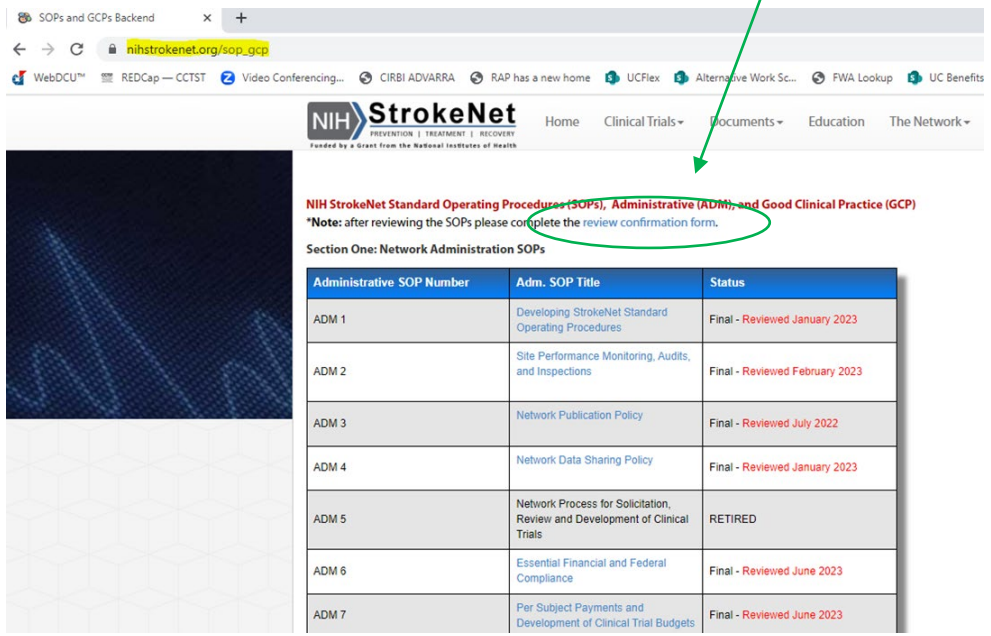
NIH StrokeNet Coordinator Webinar 10/25/23

All **RCC PIs** and **RCC Managers** will be required to review and attest they have reviewed all StrokeNet SOPs

Attestation Form



SOP#	SOP Title
ADM 21	Regulatory Document Maintenance and Storage
GCP 09	Site Performance Monitoring, Audits and Inspections

ADM 21 – Regulatory Document Maintenance and Storage

- This SOP describes regulatory document collection and maintenance procedures for StrokeNet clinical trials
- ICH-GCP Guidelines have 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

ADM 21 – Regulatory Document Maintenance and Storage

Regulatory Document Collection:

- The Trial Master File (TMF) of essential regulatory documents will be partially maintained in WebDCU™ and other additional secure databases, e.g., SharePoint.
- Performance Sites must retain regulatory documents not uploaded to WebDCU™ (such as correspondence with their local Institutional Review Board, trial correspondence, notes to file/memorandums) in their local investigator's site file.
- Sites will be notified which documents are required to be collected for the study, and of those, which should be submitted to WebDCU™ versus retained at the site

