Investigator Responsibilities		
VCU/VCU HEALTH CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
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1. PURPOSE

The purpose of this SOP is to define the standards for investigator responsibilities for clinical research conducted at VCU/VCU Health and affiliates.

2. REQUIREMENTS

VCU/VCU Health Principal Investigators and Sponsor-Investigators are responsible for all aspects in the conduct of regulated human research and must ensure that clinical studies are carried out in accordance with the protocol, good clinical practice (GCP) guidelines, and applicable federal, state, local, and institutional policies and regulations.

3. DEFINITIONS

Key Research Personnel

Key research personnel are individuals who are involved in the design and 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.

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 requirements of both

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

All VCU/VCU Health and associated VCU/VCU Health investigators are expected to adhere to expectations in their role as PI or SI. The following is a partial list of expectations; a detailed list can be found in Good Clinical Practice:

A. Investigator Responsibilities

- Ensure regular, timely, effective, and well-documented communication.
- Establish criteria for selecting qualified contractors and document that vendors have been selected according to those criteria.
- Provide training for all employees commensurate with requirements for performing their responsibilities.
- Ensure research is conducted in accordance with the written protocol.
- Select qualified investigators based on qualifications, research experience, and knowledge of subject matter.
- Recognize, mitigate, and report all financial conflicts of interest.
- Review the safety/effectiveness evidence of investigational products from all sources.
- Ensure adequate site preparation to conduct a clinical investigation through site initiation and training activities.
- Safeguard the ethical validity of the clinical study by using only approved recruitment materials.
- Safeguard the scientific validity of the clinical study by ensuring strict adherence to subject enrollment criteria.
- Ensure that each subject signs an approved informed consent form and is informed of new data or changes to the study design that could impact personal risk as a study participant.
- Protect the rights and welfare of subjects through initial and ongoing review by an IRB.
- Safeguard the scientific and ethical validity of the clinical study by ensuring strict adherence to biological specimen collection and handling requirements.
- Ensure that adverse events are recorded and, if serious, are promptly investigated and reported per regulatory requirements.
- Ensure that all protocol deviations from the study plan are reported to the sponsor/sponsor-investigator/principal investigator for required regulatory reporting.
- Monitor the occurrence of protocol deviations/violations. Terminate any investigations that present an unreasonable or significant risk to subjects, compromised data integrity, or for noncompliance with the investigational plan.
- Ensure that secure access to subject data to maintain subjects' privacy and confidentiality is maintained.

- Maintain safeguards to protect data and observations managed by electronic systems.
- Maintain all required documents and records securely for the proper period of time.
- Cooperate with the FDA and other regulatory authorities in the assessment of the research program's compliance with applicable regulations.

B. Additional Investigator responsibilities when also acting as the sponsor (Sponsor-investigator)
- Develop, approve, and modify critical documents in a controlled manner.
- Submit complete, correct submissions and applications with regulatory entities in order to commence clinical trials.
- Facilitate effective oral and written communications and meetings with regulatory officials as appropriate.
- Ensure that clinical investigations are based on a scientifically sound protocol.
- Keep investigators, IRBs, and the FDA informed of existing or new information, adverse events, or risks relating to the investigational product.
- Ensure that investigational products are properly manufactured and labeled and are released only to qualified investigators, with full accountability.
- Monitor the progress of an investigation by periodic reviews of subject records and data to ensure that the research is being conducted according to the investigational plan.
- Maintain a system for recording and managing study data and observations.
- Conduct independent review audits of clinical study conduct and data to ensure investigator compliance and quality data.

C. Delegation of Responsibility
- Establish processes for delegating responsibility to employees.
- Identify the designated individual by name and/or by title, specifying what significant study-related functions have been assigned.
- Designate personnel and alternates to sign various documents, as approved.
- Maintain files documenting the qualifications of designees.

D. Transfer of Responsibility to Contractors
- The responsibility to conduct study-related activities may be delegated at the discretion of VCU/VCU Health to a commercial entity, such as a contract research organization or testing group, upon execution of a contract between VCU/VCU Health and the contract party. Those delegated individuals and entities also take on the responsibility for meeting regulatory requirements on behalf of VCU/VCU

  Health as stated in the agreement. However, the PI or SI retains the ultimate responsibility and must supervise those delegated activities effectively.
- Establish processes for delegating responsibility to external contractors.
- Identify activities that can be managed by designated contractors on behalf of the VCU/VCU Health PI or SI.
- Authorize and document transfer of responsibility through contracts and job descriptions, including detailed lists of delegated activities.

- Identify the designated vendor and individual(s) by name and/or by title, specifying what significant study-related functions have been assigned.
- Permit designated contractors to sign specified documents, as approved.
- Maintain files documenting the qualifications and oversight of designated vendors.

5. REFERENCES

A. Code of Federal Regulations

- 21 CFR 312 Subpart D: Responsibilities of Sponsors and Investigators
- 21 CFR 812 Subpart C: Responsibilities of Sponsors (for IDEs)

B. Good Clinical Practice

- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) March 2018
  - 2:Principles of ICH GCP
  - 4:Investigator
  - 5:Sponsor

C. IRB

- HRP-103-INVESTIGATOR MANUAL

Review/Revision History – CR-AD-105		
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CR-AD-105.4	08/15/2024	• Delineated investigator responsibilities and sponsor-investigator responsibilities • References updated • Links updated
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CR-AD-105.2a	03-01-2020	· Links updated
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