Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**

Title: **Home Health**

SOP Number: **SM45**

Date Created: **October 9, 2023**

Version Date: **October 9, 2023**

PURPOSE:

U.S. FDA Guidance and Good Clinical Practice (GCP) require that the principal Investigator (PI) of each research protocol provide direct supervision over the conduct of the trial. Good Clinical Practice (GCP) requires the PI to maintain a list of personnel, both internal and external, to who he/she has delegated significant trial-related duties. The PI should maintain essential regulatory documents for each staff member.

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, Research Coordinator, Monitor, Legal, and other research site staff.

DEFINITIONS:

- **Delegation of Authority Log (DOA):** A protocol specific form utilized by the PI to indicate which personnel are authorized to perform delegated tasks on a specific study. The DOA includes a list of delegated staff, including their role/delegated duties, and start/stop dates for each staff member. This form is generated from the eReg application and may be provided to sponsors and regulators to demonstrate proper delegation by the PI.
- **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:

A. **Investigator Responsibilities**

The PI will conduct and/or supervise the clinical research study to ensure that it is conducted according to the signed investigator statement, IRB approved protocol, institutional policies, GCP, and FDA Guidance for Industry: Investigator Responsibilities and Applicable Regulations.

The PI is ultimately responsible for the conduct of the research study but may delegate tasks to qualified research personnel when appropriate, including non-University of Nebraska Medical Center (UNMC)/Nebraska Medicine employed study team members (e.g., home health staff). Delegation must be documented by the PI for all non-exempt human subject research. The PI and delegated research team members will:

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the study.
- Meet all the qualifications specified by the applicable regulatory and sponsor requirements, and will provide evidence of such qualifications through up-to-date curriculum vitae, job description, and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.
- Disclose financial interests or relationship with sponsors as required by federal regulations and institutional policies.
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant research study-related duties for each study on the Delegation of Authority Log.
- Ensure that individuals are approved by the IRB as key personnel and/or Sub-Investigators for the research tasks they will be performing prior to engaging in such tasks.
- Ensure that all persons assisting with the research study are adequately trained about the protocol, the investigational product(s), and their study-related duties and functions as documented on the study Training Log(s).
- Protect the rights, safety, and welfare of subjects under the investigator's care.
- Ensure protocol compliance (e.g., subject eligibility, consent, and randomization).
- **Refer to CRC SOP SM16 for Delegation of Authority Procedures

B. **Research Coordinator Responsibilities**

The Research Coordinator will coordinate the clinical research study in line with delegated tasks, institutional policies, GCP, and FDA Guidance for Industry. In the event a non UNMC/Nebraska Medicine research study team member is added to the study protocol (e.g., home health staff), the Research Coordinator will:

- Notify the PI for appropriate supervision of study member
- Notify the Regulatory Coordinator

C. **Regulatory Coordinator Responsibilities**

The Regulatory Coordinator will work with the sponsor to determine site level regulatory maintenance requirements for home health staff. In the event a non UNMC/Nebraska Medicine research study team member is added to the study protocol (e.g., home health staff), the Regulatory Coordinator will:

- If required, gather the essential regulatory documents to include, but not limited to: CV, license (if applicable), CITI Training, GCP, and study specific training logs.
- If needed, store required documents in study files in line with current procedures.

The Regulatory Coordinator will maintain records and essential regulatory documents for all study team members documented on the DOA.

RESOURCES:

21CRF 50 Protection of Human Subjects
45CRF46 Protection of Human Subjects
45CRF 160 HIPAA Privacy Rule
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

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Nebraska Medicine:
TX 04 – Chain of Command/Escalation of Concern

Department Approval

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