Center for Clinical and Translational Research Standard Operating Procedure

Section: **Clinical Research Center**

Date Created: **November 1st, 2010**

Title: **Delegation of Authority**

Version Date: **January 1, 2023**

SOP Number: **SM16**

PURPOSE:

U.S. FDA Guidance and Good Clinical Practice (GCP) require that the Principal Investigator (Pl) of each research protocol provide direct supervision over the conduct of the trial. Good Clinical Practice (GCP) requires the Pl to maintain a list of personnel to whom he/she has delegated significant trial-related duties. This SOP will also describe the requirements for creating and maintaining a CRC Master Delegation of Authority Log (mDOA) for studies utilizing specific CRC services.

SCOPE:

To fulfill the requirements stated in ICH GCP E6 Guideline Section 4.1.5 "the Investigator should maintain a list of appropriately qualified and trained persons to whom the Investigator has delegated significant study – related duties" and to document study-specific roles and responsibilities assigned to all staff on the study team by the Investigator.

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, and other research site staff. CRC Research Nurse Manager is responsible for supervising all CRC clinical staff who perform clinical services for research studies and ensuring that these individuals are qualified and trained to perform these duties. CRC Clinical Staff are University of Nebraska Medical Center employees who are Nebraska Medicine credentialed and trained to perform certain clinical duties which are delegated to them within their scope of practice.

DEFINITIONS:

- **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.
- **CRC Clinical Services:** Tests/procedures performed in the CRC that can also be performed in a Nebraska Medicine (NM) location utilizing NM staff. Examples include specimen collection, specimen processing, specimen shipping, ECGs, drug administration and monitoring, oral glucose tolerance testing, COVID-19 swabbing, pregnancy testing, and 6-minute walk tests.
- **CRC Master Delegation of Authority (mDOA):** A list of staff trained to perform clinical services on clinical trials. The mDOA is maintained by the Nurse Manager and is generated from the eReg application.
- **Delegation of Authority Log (DOA)**: A protocol specific form utilized by the Pl to indicate which personnel are authorized to perform delegated tasks on a specific study. The DOA includes

a list of delegated staff, including their role/delegated duties, and start/stop dates for each staff member. This form is generated from the eReg application and may be provided to sponsors and regulators to demonstrate proper delegation by the PI.

- **Principal Investigator (PI):** The person who is responsible for the management and integrity of the design, conduct, and reporting of the research project and for managing, monitoring, and ensuring the integrity of any collaborative relationships.

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. Delegation must be documented by the PI for all non-exempt human subject research. 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.
- 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

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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 sponsor required 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.
- When appropriate, a Research Pharmacist will be delegated for drug trials, representing the pharmacy team, ensuring training and documentation of such, as necessary.
- When appropriate, representatives from the Biological Productions Facility (BPF) and apheresis will be delegated for trials involving cellular therapies, representing their respective teams, ensuring training and documentation of such, as necessary.
- 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.
- 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. Staff may only perform delegated tasks for which they have been properly trained and are within their scope of practice. UNMC/NM will require an electronic delegation process using the Advarra eReg application for PI delegation of tasks and electronic signatures for studies being coordinated by the CRC. Sponsor provided delegation logs will not be allowed.
- Prior to being assigned to any research protocol, research staff who are trained to a protocol and have significant trial-related duties must review the duties delegated to their role. The staff member must then sign-off in the eReg application on their acknowledgement of the role/duties to which they have been delegated. If a staff member serves in different roles on different studies, or serves in multiple roles on the same study, they should sign-off on their acknowledgement of each of those roles/tasks. The research staff acknowledgement must occur prior working on the study.

- To delegate research staff to assist him/her in the conduct of a research study, the PI will assign personnel to the study utilizing a protocol-specific DOA. The delegated tasks on the electronic DOA will match as close as possible in meaning to the tasks listed on a sponsor template. The DOA will include the tasks delegated to each staff member.
- The PI must update the DOA in the following circumstances:
  - Change in PI
  - Change in protocol name
  - Removal or addition of staff
  - Change in legal name of the PI or research staff
  - Change in staff member role, including end date of delegation, if applicable
  - Change in significant trial-related duties
    - If a staff member changes entire roles during the trial, the Pl will notate the end date of delegation for the previous role on the DOA. A new line on the DOA will then be created for the staff member's new role(s) and associated delegated duties.
    - The PI will complete and sign the electronic DOA in the eReg application.
    - Research staff may not perform these tasks until the DOA is signed off by a PI.

Special considerations on implementation of this policy:

All studies activated after the implementation of the eReg application will utilize the method of delegation described in this policy. At the discretion of each principal investigator, studies activated prior to the implementation of the eReg application may continue to utilize their prior delegation process or may switch to the method described within this policy.

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.

D. Clinical Research Center Master Delegation of Authority Log

The CRC Research Nurse Manager is responsible for supervising all CRC clinical staff who perform clinical services for research studies and ensuring that these individuals are qualified and trained to perform these duties. CRC Clinical Staff are University of Nebraska Medical Center employees who are Nebraska Medicine credentialed and trained to perform certain clinical duties which are delegated to them within their scope of practice.

University of Nebraska Medical Center

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Documentation of Delegation of Authority from the PI to the CRC staff

1. CRC Nurse Manager creates and manages the CRC-mDOA in Advarra eReg.
2. A new mCRC-DOA will be created yearly.
3. The mCRC-DOA is updated anytime a new service is offered or a staff member needs to be added or removed.
4. Prior to study initiation, the PI/study team works with the CRC Nurse Manager or designated CRC clinical staff member to determine study logistics and roles that will be delegated to the CRC clinical staff.
5. The CRC Training and Certification chart will document the dates of the individual's general training as related to the tasks assigned on the mCRC-DOA.
6. The CRC staff will perform duties in line with those delegated to those who are on the mCRC-DOA.

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

RESOURCES:

eReg Lite Validation Plan
SOP-EREG-001 Forte eReg Lite System Administration
SOP-EREG-002 eReg Lite System Training
Guidance for Industry Investigator Responsibilities — Protecting the Rights, Safety, and Welfare of Study Subjects.
ICH GCP E6 Guideline Section 4.1.5
Trancelerate Biopharma – Information and Guidance Sheet for Site Signature and Delegation of Responsibilities Log

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Department Approval

Signed Serena Gaines
Research Nurse Manager

Signed: 2/21/2023

Signed
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Signed: 4/3/2023