Delegation of Authority		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-525.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure provides guidance on the completion of the Delegation of Authority (DOA) log, including identification of key study personnel, review and documentation of the qualifications of key research personnel, and the establishment of a clear delegation of authority for clinical research studies conducted at VCU/VCU Health institutions, affiliates, and participating sites.

2. REQUIREMENTS

The Principal Investigator (PI) of a research project has the authority to delegate responsibility for specific study tasks to individual members of the research team. The PI may delegate defined study activities and procedures to individuals who are qualified by training and experience to carry out the functions assigned to them. While the PI may delegate study activities, the PI is ultimately responsible for the overall conduct of the study. The delegation of authority must be documented and maintained through the lifecycle of the research study. No members of the research team may perform clinical and/or protocol procedures outside their clinical qualifications or licensures, and any delegated activities must be within the employee's scope of practice. In situations where the activities are performed as part of clinical practice, delegation documentation may not be required (e.g., MRI technician, phlebotomist).

Documented delegation of authority must be completed with the key delegated tasks assigned to the appropriate personnel for all research studies conducted at VCU or VCU Health.

3. DEFINITIONS

Delegation of Authority- DOA documents the investigator's entrustment of research project-specific responsibilities to individual members of a research team according to their qualifications, training, and/or licensure. Each member of the research team will sign and/or initial, and date their understanding and assignment of delegated tasks. The PI acknowledges the delegation of responsibility for each individual member of the research team by signing and/or initialing the DOA log or approved documentation.

4. PROCESS

A. All individuals, including the PI, responsible for conducting defined study activities and/or procedures, must be listed on the DOA log or approved documentation.
   - A list of appropriately qualified, trained, and/or licensed individual(s) to whom the PI has delegated defined study activities and/or procedures will be completed prior to the initiation of the study. This listing will include, but is not limited to, the names of the study-specific research personnel, the delegated tasks, their signature and/or initials as acknowledgement of the delegated tasks, and the PI signature and/or initials as acknowledgement of the delegation of tasks.

B. Research personnel should not be delegated research-related tasks until after study-specific and non-study-specific (e.g., CITI) training has occurred.

C. Research personnel who are delegated research-related tasks should not start performing study-related tasks until after the PI acknowledges the delegation of the tasks on the DOA log.

D. The PI or their designee will maintain a current DOA log or appropriate documentation. Delegation of research-related tasks should be updated as personnel change during the course of the study.

E. For sponsored studies not requiring a DOA log, and for PI/VCU sponsor-investigator studies, a VCU DOA form or other clearly defined process that achieves documented PI delegation of authority should be used.

F. The DOA log or other approved documentation will be maintained as part of the regulatory binder.

G. Ensure that access permissions granted to investigator site staff are in accordance with delegations by the investigator and visible to the investigator

5. REFERENCES

A. US Food and Drug Administration
   - Guidance for Industry – Investigational Responsibilities

B. Good Clinical Practice
   - ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)

C. VCU
   - VCU Delegation of Authority Log Template

Review/Revision History CR-CO-525

Version No.	Effective Date	Description
CR-CO-525.3	08/04/2025	• Replaced “projects” with “study”

		● Aligned with ICH E6(R3) ● Aligned with HRPP toolkit ● Biennial review performed ● Minor formatting edits ● Updated references ● Reference links updated
CR-CO-525.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
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