Clinical Research Management System		
VCU/VCU HEALTH CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-AD-120.4	Status: Final	Version Date: 07/30/2025 Effective Date: 08/04/2025

1. PURPOSE

The purpose of this SOP is to ensure that all research teams, including participating and affiliate sites (as applicable) understand the requirements for use of VCU's Clinical Research Management System (CRMS).

2. REQUIREMENTS

Clinical research teams are required to utilize OnCore, VCU's CRMS if the clinical protocol meets the requirements outlined within VCU Compliance Notice 16-001: OnCore - Clinical Research Management System. It is essential that all research teams review this compliance notice to best plan for delegation of responsibilities.

In summary, OnCore use applies to one or more below:

- All research meeting the definition of a clinical trial (see VCU Compliance Notice 16-001)
- Studies where VCUHS patients are consented
- Studies that involve a VCU faculty-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)
- Studies subject to approval by Massey Cancer Center's Protocol Review and Monitoring Committee (PRMC)
- Externally sponsored studies that are managed by the School of Medicine through OnCore's Financial Console for the purpose of invoicing and/or reconciliation of sponsor payment

3. DEFINITIONS

Clinical Research Management System- A CRMS is an electronic platform used by an institution to maintain and manage the planning, performance, and reporting functions, participant contact information, and deadlines / milestones of clinical research.

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

Note: Studies falling under 45 CFR part 46.104(b) (4) (Exemption 4) are not considered clinical research by this definition.

Clinical Trial- A clinical trial is a type of a clinical 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.

4. PROCESS

- All clinical research teams must review the complete requirements for OnCore use (see VCU Compliance Notice 16-001: OnCore - VCU's Clinical Research Management System) and study management within OnCore as well as participate in and adhere to standards set forth through OnCore training.
- It is the responsibility of the Principal Investigator or their designee to ensure that their protocol is entered and maintained within OnCore.
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- Refer to your department's SOP for the Oncore entry timeline. The following timelines are included as part of the VCU OnCore Management Requirements:
    - To ensure participant safety, **consent** and **enrollment** of a participant in a clinical study must be entered into OnCore by the close of business on the date of consent.
    - Visit completion must be entered/updated in OnCore no later than the end of the next business day following verification of visit completion by the research team.
        - Summary accrual data must be updated monthly for all other studies in OnCore.

5. REFERENCES

A. US Health and Human Services: 45 CFR part 46 Subpart A
- 104 (b) (4) Exemption 4 – Secondary Research

B. VCU HRPP policies and guidance; HRPP Toolkit:

- HRP-103 - Investigator manual
- HRP-309 - WORKSHEET - Ancillary review matrix

C. VCU Compliance Notice:
- 16-001: OnCore - Clinical Research Management System

D. VCU Resources:
- VCU OnCore Information Website

Review/Revision History – CR-AD-120		
Version No.	**Effective Date**	**Description**
CR-AD-120.4	08/04/2025	● Added additional references ● Triennial review performed ● Minor grammatical corrections ● Links updated
CR-AD-120.3	06-01-2023	● Triennial review performed ● Minor grammatical corrections ● Links updated
CR-AD-120.2a	03-01-2020	● Links updated
CR-AD-120.2	03-01-2020	● Biennial Review performed ● Reference links updated.
CR-AD-120.1	08-12-2017	● Original