External Investigator Qualification

VCU/VCU HEALTH CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

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1. PURPOSE

The purpose of this SOP is to define the standards and processes for selecting qualified participating investigators at sites external to VCU/VCUHS.

2. REQUIREMENTS

Investigator selection will be based on the qualifications and training of the investigator, including prior experience overseeing aspects of a clinical research study. Considerations will include access to potential research participants for the clinical study, commitment to ensuring research participant safety, commitment to conduct the study according to the protocol, and any other VCU/VCU Health stipulations or applicable regulatory requirements.

3. DEFINITIONS

Principal Investigator

The Principal Investigator (PI) is the individual with overall responsibility for the scientific, technical, financial, and regulatory direction and success of a project. The PI ensures that a project is carried out in compliance with federal, state, and local regulations and policies. The PI may delegate some duties to key research personnel; however, the ultimate responsibility for the management of the project rests with the PI.

Sponsor-Investigator

The Sponsor-Investigator (SI) is an individual who both initiates and conducts an investigation and under whose immediate direction the investigational drug or device is administered or dispensed. If an investigator submits an Investigational Device Exemption (IDE) or Investigational New Drug (IND) Application to the US Food and Drug Administration (FDA) and is the PI, then the investigator is a SI and is responsible for the overall regulatory compliance (scientific, technical, financial, and regulatory) of the research study. In both situations, the SI is responsible for complying with the requirements of both the investigator and sponsor (plans, designs, conducts, monitors, manages data, prepares reports, oversees regulatory and ethical issues, and publishes manuscripts).

Sub-Investigator

An individual who is a member of the study team designated and supervised by the PI to perform critical study-related procedures and/or to make important study-related decisions.

4. PROCESS

A. Investigator Qualification

- The PI / SI or their designee is responsible for identifying, recruiting, and qualifying investigators.
- The initial contact with a potential investigator may be made to assess general interest and qualification.
- Before discussing the study details, a Confidential Disclosure Agreement (CDA) must be sent to the prospective investigator and returned to the PI / SI or their designee when signed.
- Once the signed CDA has been returned, an appointment for a prestudy site visit or detailed assessment of the potential investigator's interest and qualifications should be scheduled. The PI/SI will select investigators best suited to conduct the study based on the data gathered prior to and subsequently verified by a site visit.
- The qualification screening process and/or prestudy site visit will be assessing and verifying that the investigator meets the following criteria: has appropriate experience and meets eligibility requirements; has sufficient time to complete the study; can meet study participant accrual and patient population requirements; can complete participant information requirements for study documentation; has research staff with the necessary training, experience, and credentials; and has facilities that are suitable to conduct the study.
- The site qualification visit (or assessment) may be combined with the screening process or may be separate. The purpose of the final qualification is to gauge how well the investigator and their key research staff accept the following concepts: the investigational nature of the study and the investigational product; the roles and obligations as defined in the study contract and protocol; the applicable regulatory requirements; their responsibilities to the IRB; and the content, maintenance, and retention of source documents and records.
- If an investigator has participated in a study for VCU / VCU Health within the past year, a full qualification visit may not be necessary. In that case, a detailed and updated qualification assessment may be conducted.
- The results of the qualification screening process and/or prestudy site visit must be thoroughly documented and maintained in the regulatory file.
- If the investigative site meets the criteria to conduct the study, a copy of the protocol along with other study information should be sent to the investigator.

B. Investigator Agreement

- All affiliated investigators must sign an investigator agreement.
- The investigator agreement delineates all applicable requirements, including but not limited to proposed dates for conducting the study; budget reimbursement for direct and indirect costs; publication and presentation of study data; investigator's responsibilities (e.g., compliance with GCP and HIPAA); a statement that the investigator has read the protocol and will comply with its requirements; and any other agreements that VCU / VCU Health counsel believes necessary.

- Study-related activities should not proceed until the investigator has signed and returned the investigator agreement along with all applicable study-related documents (e.g., form FDA 1572, form FDA 3454 or 3455, Curriculum Vitae (CV) of the investigator, Protocol signature page, Investigator's Brochure acknowledgment, training certificates (e.g., Good Clinical Practice, Human Subjects Protection), site-specific regulatory documents, local IRB/ethics committee approval, Delegation of Authority Log, site initiation visit report, laboratory certifications and normal value ranges, medical licenses and credentials and any other required documents).
- A site initiation visit should be completed upon receipt of all fully executed study related documents.

C. Disqualified Investigators

- Only investigators who are in good standing with the FDA can participate in VCU / VCU Health research studies.
- Prior to the prestudy assessment and/or site visit, the FDA website should be checked to ascertain whether a potential investigator has received an FDA warning letter, been debarred, or otherwise sanctioned.
- If an investigator is being considered or selected and subsequently found to be disqualified, the investigation should be notified in writing that they are not eligible to participate in the study.
- Once selected and participating in a study, if an investigator repeatedly fails to comply with VCU/ VCU Health requirements, they will be terminated from participation in the study. All investigational products should be collected from the investigator immediately and their termination should be reported as soon as possible to all required parties (e.g., IRB, regulatory authorities) .

5. REFERENCES

A. Code of Federal Regulations

- 21 CFR 312.50: General Responsibilities of Sponsors and Investigators
- 21 CFR 312.53: Selecting Investigators and Monitors
- 21 CFR 312.70: Disqualification of a Clinical Investigator

B. Good Clinical Practice

- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) March 2018
  - o Section 2: The Principles of ICH GCP o Section 5.1: Quality Assurance and Quality Control o Section 5.6: Investigator Selection o Section 5.7: Allocation of Responsibilities
  - o Section 5.8: Compensation to Subjects and Investigators

C. VCU HRPP policies and guidance; HRPP Toolkit

- HRP-001; SOP: Definitions
- HRP-103; Investigator Manual
- HRP-103p; pSite Investigator Manual

Review/Revision History – CR-AD-110		
Version No.	**Effective Date**	**Description**
CR-AD-110.4		• Updated sub-investigator definition • Updated title and purpose for clarity • References and links updated to align with the HRPP toolkit • Links updated • Triennial review performed
CR-AD-110.3	06-01-2023	• Triennial review performed • Minor grammatical corrections • Links updated
CR-AD-110.2a	03-01-2020	• Links updated
CR-AD-110.2	03-01-2020	• Biennial review performed. • Reference links updated.
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