University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center**

Date Created/Modified: **November 1st, 2010**

Title: **Regulatory Binder**

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SOP Number: **SM11**

PURPOSE: The purpose of this standard operating procedure (SOP) is to ensure all Clinical Research Center (CRC) personnel are familiar with the documents that must be maintained in a regulatory binder.

SCOPE: This SOP applies to most documents maintained in the Regulatory binder. These documents are referred to as Essential documents. Essential documents serve to show compliance of an investigator and sponsor with the regulatory requirements of the study.

PERSONNEL RESPONSIBLE: Principal Investigator, Sub-investigators, Study Coordinators, Regulatory Coordinators and/or other pertinent staff should be familiar with the content and the location of the regulatory binder.

DEFINITIONS:

- **College of American Pathologists (CAP) –** sets quality, accuracy, and consistency standards for laboratory accreditation.
- **Clinical Laboratory Improvement Amendments (CLIA) –** Regulations that establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health.
- **Essential Documents -** Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.
- **Financial Disclosure Form (FDF) -** Official legal document that the FDA requires sponsors to certify the absence of certain financial arrangements between an investigator and/or disclose those financial interests when the sponsor has submitted a marketing application of a new investigational product in the United States.
- **Food and Drug Administration (FDA**) - Department within the United States Department of Health and Human Services. Enforces Food, Drug and Cosmetics Act and related federal public health laws.
- **Good Clinical Practice (GCP) -** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of research that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of subjects are protected.
- **Institutional Review Board (IRB) -** An independent group made up of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by reviewing and approving the clinical protocol, informed consent forms, and the methods and materials used in the trial.

- **Investigational Product (IP)** - A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, when used for an unapproved indication, or when used to gain further information about an approved use.
- **Investigator's Brochure (IB)** - Relevant clinical and non-clinical data compiled on the investigational drug, biologic or device being studied in human subjects.
- **Laboratory reference ranges** - A set of values used by a health professional to interpret a set of medical laboratory test results from blood, urine or other body fluid samples.
- **Protocol -** A document that describes how a clinical trial will be conducted to include the objective(s), design, methodology, statistical considerations, and organization. It works to ensure the safety of study participants and integrity of the data collected.
- **Protocol Amendment** - A change(s) to or formal clarification of a protocol.
- **Statement of Investigator, Form FDA 1572** - an agreement signed by the investigator to provide certain information to the sponsor and assure that he/she will comply with FDA regulations related to the conduct of a clinical investigation of an investigational drug or biologic.

PROCEDURES:

- For all studies, regulatory binder documentation will be established at the beginning of a trial and kept electronically in Advarra eReg, electronically on a network drive or in a three-ring binder. Paper binders will be locked in a cabinet when not in use.
- In order to demonstrate compliance of the investigator, sponsor, and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements, the regulatory binder must contain the following documents, when applicable:
    - Organizations
    - Staff
    - Staff Training
    - Delegation of Authority
    - 1572
    - Sponsor Correspondence
    - Data Capturing
    - Financial Disclosure Forms (FDFs)
    - IND & Device Documentation
    - Investigational Product (IP)
    - Investigator's Brochure (IB)
    - IRB
    - IBC
    - Laboratory – Local

  - Laboratory – Central
  - Miscellaneous Study Manuals
  - Monitoring Letters
  - Internal Audit
  - Notes to File/Memos to File
  - Protocol and Amendments
  - Recruitment
  - Safety Reporting
  - Study Contact
  - Study Logs or Templates
  - Subject Visit Items
  - SRC - Oncology Only
- Documents should be organized in reverse chronological order, i.e., the most current one on top.
- The regulatory binders will be made available for monitoring and audit visits.
- At study close-out and packaging for long-term storage, a paper or electronic copy of the regulatory binders will be included with all corresponding source documents and case report form copies.

RESOURCES:

ICH, Guideline for Good Clinical Practice (GCP) – E6, Section 8
Information Sheet Guidance for Sponsors, Clinical Investigators, and IRB; FAQs Statement of Investigator (Form FDA 1572)

Department Approval

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Signed: 2/21/2023

Signed
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Signed: 4/3/2023