

# VCU/VCU Health Clinical Research SOP Operational Guidelines



## VCU/VCU HEALTH CLINICAL RESEARCH STANDARD OPERATING PROCEDURES

SOP No.: CR-AD-100.5

Status: Final

Version Date: 07/01/2024

Effective Date: 07/15/2024

### 1. PURPOSE

The purpose of this SOP is to 1) define the scope of the VCU/VCU Health Clinical Research Standard Operating Procedures (SOPs) and 2) establish the process for the production, review, approval, distribution and revision of a core set of SOPs. The SOPs are designed to provide guidance and support to principal investigators, research teams, and all related persons in the conduct of quality clinical research. In addition, the SOPs should be viewed as a framework for documenting specific procedures in support of a given protocol or research team. They aim to outline best practices and do not override or replace federal, state, or local regulations or policies. The hierarchy of authority to follow begins with federal regulations, followed by state and local regulations. Local policies, in descending order of hierarchy, include University/VCUHS policies, compliance notices, department policies, then VCU/VCU Health Clinical Research Standard Operating Procedures (SOPs).

### 2. REQUIREMENTS and SCOPE

All investigators, research teams, and all related persons must be familiar with and adhere to these SOPs. Study teams, schools, and/or centers may have additional published standards or working guidelines in addition to these SOPs.

The SOPs were developed in accordance with Good Clinical Practice (GCP), an international quality standard that is required for all VCU clinical trials. The SOPs also apply to all clinical research and clinical trials utilizing VCU Health services and/or facilities. The SOPs are considered best practices and may guide clinical research within VCU and VCU Health, as applicable.

The SOP development, review, and approval process is overseen by the Wright Center for Clinical and Translational Research in collaboration with the VCU Office of the Vice President for Research and Innovation, Massey Cancer Center, and the VCU Health Office of Clinical Research. The development and subsequent revisions of these SOPs should be guided by adherence to the Code of Federal Regulations, FDA, ICH-GCP, VCU Health and VCU Policies and Procedures, and other applicable good research practice guidelines.

### 3. DEFINITIONS

Definitions should be applicable across SOPs and also across the clinical research enterprise. In rare circumstances, a definition might be tailored to a specific area/topic. If this is the case, the definition should be marked as limited applicability (to that particular SOP only).

Clinical Research - Human subjects research that is:

- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with

human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. The definition includes:


- mechanisms of human disease
- therapeutic interventions
- clinical trials
- development of new technologies.
- Epidemiological and behavioral studies.
- Outcomes research and health services research.

Clinical Trial – A clinical trial is a type of clinical research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

#### 4. FORMAT

Each SOP must include the following:

- The SOP Header shall contain:

VCU/VCU Health Clinical Research SOP Operational Guidelines		
 VCU/VCU HEALTH CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-AD-100.4	Status: Final	Version Date: 03-01-2022 Effective Date: 03-01-2025

- Title
- Header
- SOP No.: Number of SOP formatted with CR (Clinical Research), XX (two-letter designation of section (see acronyms below), XXX (three-digit number) followed by a decimal point, and X (one-digit number indicating version number) followed by a lowercase letter designating an administrative update only (e.g. corrected links) as applicable.
  - Two-letter designation of section acronyms
    - Administrative= AD
    - Start up= ST
    - Regulatory= RE
    - Investigational products= IP
    - Conducting clinical studies= CO
    - End of study and closeout= EN
- Status:
  - Draft – Under initial review and open for comment.
  - Pending Approval – Under final review for internal approval(s).
  - Final – The SOP has been formally approved and the current final version is published.
- Version Date: This is the date the document version was approved for publication.
- Effective Date: This is the date the document version is added to the

website.

- Revision History: A grid placed at the end of the document for the purpose of documenting a record of substantive revisions, date, and brief description.
- The SOP Footer shall contain (font size 8):
  - VCU/VCU Health Clinical Research SOP:
  - SOP No. (see SOP Header description)
  - SOP Title
  - Page number formatted as page x of x

## 5. REVISIONS

- VCU/VCU Health members can propose new Standard Operating Procedures (SOPs) or suggested modifications by sending an email to [crsop@vcu.edu](mailto:crsop@vcu.edu). The VCU/VCUHS Clinical Research SOP committee will evaluate the proposed changes to determine whether a new SOP or modifications will be made.
- Upon finalization of the revised SOP, the Version Date will be updated and documented in the header of the SOP. Posting of the finalized SOP on the web will represent approval and publication of the VCU/VCU Health Clinical Research SOPs. Communications outlining the changes will be sent to VCU/VCUHS containing a description of significant alterations when applicable.
- For documents that are revised, earlier versions will be archived.
- All VCU/VCU Health Clinical Research SOPs in this series will be internally reviewed periodically at least triennially. If no changes are deemed necessary, no additional actions are required.
- The revision history documents significant changes, including the date and a brief description of each modification.

## 6. REFERENCES

- A. [NIH Definition of Clinical Research](#)
- B. [NIH Definition of Clinical Trial](#)
- C. [Clinical Research Standard Operating Procedures](#)

Review/Revision History – CR-AD-100		
Version No.	Effective Date	Description
CR-AD-100.5	07-15-2024	<ul style="list-style-type: none"><li>● Updated process for new SOP suggestions and revision of current SOPs</li><li>● Defined SOP acronym</li><li>● Clarified hierarchy of authority for regulations and guidance</li></ul>
CR-AD-100.4	03-01-2022	<ul style="list-style-type: none"><li>● Biennial review performed.</li><li>● Process updated to reflect collaboration roles for development of the SOPs</li></ul>
CR-AD-100.3b		<ul style="list-style-type: none"><li>● “Final” status replaces “active” status for alignment to use in SOPs</li><li>● Periodic review will be triennial in alignment with VCU</li></ul>

		<p>compliance notices and policies</p> <ul style="list-style-type: none"> <li>● Links updated</li> </ul>
CR-AD-100.3a	03-01-2020	<ul style="list-style-type: none"> <li>● Links updated</li> </ul>
CR-AD-100.3	03-01-2020	<ul style="list-style-type: none"> <li>● Biennial review performed.</li> <li>● Process updated to reflect the role of the VCU OVPRI Executive Director of Clinical Research and Compliance.</li> <li>● Reference links updated.</li> <li>● Clinical Trials definition revised with compliance notice reference added.</li> </ul>
CR-AD-100.2	08-10-2018	<ul style="list-style-type: none"> <li>● Added scope and added definitions of clinical research and clinical trials.</li> <li>● Changed “bi-annually” to “biennially.”</li> </ul>
CR-AD-100.1	08-12-2017	<ul style="list-style-type: none"> <li>● Original</li> </ul>