1. PURPOSE

To describe the duties and responsibilities required of the Principal Investigator (PI).

2. SCOPE

All clinical research units that are used to conduct study-related procedures in human research clinical trials.

3. RESPONSIBILITIES

The PI is responsible for the training of all Investigators and clinical research staff.

4. BACKGROUND

The PI is responsible for the overall conduct of a research study at the clinical site; however, delegation allows additional Investigators and other clinical research personnel to actively participate in the implementation and conduct of a clinical trial.

5. PROCEDURE

Clinical trials will have a PI who is the individual of record who assumes authority and accountability for the ethical conduct of a clinical study in accordance with all applicable federal and state laws and regulations and university policy. The PI is fully responsible for:

5.1. The safety and welfare of participants in the trial, including ensuring that adequate medical care is provided to a participant for any adverse events, including clinically significant laboratory values related to the clinical trial.

5.2. Reading and understanding all the information in the grant documents, the Investigator's Brochure, the Informed Consent Form (ICF), and the protocol.

5.3. Informing all Study Participants (SPs), including participants used as controls, that the investigational agents are being used for investigational purposes, and following all requirements relating to obtaining informed consent.

5.4. Preparing and submitting protocol documents for initial Institutional Review Board (IRB) review and approval.

5.5. Conducting study activities only after IRB approval and in accordance with the approved protocol, and ensuring that IRB requirements are met.

5.6. Reporting adverse events to the IRB and the sponsor as they require.

5.7. Implementing modifications to approved research only after review and approval of the modification by the IRB, except where necessary to eliminate apparent immediate hazards to study participants.

5.8. Reporting unanticipated events to the IRB and sponsor that may present risks, affect the safety and welfare of study subjects or others, or that may affect the integrity of the research. Examples of such unanticipated problems include a pattern of greater than anticipated toxicity of the investigational agent, or difficulty participants may have understanding the ICF.

5.9. Providing progress reports to the IRB in a timely manner.

5.10. Ensuring that federal (FDA and HHS), state, and local laws and regulations governing clinical trials and the policies and procedures of Creighton University are followed.

5.11. Ensuring the disclosure to the sponsor and the IRB, and if required by the IRB, to SPs, of financial interest and arrangements by any member of the research team that may present a conflict with the interests of participants in the study.

5.12. While retaining knowledge of and overall authority for the conduct of all research studies, supervise members of the research team qualified by appropriate education and experience to accept responsibility for study-related activities not directly performed by the PI. The PI must also ensure that delegation of responsibilities is appropriate and is documented, and that individuals recruited as members of the research team are appropriately licensed and trained.

5.13. Maintaining adequate and accurate records and making records available for inspection by external and internal monitors. Meeting with auditors (FDA, sponsor, and/or internal) at the conclusion of their audits to review findings and to implement changes to correct weaknesses or deficiencies.

5.14. Delegating responsibility to individual members of the research team; however the PI cannot delegate accountability for the ethical conduct of the study. The PI must sign the form that delegates responsibilities to each member of the research team. Each individual's name must be initialed and dated. The form must be updated, initialed, and dated each time there is a personnel change.

5.15. Ensuring that adequate resources are available to protect the rights and welfare of SPs. These resources include personnel, time, and access to the required study population. Investigators should not commence a research study without adequate resources to protect participants, and should stop a research study if resources become unavailable.

6. TERMS & ABBREVIATIONS

CRF Case Report Form
FDA Food and Drug Administration
HHS Heath and Human Services
IB Investigator's Brochure
ICF Informed Consent Form
IRB Institutional Review Board
PI Principal Investigator
SP Study Participant

7. REFERENCES

7.1. ICH GCP Guidelines Section 4.0

8. ATTACHMENTS

None