Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**
Date Created: **July 1, 2019**
Title: **Management of Regulatory Documents**
Version Date: **January 1, 2023**
SOP Number: **SM13**

PURPOSE:

Essential regulatory documents will be maintained for research conduct at UNMC/NM to assure compliance with regulatory requirements.

SCOPE:

Essential documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the Investigator, Sponsor, and Monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements.

PERSONNEL RESPONSIBLE:

Sponsor
Sponsor-Investigator
Principal Investigator
Regulatory Designee
Monitor

DEFINITIONS:

- **Essential Documents:** Documents that individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.
- **Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
- **Principal Investigator (PI):** The person who is responsible for the management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships.
- **Regulatory Binder:** Contains all study-specific information and regulatory documentation. It organizes essential documents, provides easy access to essential documents by the trial monitor, auditor, IRB, or regulatory authorities (e.g., Office for Human Research Protections, FDA) for review/audit purposes, and allows research team members to reference information.

- **Source Documents:** Original documents, data and records (e.g., hospital records, clinical and office charts, laboratory results, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records) that contain the first recording of pertinent information.
- **Sponsor:** An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of the research.

PROCEDURES:

Study regulatory files are maintained by the Sponsor or Sponsor-Investigator, established at the beginning of the trial and updated and maintained on a continuous basis during the course of the trial.

An investigator regulatory binder, a collection of all essential documents, is maintained by the Principal Investigator/Study Coordinator/Regulatory Coordinator who is responsible for updating and maintaining the files on a continuous basis during the course of the trial. These documents are subject to regulatory review.

The regulatory files will be maintained electronically on a secure network drive, with the exception of the following documents with original signatures which will be maintained in paper format: IRB approval documents (prior to April 2015), Form FDA 1572(s) (if the original is not requested by the sponsor or provided to the FDA), monitor sign-in log(s), the Delegation of Authority Log, and any other applicable study logs. Other documents will be scanned, certified (as described below), saved electronically, and then originals will be destroyed, unless requested in advance by the Sponsor.

A certified copy is a copy (irrespective of the type of media used) of original information that has been verified, as indicated by a dated signature, as an exact copy, having all of the same attributes and information as the original. The certification process will be as follows:

1. A designated regulatory team member will complete a Certified Copy Log (see appendix 1 as an example) for each study. The log will note study name, IRB number, and PI. For each certified study document, the regulatory team member will record the document name and number of pages on the log.

2. The original documents will be scanned into Adobe® portable document file (PDF) electronic format and saved to the secure network drive. The team member will ensure that the scanned PDF version appears as the original paper version; verification must

include the following: legibility of the scanned document, intact header and footer, and all pages appear "in total". Once verified, the team member will initial and date the Log for each certified item.

3. A second team member will confirm the verification is accurate. Following review of the scanned documents, the second team member will also initial and date the log for each certified item. If the scanned documents do not meet the requirements of a certified copy (an exact copy having all of the same attributes and information as the original), the process will be repeated.

4. Scanned and certified documents will be named in such manner that they clearly reference the document content.

5. Electronic documents provided by sponsor or from secure electronic systems will be renamed and placed in the designated secure drive directly without any conversion. The designated study staff member will name these documents so that they reference their original content.

6. Paper documents that have been scanned, certified, and placed into the designated HIPAA secure location can be returned to sponsor, if requested or destroyed by shredding the document.

Audit, financial, and contractual information are not subject to regulatory review and will not be made available. Screening and enrollment logs will not be maintained in the regulatory binder/files.

Box.com (“Box”), a cloud-based content platform for sharing and accessing digital files, will be used to provide monitors access to electronic regulatory binders. A File Transfer Protocol (FTP) will be used to transfer the digital files from the secured network drive to Box. The Box platform meets the obligations required by federal mandate to be HIPAA compliant. Box may be accessed remotely from a personal device, however, files saved on Box should not be synched to personal hard drives.

The regulatory binder will be uploaded to Box and made available to monitors prior to their visit. The binder will be a mirror image of the current regulatory files stored on the secure network drive. Access will be granted by the regulatory coordinator the day of the monitor visit. After the visit, the binder will be removed from Box and monitor access will be withdrawn.

The regulatory documents stored on the secure network drive will be maintained for the period specified in the study protocol, clinical trial agreement, institutional policies, cooperative study group policies, and/or research regulation for whichever period is longer. Electronic documents will be archived on the secure network drive and hard copy documents will be sent to long term storage following study closure with the IRB of record.

Regulatory binders will not be provided in any other format.

ASSOCIATED FORMS:

Appendix 1: Certified Copy Log

RESOURCES:

21 CFR Part 56: Institutional Review Boards
21CFR Part 312: Investigational New Drugs
21CFR Part 812: Investigational Device Exemption
Regulatory e-Binder Structure Guidance Document:
Essential Regulatory Documents Guidance : https://nccih.nih.gov/sites/nccam.nih.gov/files/CR-Toolbox/Regulatory_Binder_Guidance_and_Tabs_ver2_07-17-2015.pdf
What is a certified copy? https://www.invioinc.com/2017/09/27/using-certified-copy-in-a-clinical-trial-part-2/

Department Approval

Signed Katie Penas Signed: 2/21/2023
Clinical Research Manager

Signed Signed: 4/3/2023
Assistant Vice Chancellor for Clinical Research

Certified Copy Log

Study Name: _____ IRB # _____

PI Name: _____

The following documents are a copy of the original document which has been scanned into the ADOBE® portable document file (PDF) format, and verified as a true and accurate copy, according to Standard Operating Procedure SM13 Management of Regulatory Documents.

File Name	Date	Number of Pages	Team Member #1	Team Member #2

Initials	Name (Printed)	Signature