SOP Number: GCP 12
SOP NAME: Regulatory and Clinical Data Maintenance Storage
Effective Date: 4-Jan-2016

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 assures 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), 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 Abbreviations

CIRB	Central Institutional Review Board
CPS	Clinical Performance Sites
CTA	Clinical Trial Agreement
CV	Curricula 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 – located at the University of Cincinnati
NDMC	National Data Management Center – located at the Medical University of South Carolina
PI	Principal Investigator
PPI	Protocol Principal Investigator

SAE	Serious Adverse Event
WebDCU™	Clinical trial management system

3. Scope

This SOP has been developed to ensure compliance with federal regulations and Good Clinical Practice, as set forth in the 1996 ICH E6 Consolidated Guidance manual. The policies and procedures described in this SOP apply to CPS 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 CPS.

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.

If the local institution requires a paper copy (or binder) of centrally stored documents be maintained the site is expected to comply with that standard. If electronic or scanned copies of required documents in a similarly organized electronic file is an acceptable form of onsite documentation by the local institution it will be considered acceptable by the NIH StrokeNet.

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 check reference

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 –** None

8. Specific Procedures

For each NIH StrokeNet trial all RCCS and CPS should have the following documents available for review by monitoring staff either as electronic documents in a regulatory management function in a trial specific database (preferred) or as a paper copy:

	Name/Type of Document	Anticipated Filing Location	Effective Date and (/) Expiration Date	Retention Requirements	Comments
a.	Fully executed CTA	• Regulatory file at CPS • NIH StrokeNet intranet awardee folder	Date of executed agreement/re-signature by amendment *yearly*	While trial active and + 5 years	The end date of the agreement is noted on the first page of the CTA
b.	Copy - FWA document	• WebDCU™	Date of Approval and Expiration noted on the document	While trial active	
c.	Signed protocol face or signature page (all approved versions) • Original retained CPS • Copy of all protocol versions • Copy all amendments and change logs	• WebDCU™ • Regulatory file at CPS	Date of protocol approval or protocol amendment approval/expiration date must be within 365 days of approval.	While trial active	First page of each protocol and/or amendment and/or addenda are signed by the site PI
d.	Signed investigators Agreement • Original documents retained by CPS	• WebDCU™ • Trial Sponsor central file • Regulatory file at CPS	Date of signature, no expiration	While trial active	New document is required if PI changes
e.	Financial Interest Disclosure Form	• WebDCU™ for site PI, other study personnel forms in onsite regulatory file	Expires yearly within 30 days prior to next annual CIRB review	While trial active	New document is required annually for all personnel listed on the DOA log
f.	Delegation of Authority Log listing involved personnel documenting trial specific tasks	• WebDCU™	With subsequent protocol or personnel changes	While trial active	The WebDCU generated DOA will be used by the CIRB

g.	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) • Personnel HIPAA 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 • HIPAA training- if no expiration date on certificate, 5 years from issuance • NIHSS certification expires 2 years from date of completion. If expiration is longer than 2 years, use that date. • Protocol Training – no expiration	While trial active	CVs should be reflective *current* addresses, institutional and/or clinical affiliations, etc. to CPS
H.	CIRB written approvals, annual renewals, and approved amendments with date of approval and duration of approval • Evidence of Local IRB review and signoff • Site specific approvals for recruitment materials and/or appropriate ancillary institutional reviews	• WebDCU™ • Regulatory file at CPS	Approval dates and expiration on the document.	While trial active	CIRB approval trial specific procedures will be located on the protocol/ amendment approval.
I.	CIRB communications specific for trial	• WebDCU™	Dates of Correspondence	While trial active	

	• Notifications of SAEs to CIRB and from CIRB to Local CPS IRB • Documentation of study discontinuance from CIRB to local CPS IRB	• Regulatory file at CPS	required		
J.	Substantive correspondence with trial sponsor and/or its agents • Trial specific reports, emails, letters	• Regulatory file at CPS	Dates of correspondence required	While trial active	Including and not limited to reports, emails, letters, etc. Site may be defined as either the SS/CPS or CPS.
K.	Test article accountability • Shipping and receipt records, • Supplies storage, • Supplies dispensing and tracking • Final supplies disposition	• Regulatory file at CPS	Dated shipment receipts and packing lists for each shipment of test article or trial supplies	While trial active	Documentation required for all supplies received from trial PPI sponsor.
L.	Trial informed consents • All site consent versions • Copy of signed ICF for all participants	• CPS Consent versions in WebDCU™ • Signed consents in regulatory file at CPS	NA	While trial active	Each consent document will have approval date and a do not use after date in header of each page. The *original* ICS is stored in the subject file.
M.	Randomization and blinding • Plan for notification of errors in subject randomization and unblinding errors.	• Regulatory file at CPS	As needed	While trial active	Documentation as applicable for study
N.	Monitor signature log and visit reports	• WebDCU™ • Regulatory file at CPS	Located on document	While trial active	Documentation of the frequency and type of monitoring visits as deemed necessary by the protocol and trial PPI.
O.	Master randomization (CPS participant) list	• Regulatory file at CPS	Located on document	While trial active and + 15 years	

	• Unblinded list of subjects enrolled in trial with PHI and contact information	Maintained in a locked cabinet/ drawer.			
P.	NCC or PPI exemption to protocol approvals	• Regulatory file at CPS	Located on document	While trial active	Description of reason for exemption to be included

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