

DELEGATION OF AUTHORITY

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 purpose of this SOP is to describe the method by which the Principal Investigator (PI) delegates the authority to conduct clinical study procedures and tasks to sub-investigators and other study personnel as well as maintain documentation of staff and investigator signatures and handwriting samples.

A PI conducting a clinical trial is required to follow regulations governing informed consent (21 CFR 50) and the regulations governing review and approval from an IRB (21 CFR 56). If the study involves an investigational drug or device, the investigator must also adhere to regulations in 21 CFR 312 or 21 CFR 812. In addition, all clinical study investigators should follow the ICH guidelines on Good Clinical Practice (GCP).

The responsibilities of the PI based on the regulations and guidance listed above may be delegated, with adequate oversight, to qualified sub-investigators and other study personnel.

Principal Investigator: The PI is responsible for compliance to the principles of Good Clinical Practice (GCP) and to applicable local and national regulations and guidance. The PI may delegate authority to conduct study tasks and duties to sub-investigators and other qualified personnel; however, the investigator retains the responsibility of overall study conduct. The PI must maintain a list of qualified staff members and investigators to whom study-specific responsibilities are delegated. Additionally, the PI should maintain a list of signatures and handwriting samples of delegated staff members and investigators. The delegation of authority list, signatures list, and handwriting samples are maintained on the same document for each study.

Sub-Investigators and other Study Personnel: Sub-investigators and other qualified study personnel are responsible to conduct study-related duties as authorized by the Principal Investigator in accordance with GCP and other applicable local and national regulations.

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

Procedure

1. **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.
 - 1.1. The PI should ensure that delegation of study-related tasks is appropriate to the education, training, and experience (including state licensure where applicable) to the individual.
 - 1.1.1. The investigator should maintain a list of appropriately qualified persons to whom trial-related duties have been assigned. This list may be maintained on a Delegation of Authority log, Research Delegation of Authority Profiles, or another mechanism.
 - 1.1.2. Tasks considered to be clinical or medical in nature must be delegated to sub-investigators or study staff with appropriate education, experience, and licensing or credentials to perform those tasks.
 - 1.1.3. The following tasks are commonly delegated to study sub-investigators:
 - Obtaining informed consent
 - Screening evaluations, assessment of eligibility criteria, and randomization of participants

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- Physical exams and vital signs
 - Evaluation of adverse events
 - Prescribing study treatment, or making medical determinations for treatment adjustments
 - Review and interpretation of lab results and other study assessments
 - Assessments of primary and secondary endpoints
 - Investigational product maintenance, dispensing, and accountability
- 1.1.4. The following tasks are commonly delegated to clinical research coordinators or other study staff:
- Obtaining informed consent
 - Screening evaluations, assessment of eligibility criteria, and randomization of participants
 - Obtaining medical history
 - Case report form completion
 - IRB submissions
 - Collection and maintenance of regulatory documents
- 1.2. The PI may use a Delegation of Authority log provided by the study sponsor or may use a comparable departmental or divisional form to document the delegation of duties.
- 1.2.1. The Delegation of Authority log should be completed at study initiation (e.g. site initiation visit) and should be kept up-to-date throughout the trial to account for new study personnel and turnover.
- 1.2.2. Individuals without a dedicated or permanent role or who are performing roles that are routine for their daily job (e.g. clinical staff including nurses, medical assistants, radiology staff, residents, pharmacy technicians, ECG techs, phlebotomists, etc.) do not need to be individually listed on the Delegation of Authority log. These individuals work on a rotating basis within their department, and their qualifications, training, and work performed is monitored by their department heads.
- 1.2.3. Individuals working outside the University of Utah Healthcare system (e.g. ARUP Laboratories) will also not be listed on the Delegation of Authority log, as their training and oversight will be ensured and monitored by their employer.

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- 1.3. The names of sub-investigators assisting the investigator in the conduct of the study should be listed on form FDA 1572 for clinical trials of investigational drugs.
 - 1.3.1. Generally, only physician and mid-level (Nurse Practitioners, Physician Assistants, etc.) sub-investigators who have a permanent and specific role in the clinical trial and are directly involved in the treatment or evaluation of research participants should be included on the FDA 1572.
- 1.4. The delegation of authority record is an official study “essential document,” and should be created and maintained with care. If the document is destroyed or misplaced during the course of a study, it should be recreated as completely and as expeditiously as possible.
 - 1.4.1. Corrections made to the delegation of authority record should follow standard “good clinical practice” procedures: single line-through incorrect entry, enter appropriate information, initial & date correction - do not use white-out or otherwise obliterate the original entry. Only delegated members of the study can make revisions to the log when needed.
- 1.5. The delegation of authority record may be created and maintained electronically in a system compliant with 21 CFR Part 11 requirements for electronic records and electronic signatures.
- 1.6. At completion of the clinical trial, the original delegation of authority log will be maintained with the other study essential documents.
 - 1.6.1. A copy of the delegation of authority log may be provided to the Sponsor upon request but the original will not be removed from the study site.

2. Principal Investigator Change

- 2.1. There are two options for updating the delegation log for a change in PI. Either option is acceptable, depending upon departmental guidance and the needs/preference of the PI and/or study team.
 - 2.1.1. Option A – The departing PI assigns an end date to their line on the delegation log. The new PI completes a new line and enters their start date, which should be the same date or next day following the end date of the departing PI. The new PI specifies, either in the comments section or a Note to File, that he/she has reviewed all delegated tasks and agrees with the delegations made by the departing PI.
 - 2.1.2. Option B – An end date is listed for all personnel on the delegation log. The departing PI signs off on all end dates effectively ‘closing’ the delegation log. The new PI creates a completely new delegation log.

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3. Roles or Key Study Tasks Changes

- 3.1. If the role of a staff member changes during the trial, an end date should be entered at the time the role is no longer being completed by the individual (e.g., Sub-I, becomes the new PI).
- 3.2. If there are any changes to study tasks for an individual, the current delegation line should be updated with an end date. A new line is then started with the updated delegated study tasks. End dates should be assigned, and the new study tasks entered on a new line.
- 3.3. The PI is required to initial and date changes to confirm and acknowledge any additional or deleted tasks.

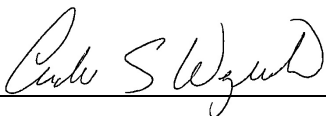
Materials Required

- Delegation of Authority log
- Protocol Training Log or other documentation of protocol-specific training
- GCP Essential Documents
- FDA Form 1572 if applicable

References

- 21 CFR Part 312 Subpart D: Responsibilities of Sponsors and Investigators
- 21 CFR Part 50: Protection of Human Subjects research
- 21CFR Part 56: Institutional Review Boards
- ICH Guidance for Industry E6(R2): Good Clinical Practice
- FDA Guidance for Industry – Investigator Responsibilities (October 2009)

Document Approval



3/12/2021

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DATE

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Revision History

Version Date	Change Summary
09Aug2019	Original Version
26Jun2020	Version #2 – minor updates for clarity and ease of reading
05Mar2021	Version #3 – guidance added for PI and key personnel role changes

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