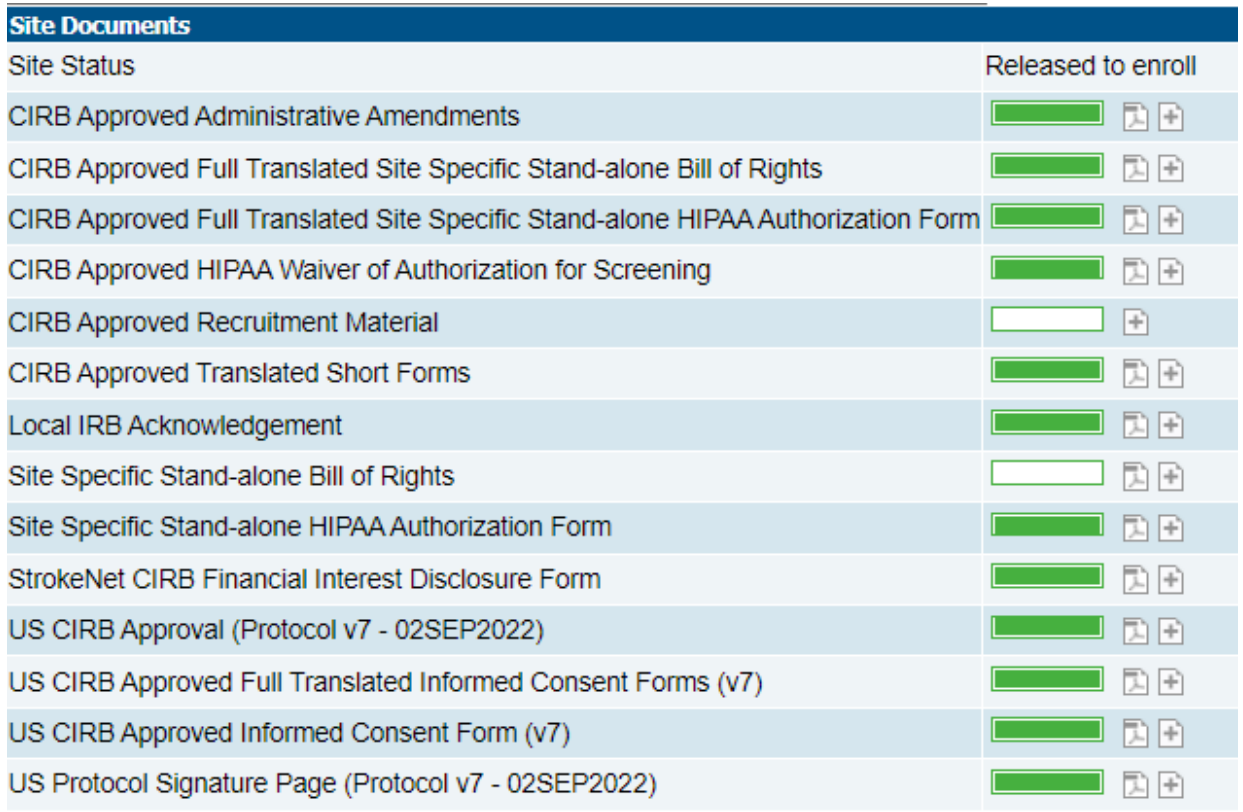
ADM 21 – Regulatory Document Maintenance and Storage

WebDCU ™

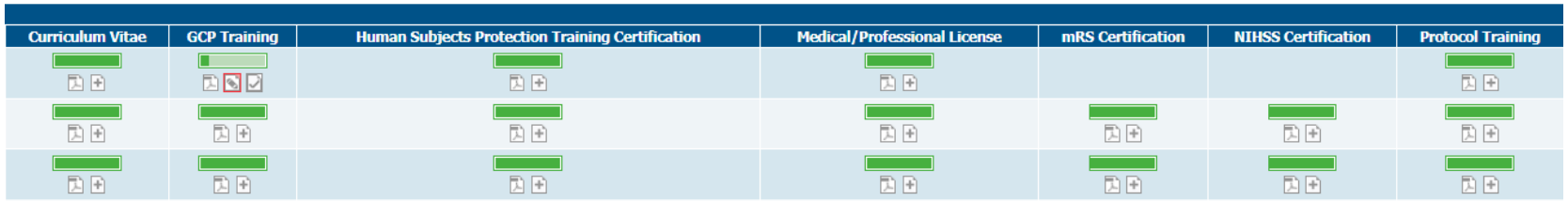
- Web-based central trial management system developed by NDMC
- Programmed specifically for each study by the NDMC through a list of required documents provided by the Project Manager
- A Regulatory Documents Parameters guide will be provided detailing the specific requirements of each document.
- As documents change during the course of the study (for example, protocol amendment), the Project Manager will notify the NDMC to add new document placeholders and the Regulatory Document Parameters will be updated accordingly.

