Site Initiation Visit		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
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1. PURPOSE

This SOP describes the site initiation visit as typically conducted by external sponsors as the final step of the clinical research study start-up process at VCU.

2. REQUIREMENTS

Generally, the Site Initiation Visit (SIV) is conducted once an institutional review board approval letter is received, depending on sponsor requirements. It may occur before the contract is finalized. However, prior to enrolling the first subject, all regulatory and institutional requirements must be met and preparations for protocol procedures must be complete.

3. DEFINITIONS

Site Initiation Visit (SIV)

The SIV is a meeting to ensure each study personnel staff is adequately trained, understands the protocol, and is well versed with the study-specific procedures before enrollment is initiated.

4. PROCESS

A. Preparation for the Site Initiation Visit

- The Principal Investigator (PI) should ensure that study-related responsibilities designated to research personnel (study site staff) are clearly defined and appropriate to their skills and qualifications.

- The PI, or their designee, will communicate with the sponsor/CRO, the study site contact, the regulatory or study coordinator, the Investigational Pharmacy contact (Pharmacist), the clinical research administration team member, and others as needed to establish the SIV agenda. The SIV agenda should be distributed to all members of the study team prior to the SIV. Any required facilities tours will be coordinated by the PI or his/her designee.

- The PI, or their designee, will confirm the SIV date and times with research staff and distribute any materials needed for the meeting.

- The PI should attend the SIV and also ensure that all study site staff have been advised of the meeting and are able to attend. According to the E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) (Section 4, Investigator Responsibilities), the PI should ensure that all site staff assisting with the trial are adequately informed about the protocol, the investigational product (as applicable) and their specific trial-related duties and functions. The SIV is a good opportunity for every staff member of the site to learn the study procedures.
- When appropriate, the entire study team should discuss and work out the flow of each study procedure. This will ensure that the team can resolve any potential problems or questions before the procedures are put in place.

B. Conducting the Site Initiation Visit
   - Designated individuals will meet with the sponsor/CRO at the SIV.

   - The SIV may include, but is not limited to, a detailed introduction and discussion of the following topics:
     - Study rationale
     - Study design, eligibility criteria of trial subjects and schedule of assessments
     - Trial subject confidentiality
     - Informed consent
     - Investigational product (IP) management & administration
     - Laboratory samples handling procedures
     - Special requirements for imaging techniques
     - Safety reporting procedures
     - Procedures for completion of the case report forms (CRFs) and maintenance of source data
     - Any study-specific procedures
     - Good clinical practice (GCP) compliance and obligations of the investigator and their study team in conducting the study
     - Local regulatory or legal requirements that could impact the conduct of the study

   - If necessary, the SIV may include a facilities tour.

   - The PI ensures written documentation of their delegation of research related tasks to research team staff.

   - Study procedures will be reviewed with staff as necessary. Attendance and all protocol-specific training will be documented.

C. Site Initiation Visit Follow-Up

- The sponsor/CRO or designee who completed the SIV should provide detailed documentation of what was done during the visit as well as any outstanding issues. Documentation of the SIV will be archived in the investigator site file. Documentation may take the form of a SIV Report, sponsor follow-up letter or sign-in sheet and agenda/handout of SIV topic(s). All official documentation should be filed in the regulatory binder.

- Communication will be maintained with the sponsor/CRO to ensure that any outstanding issues discussed during the SIV are resolved.

- Following the SIV and resolution of any outstanding issues, the site will be ready for activation and patient enrollment. Once the sponsor's notification of site activation has been received, the designated research team member (a member of the research team designated by the PI for this purpose) will notify the appropriate personnel of the activation status.

- The research team shall follow the requirements of the school or center for final activation of the study where the status of the study in OnCore is changed to indicate that the study is open to enrollment.

5. REFERENCES

A. FDA

- Information Sheet - Investigator Responsibilities: Protecting the Rights, Safety, and Welfare of Study Subjects
- Guidance- Oversight of Clinical Investigations- A Risk-Based Approach to Monitoring

B. Good Clinical Practice

- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)
    - 4.1 - Investigator's Qualifications and Agreements
    - 4.2 - Adequate Resources
    - 4.4 - Communication with IRB/IEC

Review/Revision History CR-ST-235		
Version No.	**Effective Date**	**Description**
CR-ST-235.3		● Biennial review performed ● Minor formatting edits ● Clarified PI responsibility during SIV ● Links and references updated
CR-ST-235.2a	06-01-2020	● Links Updated
CR-ST-235.2	06-01-2020	● Biennial review performed ● Minor formatting edits
		● Reference links updated
CR-ST-235.1	09-27-2017	● Original