University of Nebraska Medical Center

Center for Clinical and Translational Research Standard Operating Procedure

Nebraska Medicine

Section: **Clinical Research Center**

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

Title: **Obtaining & Maintaining IRB Approval**

Version Date: **January 1, 2023**

SOP Number: **SM14**

PURPOSE: The purpose of this standard operating procedure (SOP) is to outline the basic procedures required for obtaining and maintaining Institutional Review Board (IRB) approval at the University of Nebraska Medical Center (UNMC)/Nebraska Medicine (NM) institution.

SCOPE: This SOP applies to all human subject research performed in Clinical Research Center (CRC) at UNMC/NM.

PERSONNEL RESPONSIBLE: Principal Investigator and when delegated by the principal investigator; Sub-investigators, Study Coordinator and/or other pertinent staff.

DEFINITIONS:

- **Adverse Event (AE) – (**adapted from the ICH definition) any undesirable medical occurrence in a clinical trial subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can include any unfavorable and unintended signs, symptoms, or the exacerbation of a pre-existing condition associated with the use of an investigational product, whether related to the product. When an AE has been determined to be related to the investigational product, it is considered an Adverse Drug Reaction.
- **Data Safety Monitoring Board (DSMB**) - An independent data monitoring committee that may be established by the sponsor which meet at designated intervals to assess the progress of research, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop the research.
- **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.

- **Sponsor -**An individual, company, institution, or organization that takes responsibility for the initiation, management, and/or financing of the research.

PROCEDURES:

- The principal investigator or his/her designee will submit all proposed research for review to the UNMC Institutional Review Board (IRB), using the UNMC RSS electronic application system. When utilizing a central IRB, the UNMC Office of Regulatory Affairs (ORA) will ensure all institutional requirements are met.
- The principal investigator or his/her designee will obtain written approval before any potential subject is approached and asked to participate in the research except as provided in 21 CFR 56.104 (Exemptions from IRB requirement) and 56.105 (waiver of IRB requirement).
- The principal investigator or his/her designee is responsible for submitting all documents to the reviewing IRB in a timely manner. Documents requiring IRB review include:
    - Protocol and any amendments
    - Investigator's brochure and any amendments
    - Consent form(s) and any revisions
    - Advertisements to be used for subject recruitment
    - Other materials that will be provided to subjects (such as diaries and questionnaires)
    - Safety reports, DSMB reports and other related information
    - Any site adverse events that are serious and considered related to the study
    - Report of any protocol deviations/violations per IRB requirements
    - Any other documents as required by the IRB
- Continuing (usually annual unless IRB requires it to be more frequent) review reports will be submitted as required by the IRB. The annual review should be submitted timely to assure no lapse in approval.
- Demographic information will be submitted to the ORA as requested.
- If directed by the IRB, the consent forms will be revised in the event of new safety information that may impact subject's willingness to participate in the research. Only current, IRB-approved versions of consent forms will be utilized for obtaining informed consent. NOTE: If there is a sponsoring company involved, they will be informed of the IRB required revision and given a chance to review the consent before final approval.
- The principal investigator or his/her designee will submit all protocol amendments (and related consent form revisions) to the IRB for approval prior to implementation, except whereas to eliminate immediate hazards to subjects. NOTE: All revisions will be submitted to the IRB as soon as possible after immediate danger to subjects has been resolved.
- At the end of the research, the principal investigator will complete and submit a final report to the IRB.

RESOURCES:

- 21 CFR 54.25—Institutional Review Board
- 21 CFR 56.103 –Circumstances in which IRB Review is Required
- 21 CFR 56.109- IRB Review of Research
- 21 CFR 56.111 Criteria for IRB Approval of Research
- 45 CFR 46.109—IRB Review of Research (if applicable)
- ICH GCP Consolidated Guideline—Part 4.4 Communication with IRB/IEC

UNMC IRB Forms and Policies found at Office of Vice Chancellor for Research Institutional Review Board website. (https://www.unmc.edu/irb/)

Department Approval

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

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