

Section Clinical Research Center

Date Created: December 5, 2003 as POL-3

Title: Delegation of Authority

Date Last Reviewed/Modified: April 1, 2019

SOP Number: SOP- 20

Version Number: 4

PURPOSE: The purpose of this standard operating procedure (SOP) is to describe the responsibilities of the Principal Investigator (PI) and the procedures for identifying and delegating specific responsibilities to research team members for conducting clinical research.

SCOPE:

To ensure that the PI and all research team members assisting in the conduct of clinical research are informed about their obligations and responsibilities as they pertain to Good Clinical Practices (GCP), the investigational plan, applicable regulations, guidance, and institutional policies.

The PI is ultimately accountable for all clinical research activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks.

PERSONNEL RESPONSIBLE:

Principal investigators (PIs), sub-investigators (SUB-I), Research Study Coordinators, Clinical Research Associates, other research site staff.

DEFINITIONS:

- **Delegation of Authority Log (DOA):** The purpose of this form is to: a) serve as the Delegation of Authority Log and b) ensure that the individuals performing study-related tasks/procedures are appropriately trained and authorized by the investigator to perform the tasks/procedures.
- **Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

PROCEDURES:

A. Investigator Responsibilities

The PI will conduct and/or supervise the clinical research study to ensure that it is conducted according to the signed investigator statement, IRB approved protocol, institutional policies, GCP, FDA Guidance for Industry: Investigator Responsibilities and applicable regulations.

The PI is ultimately responsible for the conduct of the research study but may delegate tasks to qualified research personnel when appropriate. The PI and delegated research team members will:

- Be qualified by education, training, and experience to assume responsibility for the proper conduct of the study.
- Meet all the qualifications specified by the applicable regulatory and sponsor requirements, and will provide evidence of such qualifications through up-to-date curriculum vitae, job description, and/or other relevant documentation requested by the sponsor, the IRB, and/or the regulatory authorities.

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- Disclose financial interests or relationships with sponsors as required by federal regulations and institutional policies.
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant research study-related duties for each study on the Delegation of Authority Log.
- Ensure that individuals are approved by the IRB as key personnel and/or Sub-Investigators for the research tasks they will be performing prior to engaging in such tasks.
- Ensure that all persons assisting with the research study are adequately trained about the protocol, the investigational product(s), and their study-related duties and functions as documented on the study Training Log.
- Protect the rights, safety, and welfare of subjects under the investigator's care.
- Ensure protocol compliance (e.g., subject eligibility, consent, and randomization).

B. Procedure for Delegation of Research Responsibilities

The PI is the individual who assumes the authority and responsibility for the conduct of a clinical research study. However, the PI has the authority to delegate responsibilities to individual members of the research team if appropriate.

- The PI will select Sub-Investigators with appropriate education and training to ensure that the investigation is conducted according to the signed investigator statement, the investigational plan, GCP, institutional policies, and applicable regulations.
- The PI will determine the appropriate delegation of authority to specific research team members for each clinical research study conducted at this investigational site.
- Delegation of specific responsibilities will be documented appropriately and kept on file with the regulatory documents for each clinical research study on the Delegation of Authority Log.
- Inclusion on the DOA log is not typically required for individuals providing routine patient care at NM/UNMC who are not acting outside their normal scope of duties, are not conducting study-specific activities, and do not make a direct or significant contributions to the clinical study data.
- Clinical and laboratory departments that provide ancillary research services such as study drug infusion and/or specimen collection and processing may in certain instances be represented on the DOA log by obtaining the signature of managerial or supervisory staff member(s) who take accountability for training and performance within the department.

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- All members of the research team that are delegated specific responsibilities will have regular communication with the PI to ensure that he/she is informed in a timely manner of all study-related activities.

C. Information Required on Delegation of Authority Log

At a minimum, the Delegation of Authority Log should contain the individuals full name, signature, initials, duties assigned, date duties assigned, dates duties completed (if applicable) and signature of PI indicating that he/she has reviewed the duties delegated to an individual. The log must be updated with any staff changes that would result in a change or termination of duties as it pertains to that particular protocol.

RESOURCES:

21CRF 50 Protection of Human Subjects

21CRF54 Financial Disclosure by Clinical Investigators

45CRF46 Protection of Human Subjects

45CRF 160 HIPAA Privacy Rule

Nebraska Medicine:



- [HR16 - Identification Badge](#)
- [TX 04 – Chain of Command/Escalation of Concern](#)

Staff Accountability:

Developed By: Director of Clinical Research Operations, Clinical Research Center
Associate Vice Chancellor for Clinical Research, Clinical Research Center

Reviewed By: Director of Clinical Research Operations, Clinical Research Center

Department Approval

Signed  Director of Clinical Research Operations	Signed  Medical Director of Clinical Research Center
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