General Research Staff Training and Clinical Permissions		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-ST-230.4	Status: Final	Version Date: 11/22/2024 Effective Date: 01/01/2025

1. PURPOSE

The purpose of this SOP is to define the standards and appropriate documentation of research personnel qualifications necessary to conduct research at a VCU/VCU Health facility.

2. REQUIREMENTS

Sponsors and institutions conducting research are required to select only research personnel qualified by training and experience as appropriate experts to participate in a research project per FDA 21 CFR 312 or 21 CFR 812. To ensure compliance with this federal regulation, research personnel must maintain current documentation of research qualifications and training to be eligible to conduct human subjects research at a VCU/VCU Health facility, affiliate, or participating site.

Research personnel must comply with all training requirements per the IRB Policies, VCU Employee and Facility Use Guidelines for Clinical Research, and VCU Health Clinical Research Clinical Permissions.

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, co-investigators, sub-investigators, research coordinators, and any other research team member 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, but offer no additional role in research, are not considered key research personnel.

4. PROCESS

A. Research personnel must maintain a current file of qualification documents which may include, but not limited to, the following:
   - Up-to-date training in human subjects research (HSR). All research personnel conducting clinical trials must also maintain Good Clinical Practice (GCP) training.
   - Up-to-date curriculum vitae (CV), including education, training, and employment, signed and dated within the past two years. Licenses and certifications, as applicable.

- Hazardous Materials Shipping Certification (Dangerous Goods Shipping Training) per FDA 49 CFR 172 Subpart H: Each department must maintain a minimum of one (1) staff member as certified in hazardous materials shipping. It is recommended that departments maintain multiple staff members certified in hazardous materials shipping to ensure full coverage. The VCU Safety and Risk Management's Dangerous Goods Shipping Training course, available through the BioRAFT portal, fulfills the certification requirement.
- Study-specific supporting documentation including, but not limited to, financial disclosures, statement of experience, and delegation of authority log. For additional information regarding study-specific training, see SOP CR-ST-240.2 Study-Specific Staff Education and Training.
- **Oncology only**: Active National Cancer Institute/Cancer Therapy Evaluation Program (NCI/CTEP) Investigator number (applicable to oncology investigators who will obtain consent from participants for research-related therapy or who will write orders for research-related therapy). For additional information, consult the NCI Registration and Credential Repository Investigator Resources.

B. All research personnel performing study procedures in VCU Health space must have appropriate clinical permissions for all study-related tasks. Current clinical permissions for VCU Health for clinical research are located on the VCU Health clinical research intranet site: https://intranet.vcuhealth.org/sites/clinical-research/. All research personnel performing clinical skills in a VCU Health facility must first attend clinical orientation for VCU Health. For assistance with fulfilling the clinical orientation requirements, please contact your department administrator.

5. REFERENCES

A. Code of Federal Regulations
- 21 CFR 312 – Investigational New Drug Application
- 21 CFR 812- Investigational Device Exemptions
- 49 CFR 172 Subpart H

B. VCU
  - HRPP Policies and Guidance; HRPP Toolkit HRP-103; Investigator Manual
  - HRP-103p; pSite Investigator Manual

C. HRP-309; Ancillary Review Matrix
- VCU Employee and Facility Use Guidelines for Clinical Research
- Safety and Risk Management

D. VCU Health
- VCUHS Clinical Research Team-Clinical Permissions

Review/Revision History CR-ST-230

Version No.	Effective Date	Description
CR-ST-230.4	**01/01/2025**	● Biennial review performed ● Minor formatting edits ● Added additional information about FDA 49 CFR 172 Subpart H ● Added additional information about clinical permissions
CR-ST-230.3a	06-01-2020	● Updated links
CR-ST-230.3	06-01-2020	● Biennial review performed ● Minor formatting edits
CR-ST-230.2	08-10-2018	● Modification of scope with the creation of CR-ST-240.1 Study-Specific Staff Education and Training ● Addition of Clinical Permissions requirement and reference
CR-ST-230.1	09-21-2017	● Original