ADM 21 – Regulatory Document Maintenance and Storage

- Site responsible for uploading documents
- PDFs only please
- Project Manager or Regulatory Specialist review and reject/approve documents
- Part of the requirement for release to enroll
- Sites must retain regulatory documents not filed in WebDCU™ in their local investigator's site file.



Site Documents	
Site Status	Released to enroll
CIRB Approved Administrative Amendments	
CIRB Approved Full Translated Site Specific Stand-alone Bill of Rights	
CIRB Approved Full Translated Site Specific Stand-alone HIPAA Authorization Form	
CIRB Approved HIPAA Waiver of Authorization for Screening	
CIRB Approved Recruitment Material	
CIRB Approved Translated Short Forms	
Local IRB Acknowledgement	
Site Specific Stand-alone Bill of Rights	
Site Specific Stand-alone HIPAA Authorization Form	
StrokeNet CIRB Financial Interest Disclosure Form	
US CIRB Approval (Protocol v7 - 02SEP2022)	
US CIRB Approved Full Translated Informed Consent Forms (v7)	
US CIRB Approved Informed Consent Form (v7)	
US Protocol Signature Page (Protocol v7 - 02SEP2022)	

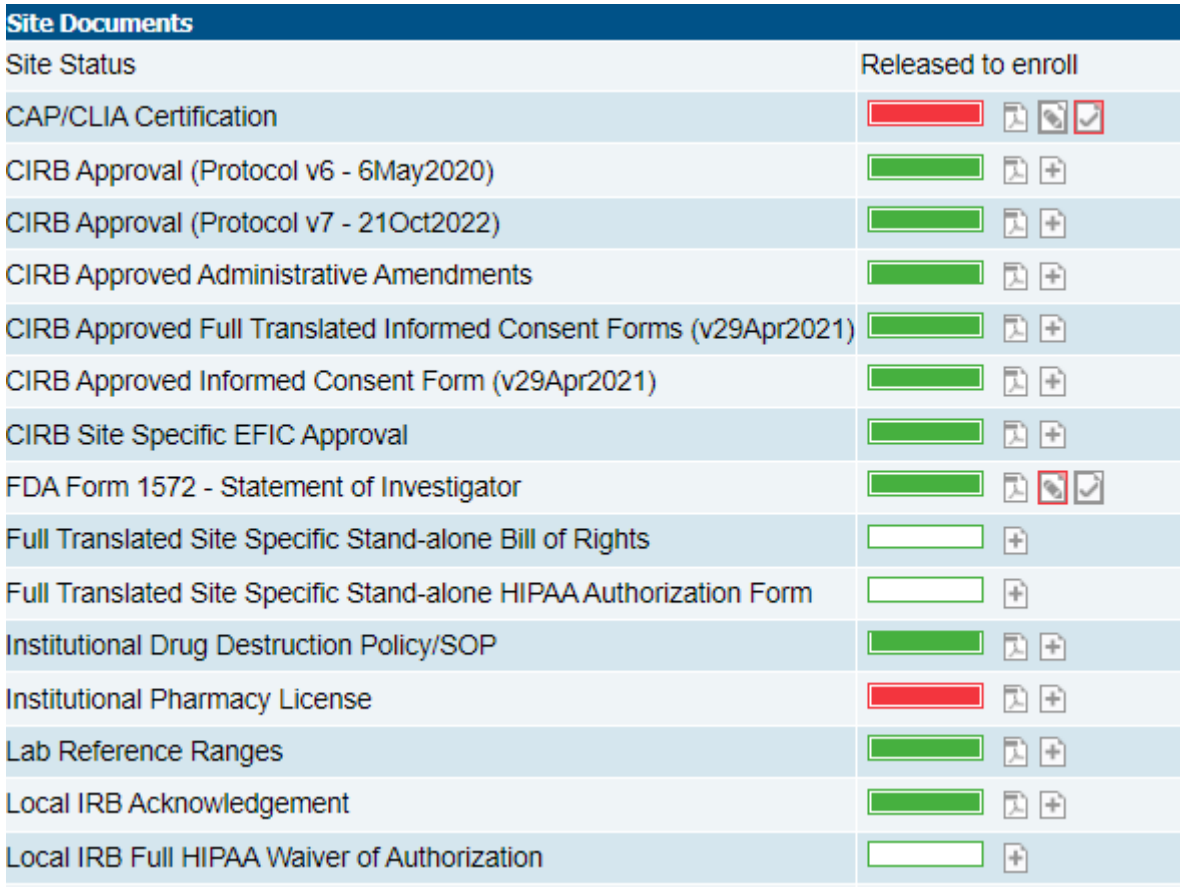


Curriculum Vitae	GCP Training	Human Subjects Protection Training Certification	Medical/Professional License	mRS Certification	NIHSS Certification	Protocol Training

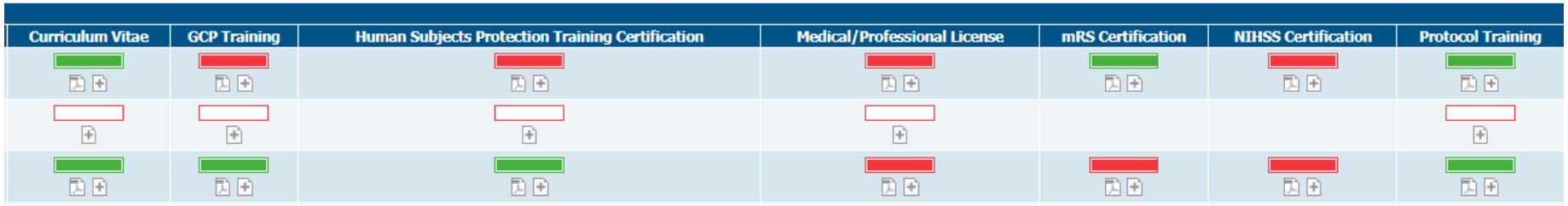
ADM 21 – Regulatory Document Maintenance and Storage

Maintenance of documents in WebDCU:

- Site responsibility to correct/update any
  - Rejected
  - Outdated
    - CAP/CLIA, Lab ranges, 1572s etc.
  - Expired
    - Lapse in Training
- WebDCU ™ sends automated email 60 days prior to the expiration date of any training/certification



Site Documents	
Site Status	Released to enroll
CAP/CLIA Certification	
CIRB Approval (Protocol v6 - 6May2020)	
CIRB Approval (Protocol v7 - 21Oct2022)	
CIRB Approved Administrative Amendments	
CIRB Approved Full Translated Informed Consent Forms (v29Apr2021)	
CIRB Approved Informed Consent Form (v29Apr2021)	
CIRB Site Specific EFIC Approval	
