University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center**

Title: **Protocol Training**

SOP Number: **SM15**

Date Created: **May 27, 2016**

Version Date: **January 1, 2023**

PURPOSE: This standard operating procedure (SOP) outlines the procedures required for initial and continuing training of the investigators and research staff. Training will allow study personnel to receive an introduction to continued education about their roles and responsibilities with the protocol. Training should include information needed to conduct research properly, in addition to background information on structure, expectation, and goals.

SCOPE: This SOP applies to the investigator and all research site personnel involved in the implementation and coordination of clinical research.

PERSONNEL RESPONSIBLE: Clinical Research Center (CRC) Regulatory Staff and all members of the study team.

DEFINITIONS:

- **Delegation of Responsibility Log (DOR):** a sponsor-provided log that documents who is responsible for various activities on the study. Every person involved with the study needs to be listed and provide their signature.
- **Investigator Meeting:** a study sponsored meeting to ensure that all investigators have an understanding of how to conduct the trial in strict compliance with the protocol, SOP's, guidelines and applicable regulations.
- **Site Initiation Visit (SIV):** a visit by the study sponsor and/ or contracted CRO's personnel to assess site readiness to begin a clinical trial. This generally includes a tour of the facilities, meeting most staff assigned to the study, and protocol training.
- **Site Training Log**: this document is to record that study personnel training has taken place. Those unable to attend the SIV are trained separately, and the form is filled out once training has been completed.

PROCEDURES:

A. Protocol Training
   a. Protocol training for study team members may occur at the time of:
      i. Site Initiation Visit (SIV)
      ii. Investigators Meetings
      iii. After Institutional Review Board (IRB) approval for major amendments to the protocol

iv. Significant adverse events/violation where the IRB approves consent or practice change. Unless it impacts patient safety, then timely training implementation should occur.
v. A new study member joins the team
vi. Any additional trainings as required by sponsor.

b. If possible, the members of the study team listed on the delegation of authority log should obtain protocol training during the SIV and complete a sign-in sheet. Study team members not in attendance at the SIV or training session should be trained via email, face-to- face interaction, or campus mail with the review of power point slides, a copy of the protocol, or demonstration. This should also be documented on the training form.
c. IRB approved study materials will be sent to the study team for training, such as the protocol, informed consent forms and investigator brochures. Additional materials requiring training must be specified by the sponsor, which includes but is not limited to pharmacy manuals, laboratory manuals and patient facing documents. Please reference the regulatory binder.

B. Training may be provided in several ways:
a. Training information may be requested from the sponsor and should be distributed to study team members once IRB approval has been received. Examples of the new information one can request are: new study synopsis, summary of changes to the protocol, review of sponsor provided materials, etc.
b. If training is provided via campus mail, email, or face-to-face, a copy of any training materials should be available to each person trained. Completed protocol training should be documented in the study regulatory binder.
c. Sponsor protocol training should be provided as electronic documents. If a sponsor requires web-based training with password access, this should be honored but is not preferred. All training should be documented in the regulatory binder.

Resources:

- 21 CFR 312.50 General Responsibilities of Sponsors
- 21 CFR 312.60 General Responsibilities of Investigators
- ICH GCP Consolidated Guideline—Part 4.5.2 Compliance with Protocol

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Department Approval

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Signed: 2/21/2023

Signed
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Signed: 4/3/2023