

PROTOCOL TRAINING FOR INVESTIGATORS AND STUDY STAFF

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

Prior to conducting clinical research, the Principal Investigator (PI), sub-investigators, and study staff are required to receive training in the protection of human subject research participants (i.e. CITI), protection of personal health information (i.e. HIPAA), and in Good Clinical Practice (GCP) guidelines, Conflict of Interest (COI), and when applicable Biosafety Training.

Additionally, the PI and all other study personnel must receive specific study/protocol training to ensure:

- Compliance with the investigational plan
- Protection of the rights, safety, and welfare of study participants, and
- Validity and integrity of study results

Protocol training is required for interventional clinical trials, including industry-sponsored trials, network trials, institutional trials, and investigator-initiated trials. The PI is responsible for all aspects of conduct for a clinical trial, but will generally delegate authority to perform certain functions or aspects of the study to sub-investigators, clinical research coordinators, study coordinators, data coordinators, or other study personnel. The PI and every other individual with a dedicated role on the study should receive adequate training *prior to* their involvement in the clinical trial.

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
GCP: Good Clinical Practice

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HIPAA:	Health Insurance Portability and Accountability Act
ICH:	International Council on Harmonization
IDS:	Investigational Drug Services
IRB:	Institutional Review Board
PI:	Principal Investigator
SIV:	Site Initiation Visit
SOP:	Standard Operating Procedure

Procedure

1. Initial Protocol Training

- 1.1. Prior to any study-related research procedures being initiated initial protocol-specific training is typically conducted by the sponsor, a sponsor representative, or a delegated trainer during a site initiation visit (SIV) or initial training meeting [this excludes self-training]. During this training meeting, the research team is provided with the information needed to conduct the investigation properly. This generally includes the purpose of the research and the protocol design; attributes and administration of the investigational product; skills needed to perform assigned tasks; regulatory requirements; and acceptable standards for the conduct of research and the protection of human participants.
- 1.2. For investigator-initiated trials, initial protocol-specific training should be conducted by the PI after IRB approval of the study and before any study-related research procedures are initiated. The attendance, topics covered, and goals of this initial training are the same as those above.
- 1.3. Study personnel unable to attend the SIV or initial training meeting, or who are added to the research team after study initiation, must complete and document training prior to performing any study-related research procedures.
 - Training must be conducted by the PI, sub-investigator, clinical research coordinator, or other appropriate study personnel who was in attendance at the SIV, or otherwise has been previously trained.
- 1.4. **Protocol training must be documented:** all study personnel who participated in the SIV or other protocol training session should sign the protocol training log (or other appropriate format) including names of the trainee and trainer, the date of training, and content including protocol version in order to adequately document the content and completion of training.
- 1.5. Investigational Drug Services (IDS): for clinical trials of an investigational drug

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utilizing the IDS pharmacy, the study lead pharmacist will attend the investigational drug/pharmacy portion of the SIV. The lead pharmacist will then conduct training for other pharmacists and technicians prior to their involvement in the study. IDS pharmacy personnel will maintain separate protocol training records.

- 1.6. Other specialized groups with study-specific roles and protocol-specified tasks (e.g. specimen collection & processing, non-standard imaging, etc.), may have individual(s) assigned to the study who attend the SIV or protocol training meeting. Alternatively, a representative from the group may receive initial training at the SIV, and in turn provide training for the other individuals in the group prior to their involvement in the study.
 - For in-patient clinical trials, or studies with in-patient periods or visits, the appropriate clinic Nurse Manager or Nurse Educator should attend the SIV to ensure the clinic nursing staff are trained on the study treatment plan and monitoring parameters.
- 1.7. Individuals performing routine job procedures and are not delegated by the PI with a specific or permanent role on the study will have training within their department and will not be required to have study specific training documented.

2. Ongoing and Continuing Protocol Training

- 2.1. The PI and study personnel should hold routine meetings throughout the clinical trial to conduct protocol refresher training as necessary, and to review study status, subject enrollment, adverse events, deviations, monitoring findings, assignment of responsibilities, etc.
 - Brief documentation of study team meetings should be recorded, including: date, attendance, agenda items, and follow-up assignments. Meeting notes should be maintained, and if requested, made available for review with study records.
- 2.2. If the protocol is amended, additional training may be required for the investigator and study personnel, depending on the scope and nature of the changes.
 - Notification of an amended protocol is sent to the PI and all sub-investigators, coordinators, and other study staff listed on the IRB application through the ERICA program.
 - For administrative changes made in a protocol amendment, such as

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typographical corrections or other minor errors and changes to non-operational sections, re-training is not required.

- For protocol amendments that affect operational aspects of the study, such as eligibility criteria, treatment parameters, changes to cohorts or study arms, safety or efficacy assessments, data collection and reporting, etc., protocol re-training should take place.
- Additional protocol training following an amendment may be conducted by the sponsor, or overseen by the PI. This training may take place in a formal meeting with all study personnel, or done by individual review of the protocol. As per 1.4 training should be documented.
- Electronic confirmation of individual review completion may serve as documentation of this training.

3. Maintenance of Training Records

- 3.1. All protocol-specific training records for the PI, sub-investigators, and other study personnel should be maintained with the study records. Training records are generally maintained in the Regulatory Binder with the other study essential documents.
- 3.2. Individual training records that are not protocol-specific (GCP, HIPAA, CITI, etc.), can be maintained separate from the study records in an electronic or paper individual training file. These training records should be made available for review by the study monitor or a regulatory inspector upon request.

Materials Required

- Protocol Training Log or other documentation of protocol-specific training
- Current version of study protocol
- Agenda and training materials from SIV or PI-led training of investigator-initiated clinical trial
- Delegation of Authority log

References

- 21 CFR Part 312 Subpart D: Responsibilities of Sponsors and Investigators
- ICH Guidance for Industry E6(R2): Good Clinical Practice 1.29, 6.10
- FDA Guidance for Industry – Investigator Responsibilities (October 2009)

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Document Approval



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DATE

Revision History

Version Date	Change Summary
09Aug2019	Original Version
26Jun2020	Version #2 – Electronic confirmation of review for documentation of training included in 2.2

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