Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**

Title: **Protocol Amendments**

SOP Number: **SM36**

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

Version Date: **January 1, 2023**

PURPOSE: The purpose of this standard operating procedure (SOP) is to outline the process of implementing protocol, investigator brochure and/or Informed consent amendments.

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

PERSONNEL RESPONSIBLE: Principal Investigator and when delegated by the principal investigator, sub-investigators, study coordinator, regulatory coordinator and/or other pertinent staff.

DEFINITIONS:

- **Informed consent -** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.
- **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.
- **Investigator's Brochure -** Relevant clinical and non-clinical data compiled on the investigational drug, biologic or device being studied in human subjects.
- **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 clarifications of a protocol.
- **Protocol Amendment Summary of Changes -** A written description of a change(s) to or formal clarifications of a protocol.
- **Sponsor-**An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of the research.
- **COOP: Cooperative Group study** – A research project of the National Cancer Institute (NCI) that brings together many investigators from hospitals and academic research centers throughout the United States.
- **Research Support System (RSS) -** RSS is the online IRB system (https://net.unmc.edu/rss) used for completing IRB applications, requests for change, and continuing reviews. The IRB policies and procedures manual can also be found on this site.

PROCEDURES:

Prior to IRB Approval of the Amendment

- Upon receipt of an amendment from the sponsor, the individual receiving the amendment will send amendment documents to studyintake@unmc.edu.
- The clinical trials analyst will review the amendment documents and update the billing grid and coverage analysis if necessary.
- The clinical trials analyst or budget negotiator will review the amendment documents and re-negotiate the budget if necessary.
- The contract negotiator will review the amendment documents and amend the contract if necessary.
- The regulatory coordinator will review the amendment documents and make any applicable revisions to the ICF and submit it to the sponsor for review and approval for industry studies or to the department project manager if a COOP study, prior to submitting to the IRB.
- The regulatory coordinator will submit a request for change to the IRB by updating the application, completing the Request for Change form, and uploading any relevant documents to RSS.
- No changes will be implemented without IRB approval, except to eliminate an apparent hazard to study subject. If this is the case, the Office of Regulatory Affairs, must be notified no later than 2 business days from the time the change was implemented by using the Request for Change Form or the Single Subject Protocol Deviation Form, as applicable.
- Upon receipt of written approval (or disapproval), the regulatory coordinator will submit a copy of the IRB documentation and the signed protocol amendment signature page to the sponsor of the protocol.

Implementing the Protocol Amendment

- All research personnel including investigators, nurse coordinators, CRAs, data coordinators and pharmacy staff will be provided copies of the amendment documents and will be trained regarding the amendment. Training will be documented and filed in the regulatory binder.
- Amendment documents will be saved in the regulatory binder.
- The principal investigator or designee will inform all study subjects currently enrolled in the research of amendment changes or new information that may impact their decision to continue participation in the study.
- If the amendment changed the informed consent, all subjects may be re-consented by the Principal Investigator at their next visit as approved by the IRB. However, if the change has immediate impact on the subject's safety or protocol compliance, subjects would be

contacted as soon as possible and if applicable, subjects would come in for an unscheduled study visit. All correspondence with the subject is documented in the subject's research file.

RESOURCES:

- 21 CFR 54.25—Institutional Review Board
- 21 CFR 56.103 –Circumstances in which IRB Review is Required
- 21 CFR 56.108- IRB Functions and Operations
- 21 CFR 56.109- IRB Review of Research
- 21 CFR 56.111- Criteria for IRB Approval of Research
- 21 CFR 312.30-Protocol Amendments
- 21 CFR 812.64 IRB Continuing Review
- 45 CFR 46.109—IRB Review of Research (if applicable)
- ICH GCP Consolidated Guideline—Part 4.4 Communication with IRB/IEC
- ICH GCP Consolidated Guideline—Part 4.5.2 Compliance with Protocol

Department Approval

Signed Katie Penas
Clinical Research Manager

Signed: 2/21/2023

Signed
Assistant Vice Chancellor for Clinical Research

Signed: 4/3/2023