Data Management		
	VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES	
SOP No.: CR-CO-520.3	Status: Final	Version Date:07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure establishes the standards and procedures for the management and storage of research-related information on departmental computers, shared drives, and websites for clinical research studies conducted at VCU/VCU Health facility, affiliate, or participating site. The procedures outlined in this policy are intended to ensure, to the best of our ability, the confidentiality of research records and compliance with all federal and state requirements and contractual obligations.

2. REQUIREMENTS

All research-related data should be managed responsibly and in compliance with all federal, state, and institutional policies and regulations. Access to research records will be controlled to prevent unauthorized use, removal, disclosure, or destruction of the records.

3. DEFINITIONS

Research Record- A research record is any data, document, computer file, compact disc, computer disk, or any other written or non-written information regarding proposed, conducted, or reported research. Documentation that comprises a research record includes but is not limited to: laboratory notes, correspondence, videos, photographs, X-ray film, slides, biological materials, computer files and printouts, manuscripts and publications, equipment use logs, laboratory procurement records, human protocols, consent forms, medical charts, and participant research files.

4. PROCESS

Management of research records should adhere to the following procedures:

A. Investigators and study teams must familiarize themselves with the data security standards set forth by VCU's Information Security Office and Integrity and Compliance Office:
   - VCU Policy - Information Security (Office of Technology Services)
   - VCU Policy – Research Data Ownership, Retention, Access, and Security
   - VCU Policy – Intellectual Property
   - Records Management

B. All electronic research records will be maintained within the VCU or VCU Health managed and protected information systems. Electronic access is available to all delegated study personnel through a request made to the [VCU Technology Services](#) or VCU Health Information Services Department (via Keystone on the VCU Health intranet).

C. All hard copy research records must be maintained in a secure area (i.e., behind a locked door, in a locked filing cabinet, etc.) within a VCU or VCU Health facility, affiliate, or participating site.

D. Electronic research records and participant data must never be saved to personal computers, personal electronic storage devices, or unencrypted VCU or VCU Health managed computers.

E. VCU Technology Services and VCU Health Information Services are responsible for security and disaster recovery for all electronic systems utilized by research to maintain electronic research records and participant data.

F. Should access to a sponsor website require modification to a VCU or VCU Health computer or system for the purposes of study-specific data collection, the request must be forwarded to VCU Technology Services and/or VCU Health Information Services for review and completion.

G. Investigators and study teams are responsible for reviewing any study-related executed agreements (confidential disclosure agreements, research contracts) and ensuring that all disclosures of study-specific participant data are authorized under the terms of the agreement and approved by the applicable IRB(s).

5. REFERENCES
  A. US Code of Federal Regulations
  - [21 CFR 11 – Electronic Records; Electronic Signatures](#)
  B. VCU Policies
  - [Information Security (Office of Technology Services)](#)
  - [Research Data Ownership, Retention, Access, and Security](#)
  - [VCU Policy – Intellectual Property](#)
  - [Records Management](#)
  C. [VCU Health Policies](#)
  - Network and Computer Security
  - Access to VCUHS Computing Systems and Electronic Medical Records: Personnel Security

Review/Revision History CR-CO-520		
Version No.	**Effective Date**	**Description**
CR-CO-520.3	08/04/2025	● Removed information about accessing PHI for the ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-520.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
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