1. PURPOSE

To establish standard procedures required to obtain and maintain Institutional Review Board (IRB) approval.

2. SCOPE

Applies to Principal Investigator (PI), and when delegated by the PI, additional Investigator(s), Study Coordinators (SCs), and other designated site personnel.

3. RESPONSIBILITIES

The PI is responsible for securing IRB approval of all human research prior to discussion with potential subjects, reviewing subject medical records, or performing study procedures.

4. BACKGROUND

Except as provided in 21 CFR 56.104 and 56.105, any clinical investigation that must meet the requirements for prior submission to the FDA shall not be initiated unless that investigation has been reviewed and approved by, and remains subject to continuing review by, an IRB meeting the requirements of 21 CFR 56 [21 CFR 56.103].

IRB approval is required for all behavioral or biomedical research on human subjects to ensure that the risks to subjects are minimal and reasonable in relation to expected benefits. The IRB serves to protect the rights, welfare, and safety of human research subjects.

The IRB will notify the Investigator in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval. If the IRB decides to disapprove the research, it will include in the written notification a statement of the reasons for its decision and give the Investigator an opportunity to respond in person or in writing [21 CFR 56.109(d)].

The PI should not implement any deviations from or changes to the protocol without agreement by the sponsor and prior review and documented approval from the IRB, except where necessary to eliminate immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change in telephone number(s)) [ICH GCP 4.5.2].

IRBs conduct continuing review of research covered by federal regulations at intervals appropriate to the degree of risk, but no less than once per year [21 CFR 56.109 (e)].

5. PROCEDURE

5.1. The PI will submit all proposed clinical investigations for IRB review to an IRB designated and authorized by the research facility.

5.2. The PI will obtain written approval from the IRB before any human subjects are allowed to participate in a clinical investigation, except as provided in 21 CFR 56.104 and 56.105.

5.3. The PI is responsible for submitting all records requiring IRB review in a timely manner. The PI may assign the duty of record submission to the Regulatory Documents Specialist (RDS) or appropriate clinical site research personnel. Records requiring IRB review include:

- 5.3.1. Protocol and any modifications
- 5.3.2. Investigator's brochure and any modifications
- 5.3.3. Informed Consent Form (ICF) and any revisions
- 5.3.4. A report of prior investigations, if a medical device for human use
- 5.3.5. Advertisements to be used for subject recruitment
- 5.3.6. Other written materials to be provided to subjects
- 5.3.7. Safety reports and information
- 5.3.8. FDA Form 1572 and any modifications
- 5.3.9. Other documents as required by individual IRBs

5.4. The PI and RDS or designee will follow IRB-specific reporting requirements and submit all reports accordingly.

5.5. The PI and RDS or designee will maintain records of all submissions, correspondence, and actions by the IRB regarding the clinical investigation in the Investigator regulatory files.

5.6. The PI and RDS or designee will provide the sponsor with a copy of all correspondence related to IRB application and records submission.

5.7. The PI and RDS or designee will promptly report all unanticipated problems, including adverse events (AEs), and sponsor IND/IDE safety reports to the reviewing IRB per IRB policies.

5.8. If directed by the IRB, the ICFs will be revised in the event of new safety information that may impact subject willingness to participate in a trial. Only current, IRB-approved versions of ICFs will be used for obtaining informed consent.

5.9. The PI and RDS or designee will submit all protocol amendments (and related ICF revisions) to the IRB for approval prior to implementation, except those taken to eliminate immediate hazard(s) to trial subjects.

5.10. At the conclusion of a trial, the PI will file a final report to the IRB indicating the status of the trial, including any additional information required by the IRB.

6. TERMS & ABBREVIATIONS

AE Adverse Event
FDA Food and Drug Administration
ICF Informed Consent Form
IDE Investigational Device Exemption
IND Investigational New Drug
IRB Institutional Review Board
PI Principal Investigator
RDS Regulatory Document Specialist
SC Study Coordinator

7. REFERENCES

7.1. Title 21 CFR 56.103 - Circumstances in which IRB review is required
7.2. Title 21 CFR 56.109 - IRB Review of Research
7.3. Title 21 CFR 56.111 - Criteria for IRB Approval of Research
7.4. Title 45 CFR 46.109 - IRB Review of Research (if applicable)
7.5. ICH GCP Consolidated Guideline - Part 4.4 Communication with IRB/IEC
7.6. ICH GCP Consolidated Guideline - Part 4.5.2 Compliance with Protocol
7.7. Creighton University Institutional Review Board Policies and Procedures

8. ATTACHMENTS

None