjects upon receiving an automated email issued by the WebDCU™ staff. After receiving the automated email, the sites' randomization privileges will be active.
9. As document requirements change during the course of the study (for example, a new version of the protocol is released), the Regulatory Document Manager will notify NDMC and the WebDCU™ Regulatory Document Module and Regulatory Document Parameters will be updated accordingly.

B. Regulatory Document Maintenance

1. Study team members at the participating sites will update/upload any regulatory document or training that needs amending or has expired in WebDCU™ during the study. WebDCU™ will notify the participating site via automated email 60 days prior to the expiration date of any training/certification uploaded to the system.
   a) E.g., updating the 1572 of a study conducted under an Investigational New Drug (IND) application by removing an investigator who has left the performance site.
   b) E.g., uploading a new/updated GCP training certificate to the expired placeholder.
2. Regulatory Document Manager or the Project Manager will review and either approve or reject each regulatory document revision as it is submitted into WebDCU™.

C. Regulatory Document Retention

1. Regulatory documents will be retained in WebDCU™ and local investigator's site files for a minimum of three years after the prime award investigator or institution submits the final expenditure report (funding period expires) for federally funded United States (US) studies. Authorized representatives must have access to any documents or records pertinent to the NIH-funded study for the duration of this time.
2. When a site's local institutional policy is longer than the retention time specified above, the site should default to the longer retention time or consult legal counsel.
3. Prior to removing or destroying documents from the local investigator's site files or for any questions regarding retention requirements, please contact strokenetcta@ucmail.uc.edu.

5. APPLICABLE REGULATIONS AND GUIDELINES

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

US Food and Drug Administration. (2023). Public Welfare, 45 C.F.R. § 46.115 IRB Records. Retrieved from https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.115

US Food and Drug Administration. (2023). Public Welfare, 45 C.F.R. § 75.361 Retention Requirements for Records. Retrieved from https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-75/subpart-D/subject-group-ECFR7492b9ccc78b4d5/section-75.361

US Food and Drug Administration. (2023). Grants and Agreements, 2 C.F.R. 200.334 Retention Requirements for Records. Retrieved from https://www.ecfr.gov/current/title-2/subtitle-A/chapter-II/part-200/subpart-D/subject-group-ECFR4acc10e7e3b676f/section-200.334

National Institutes of Health Grants Policy Statement. (2022). 8.4.2 Record Retention Access. Retrieved from https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.4.2_record_retention_and_access.htm

6. REFERENCES TO OTHER APPLICABLE SOPS

GCP SOP #12 Regulatory and Clinical Data Maintenance Storage

7. ATTACHMENTS AND REFERENCES

8. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	25-Feb-2015	25-Feb-2015	25-Feb-2015
2.0	4. Procedures A regulatory Document Collection, items 3, 7 and 9 revised for clarification. Changed language bolded.	7-Apr-2016	7-Apr-2016	7-Apr-2016
2.1	Biannual review with minor administrative changes	15-Dec-2016		
3.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
4.0	Review with minor administrative changes	27-Jan-2023	14-Feb-23	14-Feb-23
5.0	Administrative changes	30-May-2023	30-May-2023	30-May-2023
6.0	Aligned retention requirements with more conservative NIH and FDA policy regarding federally funded studies	10-Aug-2023	10-Aug-2023	10-Aug-2023

NIH StrokeNet Network

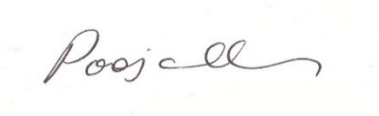
Standard Operating Procedure (SOP)

Regulatory Document Maintenance and Storage

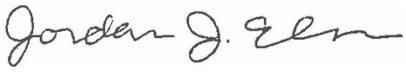
Version 6.0

ADM #21

Reviewed and Approved by:



Pooja Khatri, MD, (StrokeNet NCC Principal Investigator)



Jordan Elm, PhD, (StrokeNet NDMC Principal Investigator)

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