SOP Number: ADM 21
SOP NAME: Regulatory Document Maintenance and Storage
Effective Date: 25-February-2015 (rev 30-May-2023)

1. PURPOSE

The purpose of this SOP is to describe regulatory document collection and maintenance procedures for StrokeNet clinical trials utilizing the WebDCU™ Regulatory Document Module. 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

ICH-GCP	International Conference on Harmonization's Good Clinical Practice Guidelines
IND	Investigational New Drug Application
CIRB	Central Institutional Review Board
FDA	Food and Drug Administration
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 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 NCC) will provide NDMC with a list of required documents based upon ICH-GCP and FDA Code of Federal Regulations 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 IND 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. For US studies conducted under an IND, regulatory documents will be retained in WebDCU™ and local investigator's site files for a minimum of two years after the marketing application is approved for the drug for the indication for which it was being investigated. If no application will be filed or if the application is not approved for the requested indication, the records will be retained for a minimum of two years after the investigation is discontinued and FDA is notified.
2. For US studies not conducted under an IND, regulatory documents will be retained in WebDCU™ and local investigator's site files for at least three years after completion of the research. The three-year time period begins when the individual institution's engagement in the research activity ends.
3. When a site's local institutional policy is longer than the retention times specified above, the site should default to the longer retention time or consult legal counsel.

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. (2022). Food & Drugs, 21 C.F.R. § 54. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=54

US Food and Drug Administration. (2022). Food & Drugs, 21 C.F.R. § 312. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312

US Food and Drug Administration. (2022). Food & Drugs, 21 C.F.R. § 812. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812

6. REFERENCES TO OTHER APPLICABLE SOPS

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

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PREVENTION | TREATMENT | RECOVERY

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Standard Operating Procedure (SOP)

Regulatory and Clinical Data Maintenance and Data Storage

Version 1

ADM #21

Originators: StrokeNet National Data Management Center Personnel

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