Record Retention and Archiving		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-555.3	Status: Final	Version Date: 09/02/2025 Effective Date: 09/15/2025

1. PURPOSE

This Standard Operating Procedure provides guidance for the storage, retention and disposal of clinical research-related records. The procedures as outlined in this policy are intended to ensure compliance with all federal, state, local, and institutional requirements for clinical research records for clinical research conducted at VCU/VCU Health institutions, affiliates, and participating sites.

2. REQUIREMENTS

It is the policy of VCU/VCU Health to properly store, retain, and dispose of records in accordance with all applicable laws and other requirements. All VCU/VCU Health records related to research are the property of VCU/VCU Health regardless of their physical location, and may not be permanently removed from a VCU/VCU Health facility nor destroyed except in accordance with the VCU Policy Research Data Ownership, Retention, Access, and Security. Access to research records will be controlled to prevent unauthorized use, removal, disclosure, or destruction of the records. Records will be disposed of properly and in a timely manner once the retention period is complete.

This SOP applies to all records created, received, or maintained during the conduct of clinical research functions. All VCU/VCU Health personnel engaged in the conduct of clinical research are responsible for adhering to this policy.

3. DEFINITIONS

Research Data- Per VCU Policy Research Data Ownership, Retention, Access, and Security, research data means recorded information, regardless of form or the media in which it may be recorded, which constitute the original observations and methods of a study and the analyses of these original data that are necessary for reconstruction and evaluation of the report(s) of a study made by one or more investigators.

4. PROCESS

The procedures as outlined in this policy should be adhered to throughout the life of the research study.

A. Research-related records will be maintained for a period as set forth in the Code of

Federal Regulations (21 CFR 312.62, 21 CFR 812.140, and 45 CFR §164.530[j]), the FDA, Virginia Public Records Act (§42.1-76 through §42.1-91.1), sponsor requirements, and per VCU Policy Research Data Ownership, Retention, Access, and Security.

B. When records may be subject to more than one category and corresponding retention period, records must be maintained using the longest retention period.

C. Research records should be assessed, reviewed, and evaluated throughout the life of the study and at closeout, to determine the risks, benefits and costs of record retention or destruction. Records cannot be destroyed due to costs or storage limitations.

D. Paper documents and other hard copy records should be housed in durable containers that are clearly labeled with key information to identify them. Electronic records should be organized in accordance with institutional protocols for titling, classification and indexing, or according to institutional or federal guidelines. Research records are to be stored and indexed so that they can be identified and retrieved quickly and easily.

E. When research records have satisfied their legal, fiscal, administrative, and archival requirements, the record(s) should be properly disposed of unless there is an exception that requires the records to be kept for a longer period of time (e.g., contractual obligations to a sponsor.) Records shall not be destroyed before the prescribed retention period has expired, however, maintaining records past the required retention period poses an audit risk.

F. VCU requires that all individuals obtain permission for document destruction once the retention period has ended. This is applicable for both paper and electronic documents. This should be done through the completion of a Certificate of Records Destruction (RM-3 Form). This form is to be approved by your delegated office administrator for document archiving as well as the University Records officer prior to any record destruction. Convenience copies are not to be reported on the RM-3 Form and can be purged at any time if there are no holds, but should not outlive the official record. Records and convenience copies cannot be destroyed if there is an ongoing or pending audit, investigation, litigation, FERPA or FOIA request.

5. REFERENCES

A. US Code of Federal Regulations

- 21 CFR 312.62 – Investigator Recordkeeping and Record Retention
    - 21 CFR 812.140 – Records and Reports
- 45 CFR 164.530(j) – Public Welfare Subtitle A, Subchapter C, Part 164, Subpart E, Privacy of Individually Identifiable Health Information

B. Code of Virginia
- § 42.1-76 Virginia Public Records Act
- § 42.1-86.1 Timely Destruction of Records

C. Good Clinical Practice
- ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)
  - Section 2.12 – Records
  - Section 3.16 – Record Keeping and Retention
  - Appendix C – Essential Records

D. VCU Policies
- Research Data Ownership, Retention, Access, and Security
- Records Management (includes RM – 3 Form)

E. VCU HRPP Policies and Guidance; HRPP Toolkit
- HRP-103-Investigator Manual

Review/Revision History CR-CO-555

Version No.	Effective Date	Description
CR-CO-555.3	09/15/2025	● Highlighted risks associated with maintaining records past retention periods. ● Included language on proper organization, titling, and indexing of electronic records according to guidelines. ● Expanded definition section ● Clarified Roles and Responsibilities ● Aligned with ICH E6(R3) ● Aligned with HRPP toolkit ● Updated references ● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-555.2	06-01-2021	● Biennial review performed ● Minor formatting edits ● Reference links updated
CR-CO-555.1	06-01-2018	● Original