FDA Form 1572 - Statement of Investigator	
Full Translated Site Specific Stand-alone Bill of Rights	
Full Translated Site Specific Stand-alone HIPAA Authorization Form	
Institutional Drug Destruction Policy/SOP	
Institutional Pharmacy License	
Lab Reference Ranges	
Local IRB Acknowledgement	
Local IRB Full HIPAA Waiver of Authorization	



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Regulatory Document Retention

- 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.

- 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.

- 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.

SOP ADM 21

GCP 09 – Site Performance Monitoring, Audits, and Inspections

- **Access to Paper Records and EMR**
  - A site's EMR must demonstrate 21 CFR Part 11 compliance OR the site must be able to provide a certified copy of the accurate and complete medical record for the purpose of trial related monitoring visits and inspections.
  - Research studies may be periodically monitored by sponsoring agencies and other appropriate personnel for the purposes of ensuring that human subject protections are being followed, trial data are accurate and complete and that the study is being conducted according to the protocol.
  - Prior to a monitoring visit, the site will be notified of the purpose, proposed date and nature of the data to be monitored. The site PI/delegate will assure that all research data, source data and regulatory documents necessary to conduct the monitoring visit are available for review.

GCP 09 – Site Performance Monitoring, Audits, and Inspections

- **Policies for StrokeNet Site Monitoring**
  - All trial-specific site monitoring is conducted by trained, qualified personnel overseen by the NDMC.
  - The type of monitoring is either determined by the phase of the trial, or by pre-specified parameters to ensure data quality, proper documentation and/or participant safety.
  - The site PI and relevant research personnel should be accessible at all monitoring visits.

