Pre-Study Site Qualification Visit		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
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1. **PURPOSE**

This SOP outlines the recommended steps to be followed when coordinating a Pre-Study Site Qualification Visit from sponsor representative(s) for clinical research projects conducted at VCU/VCU Health institutions, affiliates, and participating sites.

2. **REQUIREMENTS**

While no specific VCU requirements exist for the Site Qualification Visit, it is typical (but not mandatory) for an external sponsor of a clinical research study to visit the site where a clinical research project is to be conducted. This type of pre-study site visit occurs most typically with corporate sponsors of clinical research/trials. The purpose of this visit is to evaluate the site's capability to conduct the clinical research study/trial before commencement.

3. **DEFINITIONS**

Pre-Study Site Qualification Visit

Also known as a Pre-Study Selection Visit (PSSV), the visit is typically scheduled following the completion of a sponsor's feasibility questionnaire. The purpose of the visit is to verify the institutional and research team capabilities to effectively and efficiently conduct and sustain the research project. The visit may include tours of the facility, verification of equipment and personnel availability and qualifications, recruitment planning and feasibility review, and interviews with key study personnel.

4. **PROCESS**

- Before the visit:
  - Request from the sponsor, several potential meeting dates and times as well as a list of who the sponsor would like to meet with and locations to visit (clinics/offices).
  - Ensure a Confidentiality Disclosure Agreement (CDA) has been fully executed as provided by the sponsor, if applicable. This may be required by corporate sponsors, prior to providing a copy of the protocol.
  - Ensure that essential clinical research team members will be available, have copies of the protocol, investigator's brochure, and other available documents for review in

advance of the meeting, and have allocated sufficient time for the Pre-Study Site Qualification Visit.

- Be prepared to outline the study start-up process and timelines and provide contact information where appropriate for:
  - School or Center procedures including:
    - Feasibility review
    - Coverage Analysis
    - Study Calendar Development in OnCore
    - Budget Development and Negotiation
    - Regulatory/IRB Preparation and Submission
  - Program-wide (centralized) procedures including:
    - IRB Review and Approval
    - Contracting (for Industry Sponsors)
    - Conflict of Interest Review
    - Award and Activation
- Prepare supporting documentation, such as:
  - List of current/prior studies
  - Copies of current Curriculum Vitae (CV) for research team members, including medical licenses and other credentials (if applicable)
  - Estimated number of potential study participants (TriNetX is a valuable resource for preparing this information)
  - Proposed participant identification/recruitment strategies
- The PI or their designee should confirm that the appropriate arrangements are made in advance of the sponsor's visit including meeting with key study personnel and tours of restricted areas. Specific areas of interest that may necessitate advanced scheduling include, but are not limited to:
  - Visiting spaces where the study will be conducted (e.g., exam rooms, record storage, monitoring space, etc.)
  - Reviewing specialized equipment needs, if any
    - Ancillary personnel and/or departments

- During the visit:
  - Confirm receipt of the most current protocol and informed consent document.
  - The investigator and clinical research coordinator (CRC) should review all applicable clinical study documents (e.g., protocol, informed consent document, investigator brochure, case report forms, etc.) and note any areas where further clarification is needed. Particular attention should be focused on any aspects of the protocol that

differ from the standard clinical practice of the site (e.g., where the protocol may require assessment or tests that are not normally performed or performed in a differing sequence).

- Discuss the details of the investigational product and the study with the sponsor's representative (or designee). The clinical research team/personnel should ensure that any written notes made at the time are retained and then subsequently filed in the investigator's site file.
- Discuss the estimated recruitment rates and applicable recruitment strategies to be used during the study with the sponsor's representative. Discuss recruitment strategies/results of any other sites, if applicable. Consider recruitment activities which might need budgetary support by the sponsor.
- The investigator may need to provide the sponsor's representative with a signed and up-to-date copy of the investigator's and clinical research coordinator's (CRC) curriculum vitae (CVs) and possibly may need to provide CVs of other key research personnel who directly perform study procedures and directly contribute to the collection of study data.
- Provide the sponsor's representative with a telephone contact number and email address for the investigator or their designee, to facilitate efficient communication.
- Request from the sponsor:
    - Information on the anticipated timeline for the study
    - Information on key dates, such as:
        - Investigators' meeting and/or study initiation meeting
        - Study drug availability
        - Indemnification agreement
        - Draft contract for review
        - Sponsor/CRO chain of command and communication plan

- Following the visit:
    - The sponsor will provide a follow-up letter or report. Study personnel must respond to the sponsor with any questions or changes needed and file these documents in the regulatory binder.

    - For industry sponsors, once the protocol is finalized, be prepared to take immediate action to begin the administrative study start-up processes outlined above.

5. **REFERENCES**

Code of Federal Regulations

- 21 CFR 312.60 – General responsibilities of investigators
- 21 CFR 312.62 – Investigator recordkeeping and record retention

Review/Revision History - CR-ST-225		
Version No.	**Effective Date**	**Description**
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