

INVESTIGATOR RESPONSIBILITIES

The scope and purpose of this SOP is to set forth requirements for the conduct of interventional *clinical trials* within the University of Utah. This SOP may be used to guide the conduct of other types of clinical research studies to promote quality and to meet Good Clinical Practice standards.

Introduction and Purpose

The Principal Investigator (PI) of a clinical trial has responsibilities and obligations for the conduct and oversight of the trial detailed in the Code of Federal Regulations (CFR) and in the Good Clinical Practice (GCP) guidelines, to ensure protection of the rights, safety and welfare of study participants, and to ensure the integrity of study results.

The PI of a clinical trial is required to follow the regulations for the protection of human subjects, including obtaining informed consent from study participants and ensuring review and approval by the Institutional Review Board (IRB), as found in the U.S. Food and Drug Administration (FDA) regulations (21 CFR §50, and 21 CFR §56).

Additionally, clinical trial investigators should adhere to the International Council on Harmonization (ICH) GCP guidelines, which provides assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible.

The PI is specifically responsible for compliance with the IRB approved protocol, GCP guidelines, and the applicable federal regulations above. The PI may delegate authority to conduct study tasks to sub-investigators, coordinators, and other qualified study personnel; however, the investigator retains ultimate responsibility of overall study conduct.

Definitions and Acronyms

Clinical Research: Clinical research includes all research involving human participants. It does not include secondary studies using existing biological specimens or data collected without identifiers or data that are publicly available.

Clinical Trial: Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

CFR: Code of Federal Regulations
FDA United States Food and Drug Administration

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GCP:	Good Clinical Practice
ICH:	International Council on Harmonization
IRB:	Institutional Review Board
PI:	Principal Investigator
SOP:	Standard Operating Procedure

Procedure

- Investigator Responsibilities:** In conducting clinical trials in compliance with federal regulations and GCP, the PI commits to personally conducting or supervising the trial, including:
 - 1.1. Ensuring the clinical trial is conducted according to the signed investigational plan (protocol), investigator statement (form FDA 1572, or Investigator Agreement for device studies), applicable regulations, and ICH guidelines on GCP.
 - 1.2. Protecting the rights, safety, and welfare of subjects under the investigator's care through obtaining informed consent and ensuring initial and ongoing IRB review and approval of the study.
 - 1.3. Providing or ensuring adequate medical care for subjects during and following their participation on the trial.
 - 1.4. Controlling, maintaining, and accounting for drugs, biologics, or devices under investigation.
 - 1.5. Maintaining adequate and accurate study records, and reporting study data, including safety data to the sponsor and/or regulatory agency in a timely manner.
- Investigator Delegation of Tasks:** When study tasks or duties are delegated by the principal investigator, the investigator is responsible for providing adequate training and supervision to all delegates (see UUSOP#: 05 Delegation of Authority)
- Investigator Supervision and Oversight:** The PI should develop a plan for the supervision and oversight of the clinical trial. This plan should include training of study personnel, and ensuring compliance to the study protocol, SOPs, and study-specific processes.
 - 3.1. The investigator should ensure that all staff participating in the conduct of the study, including any new staff, have adequate training. To provide adequate training, investigators should ensure that study staff:

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- 3.1.1. Are familiar with the purpose of the study and the general objectives of the protocol.
- 3.1.2. Have an adequate understanding of the specific details of the protocol and attributes of the investigational product to perform their assigned tasks.
- 3.1.3. Are knowledgeable of the GCPs and applicable regulatory requirements.
- 3.1.4. Are competent to perform or have been trained to perform the tasks they are delegated.
- 3.1.5. Are informed of any pertinent changes during the conduct of the trial and receive additional training as appropriate.
- 3.2. The PI should hold routine meetings throughout the clinical trial with study personnel to review study status and progress. These meetings should include sub-investigators, study coordinators, and any other individuals actively supporting the conduct of the clinical trial, and should accomplish the following:
 - 3.2.1. Review of enrollment status, and progress and condition of current study participants.
 - 3.2.2. Review of the performance of delegated study tasks and duties. Tasks should be reassigned as needed for personnel turnover.
 - 3.2.3. Ensure the informed consent process is being conducted and documented appropriately, that IRB approval is maintained, and that conduct of the clinical trial is in compliance with the protocol.
 - 3.2.4. Ensure appropriate use, storage and accountability of investigational product(s).
 - 3.2.5. Verify that clinical trial source data are complete and accurate, that data captured in the case report form or study database are consistent with source data, and that data queries and discrepancies identified by the study monitor are handled and corrected appropriately.
 - 3.2.6. Review of external safety reports, and assessment for IRB reporting criteria.
 - 3.2.7. Assessment of deviations or adverse trends, and developing corrective and preventative action when appropriate.
 - 3.2.7.1.1. Tracking the trends of adverse events (AEs) and deviations *may require* the use of “master” logs, as opposed to participant-specific logs. PIs should take stock of available resources for collecting aggregate AE and deviation data, such as Electronic

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Data Capture (EDC) systems and/or resources provide by study sponsors. If no other resource is available, the use of master logs is recommended.

- 3.2.8. Address medical and ethical issues that may arise during the course of the clinical trial.
- 3.3. It is also important to document these investigator/study staff meetings, including the agenda, additional topics covered, and attendance. This documentation should be maintained with the study records and made available for review if requested.
- 3.4. If the study is an investigator-initiated trial being conducted at multiple clinical sites, the PI should contribute to effective communication with investigators and study staff at other participating sites to provide direction, training, support, or corrective action as appropriate.
4. **Investigator Training:** Clinical investigators should receive appropriate instruction and training prior to conducting or being involved in clinical research.
 - 4.1. Investigators may receive training in the conduct of clinical research through working with a more experienced investigator mentor, professional courses or seminars, completing sponsor-required training programs, attending University of Utah clinical investigator training courses, etc.
 - 4.2. Investigators should maintain documentation of training and attendance at clinical research training events.
 - 4.3. Clinical research investigator training should include the following topics:
 - Informed consent process
 - FDA regulations for clinical research
 - ICH guidelines for Good Clinical Practice
 - IRB submissions, communications, and approval requirements
 - CITI (Collaborative Institutional Training Initiative) program on human subjects research and GCP
 - Detection, evaluation, and reporting of adverse events
 - Accountability of investigational products
 - The role of auditing and monitoring in clinical trials

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Materials Required

- Delegation of Authority log
- Protocol Training Log or other documentation of protocol-specific training
- GCP Essential Documents

References

- 21 CFR Part 312 Subpart D: Responsibilities of Sponsors and Investigators
- ICH Guidance for Industry E6(R2): Good Clinical Practice
- FDA Guidance for Industry – Investigator Responsibilities (October 2009)

Document Approval



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DATE

Revision History

Version Date	Change Summary
09Aug2019	Original Version
26Jun2020	Version #2 – minor updates for clarity and ease of reading
11Mar2021	Version 3# - Language added regarding master AE and deviation logs

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