Record Retention and Archiving		
VCU/VCUHS CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
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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/VCUHS institutions, affiliates, and participating sites.

2. REQUIREMENTS

It is the policy of VCU/VCUHS to store, retain and properly dispose of records in accordance with all applicable laws and other requirements. All VCU/VCUHS records related to research are the property of VCU/VCUHS regardless of their physical location, and may not be permanently removed from a VCU/VCUHS 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 by key clinical research study personnel during the conduct of clinical research functions. All VCU/VCUHS 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, clinical 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.

The following are categories of research data/records:

- Research Administrative Records -administrative documents relating to each research study submitted to an Institutional Review Board (IRB) for consideration, whether or not the research study is ultimately accepted by IRB and approved by the IRB. This includes, but it not limited to, IRB correspondence, application for funding, contracts, and invoices.

- Records documenting research outcomes or products.

- Participant Research Records – documents relating to and data generated in the course of research for specific participants enrolled in a research study. This includes, but is not limited to, source data (e.g. completed questionnaires, test/lab results, and diaries), photographs, and databases of quantitative or qualitative data.

Research Record Repository

The research record repository is an aggregate accumulation of records from research projects. Records may be hard copy or electronic. A research record repository can consist of on-site storage, electronic storage platforms, and off-site storage.

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 56.115, 21 CFR 812.140, and 45 CFR §164.530[j]), the FDA, 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 project and at closeout, to determine the risks, benefits and costs of record retention or destruction.

D. 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.

E. 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.

F. VCU requires that all individuals obtain permission for document destruction once the retention period has ended. 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 document destruction.

5. REFERENCES

A. US Code of Federal Regulations

- 21 CFR Part 312 – Investigational New Drug Application
  - 312.62 – Investigator Recordkeeping and Record Retention
  - 312.68 – Inspection of Investigator's Records and Reports
- 21 CFR Part 812 – Investigational Device Exemptions
  - 812.140 – Records and Reports
- 45 CFR – Public Welfare
  - Subtitle A (Department of Health and Human Services, Subchapter C (Administrative Data Standards and Related Requirements)
    - Part 164 – Security and Privacy

B. Good Clinical Practice

- ICH E6: Harmonised Tripartite Guideline for Good Clinical Practice
  - Section 5.5 – Trial Management, Data Handling and Recordkeeping
  - Section 5.15 – Record Access
  - Section 8.3.11 – Relevant Communication Other Than Site visits

C. VCU Policies

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

D. VCU IRB Written Policies and Procedures (WPPs)

- #XII-1 – General Confidentiality Safeguards, Data Sharing, and Investigator Records Retention

Review/Revision History CR-CO-555		
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CR-CO-555.2	06-01-2021	• Biennial review performed • Minor formatting edits • Reference links updated
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