Clinical Trial Registration, Reporting, and Posting		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-ST-200.3	Status: Final	Version Date: 10/11/2024 Effective Date:10/18/2024

1. **PURPOSE**

   This SOP defines the processes and standards for posting clinical research trials to http://www.clinicaltrials.gov to ensure adherence to the Food and Drug Administration (FDA), National Institutes of Health (NIH), and International Committee of Medical Journal Editors (ICMJE) requirements for clinical trials registration, reporting and posting. It also defines the requirements for posting an informed consent in accordance with the Common Rule.

2. **REQUIREMENTS**

   Principal Investigators (PI) are responsible for ensuring that clinical research trials are registered and updated as required by Section 113 of the Food and Drug Modernization Act of 1997 and the 2007 FDA Amendments Act, the FDA final rule that clarifies and expands upon the 2007 FDA Amendments Act, and the complementary National Institutes of Health policy on the Dissemination of NIH-Funded Clinical Trial Information. It is also a condition of publication as set forth by the ICMJE. Failure to register clinical research trials on clinicaltrials.gov can result in civil monetary penalties and non-consideration of publications resulting from trial data.

3. **DEFINITIONS**

   Clinical Trial - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. See Common Rule definition of research at 45 CFR 46.102(l) and human subject at 45 CFR 46.102(e)

   Prospectively assigned - A pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

   Intervention- A manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

Health-related biomedical or behavioral outcome - The pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to the quality of life. (Source: NIH NOT-OD-15-015)

Protocol Registration and Results System (PRS)- The PRS is a web-based data entry system designed to register clinical studies and to submit results information for registered studies on ClinicalTrials.gov. Each study should only have one ClinicalTrials.gov record. Individual user accounts are housed under VCU's organizational account (VirginiaCU). New users must request an individual PRS account from VCU's PRS administrators by emailing cctrctgov@vcu.edu in order to register study information on ClinicalTrials.gov. The PI must either be a record owner or on the access list for the study record. Additional users can be added to the record at the PI's discretion.

4. **PROCESS**

A. The process of posting clinical trials on clinicaltrials.gov involves the initial registration of the trial, ongoing validation, status updates, and annual verification.

B. Certain FDA-regulated and/or NIH-funded trials also require the posting of study results, protocols, statistical analysis plans, and IRB approved informed consent documents.

C. The investigator must know and comply with the local regulations and policies related to trial registration and reporting.

- VCU Compliance Notice 17-033 Clinical Research Registration and Reporting Overview for registration and results reporting requirements.

D. The investigator must also know and comply with the local regulations and policies related to informed consent posting

- VCU Compliance Notice 19-002 Posting of Clinical Trial Informed Consent Forms per 45 CFR 46, subpart A, Protection of Human Subjects 2018 (i.e., 2018 Common Rule) requirement.

E. The Wright Center ClinicalTrials.gov Administrator and Massey Cancer Center's Clinical Trials Reporting Manager offer guidance and assistance for registering and reporting for non-cancer and cancer-related trials respectively on ClinicalTrials.gov and the National Cancer Institute's Clinical Trials Reporting Program.

5. **REFERENCES**

A. Code of Federal Regulations

- Federal Register: Clinical Trials Registration and Results Information Submission (Final Rule)
- 45 CFR 46.116(h) - Posting of clinical trial consent form
- 21 CFR 50.3 – Protection of Human Subjects

B. FDA

- Food and Drug Administration Modernization Act (FDAMA) 1997, Section 113
- Food and Drug Administration Amendments Act (FDAAA) 2007

C. National Institutes of Health

- NIH Implementation of FDAAA
- NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information

D. OHRP

- Informed Consent Posting

E. VCU

- Wright Center ClinicalTrials.gov Program Website
- VCU Research Compliance Notice 17-003 Clinical Research Registration and Reporting Overview
- VCU Compliance Notice 19-002 Posting of Clinical Trial Informed Consent Forms

F. IRB

- HRPP Policies and Guidance, HRPP Toolkit
  - HRP-103/HRP-103(p) - Investigator Manual
  - HRP-309 - Ancillary Review Matrix

G. International Committee of Medical Journal Editors Clinical Trial Registration Policy

Review/Revision History CR-ST-200		
Version No.	**Effective Date**	**Description**
CR-ST-200.3	10/18/2024	● Purpose updated ● Added reminder for failure to report ● Clarified the documents that CT.gov requires to be posted ● Added a compliance notice ● Updated references ● Links updated

CR-ST-200.2a	07-01-2020	● Links updated
CR-ST-200.2	07-01-2020	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-ST-200.1	08-27-2017	● Original