SOP Number: GCP 12
SOP NAME: Regulatory and Clinical Data Maintenance Storage
Effective Date: 4-Jan-2016 (rev 09-Aug-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 but not limited to 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 assures a complete, readily retrievable history of regulatory and clinical activities. Records must be accessible for inspection by authorized representatives of the National Institute of Neurological Disorders and Stroke (NINDS), NIH StrokeNet National Data Management Center (NDMC) and National Coordinating Center (NCC), Food and Drug Administration (FDA) or other governmental agency, sponsors/sponsor agents or funding entities.

2. DEFINITIONS AND ACRONYMS

CIRB	Central Institutional Review Board
CTA	Clinical Trial Agreement
CV	Curriculum Vitae
DOA	Delegation of Authority
FDA	Food and Drug Administration
FWA	Federalwide Assurance
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
HSP	Human Subjects Protection
NCC	National Coordinating Center at the University of Cincinnati
NDMC	National Data Management Center at the Medical University of South Carolina
PI	Principal Investigator
PPI	Protocol Principal Investigator
PS	Performance Sites
SAE	Serious Adverse Event

TMF	Trial Master File
WebDCU™	Clinical trial management system

3. SCOPE

This SOP has been developed to ensure compliance with federal regulations and Good Clinical Practice (GCP), as set forth in the 1996 ICH E6 Consolidated Guidance manual. The policies and procedures described in this SOP apply to Performance Sites 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 essential documents and other study-related documents for all NIH StrokeNet studies at each selected Performance Site (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 GCP and with all applicable regulatory requirements. Filing essential documents and other study-related documents in a timely manner can greatly assist in the successful management of a clinical trial.

NIH StrokeNet utilizes WebDCU™ as the Trial Master File (TMF) and requires all PS to maintain essential documents in the system for central monitoring. Sites may also store documents in paper format (regulatory binder) or in another electronic system, in addition to WebDCU™, if required by the local institution. Regulatory documents that are not required to be submitted to WebDCU™ (such as correspondence with the Central Institutional Review Board (CIRB), trial correspondence, notes to file/memorandums) should be maintained in their local investigator's site file.

5. SPECIFIC PROCEDURES

For each NIH StrokeNet trial all PS should have the following documents available for monitoring in the specified filing location. Each NIH StrokeNet trial outlines trial-specific document requirements in the Regulatory Document Parameters. 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.

	Name/Type of Document	Filing Location	Effective Date and (/) Expiration Date	Retention Requirements	Comments
a.	Fully executed Clinical Trial Agreement (CTA)	• Regulatory file at PS	Date of executed agreement/re-	While trial active and + 5 years	The end date of the

		• NIH StrokeNet intranet awardee folder	signature by amendment		agreement is noted on the first page of the CTA
b.	Signed protocol face or signature page (all approved versions) • Original retained PS • Copy of all protocol versions • Copy all amendments and change logs	• WebDCU™	Date of protocol approval or protocol amendment approval/expiration date must be within 365 days of approval.	While trial active + 3 years from prime funding expiration	First page of each protocol and/or amendment and/or addenda are signed by the site PI
c.	Signed Investigators Agreement • Original documents retained by PS	• WebDCU™ • Trial Sponsor central file • Regulatory file at PS	Date of signature, no expiration	While trial active + 3 years from prime funding expiration	New document is required if PI changes
d.	Financial Interest Disclosure Form	• WebDCU™ for site PI • Regulatory file at PS for other study personnel	Expires yearly within 30 days prior to next annual CIRB review	While trial active + 3 years from prime funding expiration	New document is required annually for all applicable personnel according to SOP ADM02 Reporting Conflict of Interest and Financial Disclosures.
e.	Delegation of Authority Log	• WebDCU™ • Regulatory file at PS for signed versions	Date of PI approval of new personnel/end date of personnel responsibilities	While trial active + 3 years from prime funding expiration	The DOA log documents PI delegation of study-related tasks. The electronic DOA should be printed and signed by the PI upon adding new personnel to document oversight. The electronic DOA maintained in WebDCU™

