Participant Visits and Assessments		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-550.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure defines the processes relating to research participant visits and assessments at VCU/VCU Health institutions, affiliates, and participating sites. It provides an overview of the steps necessary to fulfill the regulatory and clinical requirements to ensure adherence to clinical research study procedures.

2. REQUIREMENTS

All clinical research study protocol-related assessments and procedures will be performed by the study team in a manner that ensures the collection of pertinent, reliable data and the well-being of the research participants. Visits will be scheduled and managed to ensure compliance with required protocol time points and as needed for the safety of the research participants. The results of procedures and encounters are to be documented in a timely and accurate manner per institutional and/or sponsor requirements. Research participants will be carefully monitored per protocol requirements for adverse effects, changes in health status, and compliance with the protocol.

3. DEFINITIONS

Prescreening- Prescreening is the process of evaluating whether a potential participant may be eligible or interested in a research study. This can include reviewing the participant's medical record for eligibility before any contact is made, as well as discussing the study with the participant either virtually (e.g., phone, video conferencing) or in person. This includes reviewing inclusion/exclusion and discussing the study with the participant prior to an informed consent being signed.

Screening- Screening is the study-specific process of evaluating whether a participant meets the eligibility requirements (exclusion and inclusion criteria) as outlined in the research protocol after an informed consent form has been signed.

4. PROCESS

A. Prescreening

- If approved by the IRB, review of patient charts for possible inclusion in the study (e.g., this may include a partial or full HIPAA waiver)

- If approved by the IRB, the patient may be contacted using the IRB-approved recruitment methods to discuss the study.
- Encompasses all procedures done prior to consenting.

B. Screening and Enrollment
- Reviewing the inclusion and exclusion criteria of the study to ensure participants meet enrollment criteria.
- Reviewing the informed consent form with the study participant.
- Allowing the study participant to fully discuss the study and ask any questions they may have about the study.
- Obtain informed consent, ensuring the study participant is given a copy.

C. Randomization (if applicable)
- Confirm that the research participant is eligible, per protocol, for randomization and that all screening procedures and labs have been reviewed prior to enrollment for criteria allowance.
- Notify the research participant of the randomization result (if the study is not blinded) and of subsequent appointment(s) and/or test(s).
- Begin study prescribed treatment according to the randomization outcome.
- Ensure the study participant understands all aspects of the study intervention according to the randomization outcome.

D. Preparing for and Conducting Study Visits
- Review the protocol calendar and appropriate orders.
- Schedule appointments and tests as required within the timeline of the protocol and according to VCU Health and departmental policies and procedures.
- Confirm the research appointment date/time with the study participant and provide information about what to expect at the next visit.
- At each visit, confirm that all required protocol assessments and tests have been completed prior to concluding the visit.
- Document study visits in OnCore (VCU's Clinical Research Management System) when required and as instructed by study protocol requirements.
- At the end of each visit, make sure the study participant has the study contact information and the emergency 24-hour contact number for any issues that arise between visits.

E. Follow-up, Completion, and Early Termination from the Study
- Schedule follow-up visits and/or tests as required within protocol windows.
- Confirm the research appointment with the study participant.
- Upon completion of study participation (including early termination), finalize the protocol and institution-required documentation.

5. REFERENCES

A. US Code of Federal Regulations
- 21 CFR Part 50 – Protection of Human Subjects
  - 50.20 – General requirements for informed consent
- 21 CFR Part 56 – Institutional Review Boards
  - 56.109 – IRB review of research

B. Good Clinical Practice
- ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)
  - Section 2 - Investigator
    - Section 2.5 – Compliance with Protocol
    - Section 2.8 – Informed Consent of Trial Subjects
    - Section 2.10 – Investigational Product(s)
    - Section 2.11 – Randomization Procedures and Unblinding
    - Section 2.12 – Records
    - Section 2.13 – Reports

C. VCU/VCU Health Standard Operating Procedures
- CR-AD-120 – Clinical Research Management System

D. VCU HRPP Policies and Guidance; HRPP Toolkit
- HRP-103-Investigator Manual

Review/Revision History CR-CO-550

Version No.	Effective Date	Description
CR-CO-550.3	08/04/2025	• Revised definitions of pre-screen and screening to clarify regulatory distinctions prior to and after informed consent. • Expanded explanation of randomization, including participant notification and blinding • Improved organization and flow of the process steps • Aligned with ICH E6(R3) • Aligned with HRPP toolkit • Updated references • Biennial review performed • Minor formatting edits • Reference links updated

CR-CO-550.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links added and updated
CR-CO-550.1	06-01-2018	● Original