


Screening and Recruiting Research Participants		
 VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-560.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

## 1. PURPOSE

This Standard Operating Procedure establishes the standards and procedures for screening and recruiting participants for clinical research studies at VCU/VCU Health institutions, affiliates, and participating sites.

## 2. REQUIREMENTS

It is the policy of VCU/VCU Health that all screening and recruitment plans involving human participants be thoroughly documented and receive prospective review and approval by the Institutional Review Board (IRB) of record for the research site/institution. The plan should be equitable, documented, and regularly reviewed for compliance, thoroughness, and effectiveness. It is important that there be no coercion of the participant to participate in any way.

## 3. DEFINITIONS

Recruitment- The process of identifying, contacting, and engaging individuals who may meet eligibility criteria to participate in a research study. Recruitment activities are intended to provide prospective study participants with their first introduction to the research study by providing study-related information. Recruitment is considered part of the informed consent process. This process may involve various strategies to inform and attract potential participants.

Recruitment methods - Information potential participants will see or hear that is used as part of the research recruitment process. Recruitment materials that could be used to support this process may include, but are not limited to:

- Direct one-on-one verbal or electronic communication
- Group verbal communication
- Printed materials or advertisements
- Electronic materials or advertisements
- Audio or video materials or advertisements

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**

In general, the following procedures should be followed when screening and/or recruiting participants for a research project:

- A. The Principal Investigator and research staff must be familiar with and comply with the IRB of record's policies and procedures related to screening and recruitment of study participants.
- B. Screening and recruitment of research participants cannot be initiated until the IRB has reviewed and approved the entire research study, which must include a prescreening, screening, and recruitment plan. Procedures that are to be performed as part of the practice of medicine and which would be done whether or not study entry was contemplated, such as for diagnosis or treatment of a disease or medical condition, may be performed and the results subsequently used for determining study eligibility (when allowed by the protocol) without first obtaining consent.
- C. Research participants may be prescreened and screened/recruited from a variety of sources including but not limited to:
  - Hospital records
  - Private office records
  - Health fairs
  - Businesses
  - Internet advertisements or databases
  - Referrals
  - Self-referrals
  - Approved AI databases (e.g., Deep6AI)
- D. Screening that requires access or review of participant's private health information (PHI) must comply with the requirements of HIPAA and VCU/VCU Health policies regarding confidentiality and records.

- E. Screening and recruitment activities should be documented to ensure that they adhere to the IRB-approved plan. Documentation should be maintained according to the study-specific documentation requirements.
- F. Screening logs (electronic and hard copy) must be de-identified prior to removal from VCU/VCU Health. Exceptions to this procedure must be approved by the IRB prior to the sharing of the information.
- G. Identifiable records of individuals who do not provide informed consent and who do not meet eligibility or refuse participation in a research project may be maintained in the pre-screening records as necessary for regulatory and compliance documentation purposes. However, all identifiable information must be removed before sending outside VCU/VCU Health.
- H. Identifiable records of individuals who do provide consent but do not meet eligibility (screen fail) or refuse participation in a research project may be maintained in the screening records.
- I. The initial information that a patient receives for the purpose of screening and recruitment should be from an individual who has authorized access to the patient's medical information.
- J. For research studies involving hospital inpatients, the physician of record for care of the patient during the hospitalization should approve the recruitment of the patient in the study.
- K. For the purposes of screening and/or recruitment, initial contact with potential participants identified from a privately held source (e.g., private physician's office) must be made by the proprietor of the privately held source (e.g., staff of the private physician's office). Only after the participant has provided permission for contact may the key research personnel contact the potential participant for screening and/or recruitment activities. Any reasonable exceptions to this must be reviewed and approved by the IRB prior to implementation.
- L. Informed consent must be obtained prior to the initiation of any clinical procedures that are performed solely for the purpose of determining eligibility for research (<http://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm>). However, with IRB approval, a potential participant may give verbal consent to answer some questions to determine general eligibility prior to an actual screening visit.

- M. Screening and recruitment activities should be continually monitored and assessed for compliance and effectiveness. The plan may be revised periodically if necessary. Revisions must be submitted and approved by the IRB.

## 5. REFERENCES

- A. US Food and Drug Administration
- [FDA Guidance: Screening Tests Prior to Study Enrollment](#)
- B. [VCU HRPP Policies and Guidance; HRPP Toolkit](#)
- HRP-103-Investigator Manual
  - HRP-503-Template SBS Protocol
  - HRP-503(a)-Template Protocol (BM)
  - HRP-508-Template Site Supplement
- C. [VCU Health Policies](#)
- Protected Health Information, Team Member Access
  - Research in Clinical Care Areas

Review/Revision History CR-CO-560		
Version No.	Effective Date	Description
CR-CO-560.3	08/04/2025	<ul style="list-style-type: none"> <li>• Revised definitions of recruitment, prescreening, and screening for clarity and alignment with regulations</li> <li>• Added definition of recruitment methods and clarified role in consent process</li> <li>• Expanded prescreening to include medical record review prior to contact</li> <li>• Added AI tools (e.g., Deep6AI) as approved recruitment sources</li> <li>• Clarified PHI access roles and data handling for screen failures and refusals</li> <li>• Updated guidance on initial contact and information sharing by authorized personnel</li> <li>• Aligned with ICH E6(R3)</li> <li>• Aligned with HRPP toolkit</li> <li>• Updated references</li> <li>• Biennial review performed</li> <li>• Minor formatting edits</li> <li>• Reference links updated</li> </ul>

CR-CO-560.2	06-01-2021	<ul style="list-style-type: none"> <li>• Biennial review performed</li> <li>• Minor formatting edits</li> <li>• Reference links updated</li> </ul>
CR-CO-560.1	06-01-2018	<ul style="list-style-type: none"> <li>• Original</li> </ul>