


Study-Specific Staff Education and Training		
 VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-ST-240.3a	Status: Final	Version Date: 02/11/2025 Effective Date: 03/14/2025

1. PURPOSE

This SOP establishes the standards and procedures to ensure research personnel are adequately trained on study-specific procedures and responsibilities and that training is appropriately documented.

2. REQUIREMENTS

Prior to the initiation of study-related activities, all research personnel should be adequately trained to perform study-related duties. Training should be considered a continuous process throughout the life of the study with training provided on an ongoing basis. Training should be specific to the responsibilities associated with the assigned study-related tasks. Documentation of study-specific training must be maintained in study-specific files.

This requirement applies to all research personnel for research activities that are conducted at or sponsored by a VCU/VCU Health facility, affiliate, or participating site.

3. DEFINITIONS

Research Personnel-Individuals who are involved in the design and/or conduct of a research project including, but not limited to, principal investigators (PIs), co-investigators, sub-investigators, research coordinators, and any other research team members who have contact with research participants and/or participants' research data and identifiers. Individuals whose primary contact with a research participant is in the context of clinical care and not conducting any research-specific assessments/procedures are not considered research personnel. Examples of non-research personnel include, but not limited to, phlebotomists, and CT/MRI/PET technicians.

Study-Specific Training- Study-specific training generally refers to education designed to enhance the knowledge and/or skill set of an individual that is specific to a particular clinical study that will be conducted at a VCU/VCU Health facility, affiliate, or participating site.

4. PROCESS

Prior to the initiation of study-related activities, the following procedures must be followed:

- A. The PI will ensure that all research staff have been adequately trained on protocol procedures and requirements. For non-investigator-initiated studies, the PI will ensure that the sponsor or their designee provides study-specific training to all research staff. For investigator-initiated studies, the PI acts as the sponsor and must provide study-specific training if needed. Training includes, but is not limited to:
- Initial training delivered at the site initiation visit
 - Consenting process
 - On-going training for modifications to study procedures
 - Training of new or replacement staff added after the site initiation visit
 - All protocols utilizing electronic data capture
 - Adverse event (AE) and serious adverse events (SAE) reporting.

Staff added to the study after study initiation should train on the most current IRB-approved study documents. They are not required to train on obsolete study documents. If modifications are made to any study documents, re-training of those documents is required for the research personnel who the changes affect. For example, the investigational pharmacy staff would be required to re-train on a revised pharmacy manual but a research personnel staff who works in pathology would not be required to train on the new pharmacy manual.

- B. For studies conducted within VCU Health, the PI will ensure that an in-service is conducted for all clinical staff where research-specific clinical services will be provided. Additionally, a Clinical Research Nursing Guide will be created and shared with the site nurses which outlines the study purpose, safety parameters, and nursing services needed beyond standard of care.
- C. All study-specific training should be thoroughly documented in the regulatory binder. All training documentation must be available for verification by the sponsor and institutional personnel and for inspection by external auditors.
- D. The method of documenting study-specific training may vary according to the study or mechanism provided by the sponsor. For industry-sponsored studies or multi-center studies coordinated through another institution, documentation should involve any requisite forms provided by the study sponsor or coordinating center.
- E. Documentation of training sessions must include:
- Date(s) of training
 - Title of training
 - Content/subject of training
 - Name of study
 - Roster of attendees

- F. For more formal training sessions such as investigator meetings, documentation should include certificates of completion, registration receipts, email confirmations, and/or session descriptions.

5. REFERENCES

A. Good Clinical Practice

- [ICH Harmonised Guideline Guideline For Good Clinical Practice E6\(R3\)](#)
 - Section 2 – Investigator
 - Section 3 – Sponsor

B. VCU

- [HRPP Policies and Guidance; HRPP Toolkit](#)
 - HRP-103; Investigator Manual
 - HRP-103p; pSite Investigator Manual
 - HRP-309; Ancillary Review Matrix
- VCU Compliance Notices
 - [14-002: Good Clinical Practice Training Requirement](#)

D. VCU Health

- Clinical Research Nursing Guide Template

Review/Revision History CR-ST-240		
Version No.	Effective Date	Description
CR-ST-240.3a	03/01/2025	● Updated to ICH E6(R3)
CR-ST-240.3	01/01/2024	● Biennial review performed ● Minor formatting edits ● Reference links updated ● Updated research personnel definition ● Clarified training for staff added after the SIV ● Added clinical research nursing guide
CR-ST-240.2a	06-01-2020	● Links updated
CR-ST-240.2	06-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-ST-240.1	08-10-2018	● Original