					will be used to set user permissions.
f.	Qualified site personnel • Investigators CV (Site PI and other investigators) • Professional License (all PI and therapist personnel) • Good Clinical Practice (GCP) Human Subjects Protection (HSP) and training (all personnel) • Certification as required by trial, e.g., NIHSS and mRS • Certification in protocol training for staff (all personnel)	• WebDCU™	• CV- expires 5 years from signature date • Professional License- issuance and expiration on license • GCP training – exp date on certificate. If no expiration date is listed, the expiration date is 3 years from issuance • HSP training – exp date on certificate. If no expiration date is listed, the expiration date is 5 years from issuance • NIHSS and mRS certifications expire 2 years from date of completion. If expiration is longer than 2 years, use that date. • Protocol Training – no expiration	While trial active + 3 years from prime funding expiration	CVs should be reflective current addresses, institutional and/or clinical affiliations, etc. to PS
g.	CIRB Documentation • Written approvals, annual renewals and approved amendments • Acknowledgement of SAE/UAE submissions • Acknowledgement of site close out Local IRB Documentation • Written study acknowledgement	• WebDCU™	Approval dates and expiration on the document	While trial active + 3 years from prime funding expiration	
h.	CIRB Documentation • Site specific approvals for recruitment materials and/or appropriate ancillary institutional reviews	• Regulatory file at PS	Approval dates and expiration on the document	While trial active + 3 years from prime funding expiration	CIRB approval trial specific procedures will be located on the protocol/

	Local IRB Documentation • Acknowledgement of SAEs/UAEs • Correspondence				amendment approval.
i.	Substantive correspondence with trial sponsor and/or its agents • Trial specific reports, emails, letters	• Regulatory file at PS	Dates of correspondence required	While trial active	Including and not limited to reports, emails, letters, etc. Site may be defined as either the SS/PS or PS.
j.	Test article and/or supplies accountability • Shipping and receipt records, • Storage, • Dispensing and tracking • Final disposition	• WebDCU™ or Regulatory file at PS according to trial-specific requirements	Dated shipment receipts and packing lists for each shipment of test article or trial supplies	While trial active + 3 years from prime funding expiration	Documentation required for all supplies received from trial PPI sponsor.
k.	Trial informed consents • All site consent versions • Original signed ICD for all participants	• WebDCU™ for approved ICD versions • Regulatory file at PS for participant signed ICD	NA	While trial active + 3 years from prime funding expiration	Each consent document will have approval date in header of each page. The *original* ICD is stored in the participant file.
l.	HIPAA Authorization • All site HIPAA versions • Original signed HIPAA Authorization for all participants	• WebDCU™ for approved HIPAA versions • Regulatory file at PS for participant signed HIPAA	NA	6 years from signature or longer depending on state or local medical records retention requirements	The *original* HIPAA is stored in the participant file.
m.	Source documents • Original documentation of the existence and integrity of trial data collected	• Regulatory file at PS	Date that data was first made available or accessed	While trial active + 3 years from prime funding expiration	
n.	Randomization and blinding • Plan for notification of errors in participant randomization and unblinding errors.	• Regulatory file at PS	As needed	While trial active	Documentation as applicable for study

o.	Monitor visit log and reports	• WebDCU™	Located on document	While trial active + 3 years from prime funding expiration	Documentation of the frequency and type of monitoring visits as deemed necessary by the protocol and trial PPI.
p.	Master randomization (PS participant) list • Unblinded list of participants enrolled in trial with PHI and contact information	• Regulatory file at PS Maintained in a locked cabinet/ drawer	Located on document	While trial active and + 3 years from prime funding expiration	
q.	NCC or PPI exemption to protocol approvals	• Regulatory file at PS	Located on document	While trial active	Description of reason for exemption to be included

6. Applicable Regulations and Guidelines

University of Cincinnati, General Records Retention Schedule (August 2020). https://libraries.uc.edu/content/dam/refresh/libraries-62/arb/docs/2020-08-12_UC_GeneralRecordsSchedule_final_5-2023_edit.pdf

ICH GCP Guideline for Good Clinical Practice. "Essential Documents for the Conduct of a Clinical Trial" section 8. (2016). Retrieved from https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf

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

US Food and Drug Administration. (2023). Public Welfare, 45 C.F.R. § 164.316 Policies and Procedures and Documentation Requirements. Retrieved from

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-C/section-164.316#p-164.316(b)(1)

7. References to Other Applicable SOPs

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

8. **Attachments and References –** None

9. Document History

Version	Description of Modification	Justification for Modification	Completion Date	Issue Date	Effective Date
1.0	Final		18-Dec-2015	21-Dec-2015	04-Jan-2016
2.0	Update fCOI form storage	CIRB policy change	05-Dec-2019	05-Dec-2019	05-Dec-2019
3.0	Administrative updates	WebDCU™ parameters document reconciliation	23-Jul-2021	23-Jul-2021	23-Jul-2021
4.0	Administrative updates	NIHSS and mRS certifications expiration clarification	14-Sep-2022	14-Sep-2022	14-Sep-2022
5.0	Administrative updates		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		09-Aug-2023	09-Aug-2023	09-Aug-2023