GCP 09 – Site Performance Monitoring, Audits, and Inspections

- **Site Initiation and Training Visits**
  - Purpose: to orient and train site staff on the study protocol and procedures, to confirm that the site is ready to begin recruitment, and to identify additional resources or actions are needed prior to starting the study.
  - These visits may occur **remotely** or **in-person**.
  - Prior to a site initiation visit, the site should:
    - Assure the study protocol has been approved by the CIRB and complete all necessary PS ancillary reviews.
    - Review all identified trial specific study staff roles.
    - Complete any other network, trial PPI or RCC specified site initiation procedures.

GCP 09 – Site Performance Monitoring, Audits, and Inspections

- **Routine Data Monitoring Visits**
  - Conducted periodically to protect data quality, to ensure the accuracy of collected data and to make sure procedures are being followed according to the protocol.
  - These visits may occur **remotely** or **in-person**.
  - For a routine data monitoring visit, sites should ensure that:
    - Source documentation should comply with Good Documentation Practice standards and GCP principles
    - All paper or electronic source data must be available to be checked against CRFs entered into WebDCU™
    - Adverse events should be documented and reconciled per the requirements of the trial.
    - Medication dosage information may be verified for trial participants.
    - Missing information, participant withdrawals and non-compliance must be accurately documented and reported.
    - Deviations from the protocol must be properly recorded, filed and reported to the CIRB, and to the local IRB if local requirements dictate, according to StrokeNet policies and trial specific guidelines.
    - WebDCU™ data queries must be addressed.
    - The site PI and coordinator must be available to meet with site monitors to review findings and discuss action items.

SOP GCP 09

GCP 09 – Site Performance Monitoring, Audits, and Inspections

- **Performance Monitoring Visits**
  - These visits will be conducted by PPI, NCC, or NDMC staff to observe adherence to protocol, address issues such as recruitment or in response to a concern about participant safety.
  - These visits may occur **remotely** or **in-person**.
  - For a performance monitoring visit, staff may review:
    - Recruitment and enrollment numbers, as well as materials and procedures used for recruitment and screening.
    - Requested trial documents such as participant records, informed consents, protocol approvals and amendments.

GCP 09 – Site Performance Monitoring, Audits, and Inspections

- **Auditing Visits**
  - Any entity overseeing research conduct such as NINDS, NCC, NDMC, FDA, or CIRB may conduct an auditing visit to ensure compliance with study specific, institutional and national laws, regulations, policies and procedures.
  - These visits may occur **remotely** or **in-person**.
  - During an audit, sites should be prepared to:
    - Provide documentation of locally maintained regulatory and event reporting records.
    - Provide paper or electronic source data to be checked against CRFs entered into WebDCU™
    - Provide access to EMR as needed.
    - Provide access to other requested trial documents such as training, screening, pharmacy or laboratory records.
    - **Notify the NCC and NDMC upon request of an auditing visit by another entity and provide the NCC and NDMC with a copy of the final report upon conclusion of the auditing visit.**

SOP GCP 09

GCP 09 – Site Performance Monitoring, Audits, and Inspections

- **Study Closeout**
  - May occur at the end of a trial, to ensure that all administrative actions and study procedures have been completed, data has been entered and all other requirements of the study protocol have been met including disposition of investigational product.
  - These visits may occur **remotely** or **in-person**.
  - During a close-out visit, sites should be prepared to:
    - Resolve any outstanding data queries or adverse events.
    - Perform final accountability and shipping or destruction of remaining investigational product, if required.
    - Assure appropriate labeling and storage of all study data.
    - Notify CIRB of site closure and assure all documentation with CIRB are retained at the site with other study records.

GCP 09 – Site Performance Monitoring, Audits, and Inspections

- **Non-compliance or Negligence**
  - If any serious deviations from study procedures or safety protocols are found on the part of the institution, study staff or investigator; the StrokeNet leadership, the trial sponsor or the CIRB acting collaboratively may terminate that institution’s participation in the trial.