Table of Contents

1. Overview

Purpose

The purpose of this document is to describe the process for documenting the delegation of responsibilities for individuals involved in the coordination of human subject research in which key responsibilities are delegated by the Principal Investigator (PI). This process applies to the PI, faculty mentors, co-investigators, and research personnel. Appropriate delegation of responsibilities complies with Good Clinical Practice (GCP) Guidelines, documents PI oversight, and ensures that study personnel are informed of their designated project duties.

2. Definitions

Delegation of Authority/Responsibility (DOA): The process of assigning specific tasks or responsibilities by the Principal Investigator to all persons involved in the study's conduct. In research, this means the PI can delegate study-related tasks to their staff members to perform on their behalf, however, the PI retains responsibility for those tasks and their outcomes.

3. Procedures for Delegation of Authority/Responsibility

3.1 Prior to initiation and throughout the study, the PI will delegate study responsibilities to appropriately qualified and trained individuals. If the project is under the oversight of a student principal investigator, the student PI and the student's faculty mentor retain equal responsibility for oversight and delegation. Please ensure documentation includes review by both the student PI and faculty mentor.

The assigned tasks should reflect the protocol-specific tasks required to conduct the study and are generally duties that could impact participant safety, protocol compliance, and data quality/integrity. Examples of tasks to be assigned to personnel include, but are not limited to obtaining informed consent, collecting data, regulatory compliance, attribution of adverse events, dispensation of investigational product, and administration of behavioral assessments.

3.2 The assigned tasks are documented on a DOA Log. The DOA Log may be a standard template (e.g., Drexel, DUCOM eBinder, or Sponsor-provided template), on paper or electronic, if meeting 21 CFR Part 11 compliance for FDA-regulated research.

3.3 The DOA Log must include:

1) Study Title
2) PI
3) Site (where study is being conducted)
4) Full name of personnel
5) Role on study
6) Tasks(s) assigned
7) Start date of assigned duties
8) End date of assigned duties (the end date is left blank until the completion of the study or when the individual is no longer involved in the study)

9) Signature and initials of all staff with delegated study tasks, acknowledging assigned tasks
10) PI signature/initials or acknowledgment and date, documenting that the duties are delegated by the PI prior to the individual conducting delegated tasks

3.4 The DOA Log must be updated with any personnel changes or changes in assigned tasks, including adding new personnel and the start date of their assigned responsibilities, the end date of responsibilities for personnel no longer working on the project, or changing assigned tasks for existing personnel. Ensure added personnel have appropriate documentation of training on the study procedures.

Revised/updated PI acknowledgment and date must be documented for changes to the DOA Log.

3.5 The DOA Log is maintained as part of the Regulatory Binder/Files or Essential Regulatory Documents, per GCP.

3.6 Any deviation from this procedure must be documented and kept with the study records for the research project.

4. Responsibilities

4.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, and monitoring. For inquiries regarding this guidance, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

4.2 Principal Investigator Responsibilities

The Principal Investigator retains overall responsibility for the study and delegated tasks. The PI is responsible for delegating study tasks to individuals with adequate training and education to perform the tasks, reviewing and signing the DOA Log in accordance with GCP.

4.3 Faculty Mentor Responsibilities

If the project is under the oversight of a student PI, the student's faculty mentor retains equal responsibility for project oversight and delegation. The faculty mentor should ensure adequate documentation of review and oversight of delegated responsibilities.

4.4 Other Study Personnel Responsibilities

4.3.1 Study personnel delegated the responsibility for regulatory compliance is responsible for initiating, completing, maintaining and filing the DOA Log under the oversight and review of the PI.

4.3.2 All other study personnel are responsible for completing the DOA Log and understanding the assigned study tasks.

5. Resources

- ICH Guideline for Good Clinical Practice E6(R3)
- FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)
- 21 CFR 50 – Protection of Human Research Subjects
- 45 CFR 46 – Protection of Human Subjects
- HRP-070 Investigator Obligations
- ORI-616 Supplement Delegation of Authority Log Template

6. Revision and Workgroup Members

6.1 Revision

Version 001/Effective Date 1/24/2025 – Original Document: Delegation of Authority

6.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup and Advisory Members:

Workgroup & Advisory Members	
Taish Bruton Executive Administrator College of Medicine	**Janet Matthews, MSN RN** Senior Director, Research Program Development College of Medicine
Marisa Corbett, BA, CCRC Executive Director, Research Quality Assurance Office of Research & Innovation	**Carissa Miller** Research Compliance Coordinator Office of Research & Innovation
Honora Cutler, BSN, RN Clinical Research Operations Manager College of Medicine	**Cassandra Myers, BS** Associate Vice Provost, Research Compliance and Regulatory Affairs Office of Research & Innovation
Rose Ann DiMaria-Ghalili, PhD, RN, FASPEN, FAAN, FGSA Senior Associate Dean for Research Professor College of Nursing and Health Professions	**Jacqueline Stults, MBA, BS** Research Quality Assurance/Quality Improvement Office of Research & Innovation