UNIVERSITY OF Cincinnati **Category:** CoM- Office of Clinical Research (OCR) **Applicable for:** Clinical Research Professional Faculty and Staff	**COLLEGE OF MEDICINE** **Operating Procedure/Guideline** **Delegation of Authority for Clinical Research** **Effective Date: 06/01/2023** **Prior Effective Date: 06/01/2023**	**Document Owner:** CoM Office of Clinical Research Compliance Administrator **Responsible Office(s):** CoM Office of Clinical Research **Disseminated:** CoM Office of Clinical Research 06/01/2023

Background

This document details the process of delegation of study responsibilities and duties, otherwise known as Delegation of Authority, by any given study's Principal Investigator (PI). This is a system-wide standard operating procedure that applies to clinical research conducted in the facilities of University of Cincinnati (UC) and affiliated facilities (UC Health, LLC, University of Cincinnati Physicians Company {UCPC}, LLC) and all University of Cincinnati and UC Health Clinical Research Professional Staff that conduct clinical research in these facilities.

Guidelines

- This SOP establishes the method by which the Principal Investigator (PI) delegates study-related duties to applicable personnel. This includes the PI themselves, sub-investigators or co-investigators, study coordinators, and other study staff who perform study-related duties. This method also includes maintenance of the Delegation of Authority (DOA) log.

- Individuals who perform study related duties and tasks that are part of their normal job description/duties do not need to be delegated according to this SOP. This would include but is not limited to the following: non-investigational pharmacy personnel, pathological services personnel, floor nursing staff (including those who administer study medication), IRB or DSMB members, and/or technicians (EKG technicians, imaging technicians, phlebotomists, patient care assistants.

- Any study overseen by an IRB should have a DOA and a log. This excludes exempt research and non-human subject research, which the IRB does not oversee.

Definitions

- **Delegation of Authority (or Delegation of Duties)** is the entrusting of someone that reports to a leader or manager else to do parts of that leader or manager's job. In clinical research, this means investigators can delegate study-related tasks to their staff members to perform on their behalf, but they never relinquish responsibility for those tasks and their outcomes.

- **Clinical research, or "research":** A systematic investigation including experimental or investigatory development, testing and evaluation, that involves direct interaction with research participants and/or

their families, legally authorized individual(s), or caregiver in a clinical setting, and/or the analysis of individually identifiable specimens or data, designed to develop or contribute to generalizable knowledge, with the goal of improvements in the treatment and diagnosis of human disease, relieving symptoms of human disease, and human disease prevention.

- **Exempt Research:** Research that qualifies as no or minimal risk to subjects and is exempt from most of the requirements of the Federal Policy for the Protection of Human Subjects. But is still considered research requiring an IRB review for an exemption determination.

Process

- Prior to initiation and throughout the study, the PI is responsible for reviewing the study requirements, all clinical research activities, and is responsible for the appropriate delegation of tasks and assigned duties to individuals with adequate training and education to perform such tasks.

- All members of the study team covered under section 2.1 above should be listed on the DOA Log for the study. The study team may include but is not limited to the following members:

    - Principal Investigator (PI)
    - Sub-Investigator or Co-Investigator (Sub-I/Co-I)
    - Clinical Research Coordinator (CRC)
    - Clinical Research Assistant (CRA)
    - Clinical Research Manager (CRM)
    - Clinical Research Specialist (CRS)
    - Other Research Staff as appropriate
        - Including persons involved in writing the protocol or overseeing and/or managing aspects of the research.
    - Data Entry staff
    - Regulatory Staff
    - Study Management Staff

    - In delegating duties, the PI will ensure that those delegated will uphold their duties within the scope they are delegated.

- **Initiation of a DOA Log**

    - The PI or other designated Personnel will initiate the DOA Log. A DOA log may be a standard template, electronic or on paper.
        - DOA requirements between the sponsor and IRB are different. It is best to follow sponsor requests or instructions for the DOA log
        - The DOA Log is not an IRB required document.

- A DOA log should contain spaces for the following information, and be populated at initiation of the log:
    - Full name (complete first and last name).
    - Professional title.
    - Duty delegated /authorized functions description.
    - Start Date of assigned duties.
    - End Date of assigned duties.
    - PI signature/initials or acknowledgment (For virtual/electronic DOA logs) and date – indicating that the duties are properly delegated.
    - Signature or acknowledgment (For virtual/electronic DOA logs) of delegated study team member - indicating acknowledgement and acceptance of the delegated duty(s).
- Adding personnel to or removing personnel from an active DOA Log:
    - The DOA Log must be updated with any staff changes that would result in a study team member's change or termination of duties as it pertains to the protocol, with updates to the following information:
        - Start Date: The date that the new Personnel will officially assume responsibility for delegated duties.
        - End Date: The date on which Personnel are officially relieved of responsibilities.
        - Revised/Updated PI Acknowledgment and Date: Indication from the PI documenting their approval of the delegation.
- Though the study team members have been delegated, the PI remains responsible for all study conduct. Therefore, the study team should have regular communication with the PI in regard to all study related activities.

- This delegation of specific responsibilities will be documented appropriately and kept on file with the regulatory documents for each clinical research study.

- Any deviation from this procedure must be documented and kept with the study records for each clinical research study.

Organizational units may institute policies more, but not less, restrictive than these guidelines if desired.

Related Links

- SMG 1401.1 Staff manual Guides, Volume II – Delegation of Authority
- 21 CFR 312.53
- 21 CFR 312.60
- FDA Guidance for Industry: Protecting the Rights, Safety, and Welfare of Study Subjects- Supervisory Responsibilities of Investigators
- FDA Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors FDA Inspections of Clinical Investigators
- FDA Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance sections 4.1 and 4.2
- FDA Compliance Guidance Part III - Inspectional, see "RESPONSIBILITY AND ADMINISTRATION"