Essential Records Maintenance		
VCU/VCU Health CLINICAL RESEARCH STANDARD OPERATING PROCEDURES		
SOP No.: CR-CO-540.3	Status: Final	Version Date: 07/22/2025 Effective Date: 08/04/2025

1. PURPOSE

This Standard Operating Procedure establishes the standards and procedures for collecting, filing, organizing, and storing study-related, non-clinical records and essential documents for clinical research projects conducted at VCU/VCU Health facility, affiliate, or participating site.

2. REQUIREMENTS

Federal regulations (21 CFR 312 and 21 CFR 812) require investigators to maintain a complete and accurate record of all study-related administrative activities. Study-related nonclinical records and essential records are maintained in an investigator site file (ISF), such as a regulatory file or binder. Contents of an ISF are frequently audited by the sponsor of the study and regulatory authorities as part of the process of confirming the validity of the conduct of the study. The ISF should be maintained in audit ready state for inspection by authorized representatives of the institution, sponsor, Food and Drug Administration (FDA), or other international regulatory authorities. The ISF serves as the record of compliance with federal regulations.

3. DEFINITIONS

Essential Records- Essential records are the documents and data (and relevant metadata), in any format, associated with a clinical trial that facilitate the ongoing management of the trial and collectively allow the evaluation of the methods used, the factors affecting a trial and the actions taken during the trial conduct to determine the reliability of the trial results produced and the verification that the trial was conducted in accordance with GCP and applicable regulatory requirements.

Essential records to be retained include (as applicable):

- Investigator's Brochure (including updates) with signature page(s)
- Protocol and all amendments (with dated approvals and signature pages)
- Sample Case Report Form (CRF)
- IRB/IEC Approvals for protocol, amendments, informed consent forms, recruitment materials, advertisements, and other participant-facing documents
- IRB/IEC Membership/Composition Documentation
- Regulatory Authority Approvals or Notifications (if required)

- Signed Agreements between the investigator/institution and the sponsor
- Curriculum Vitae (CV) and licenses/qualifications of Principal Investigator (PI) and study team members
- Delegation of Authority (DOA) Log (updated as needed)
- Normal Values/Ranges for medical, laboratory, and technical procedures/tests
- Signature Sheet/Log (listing personnel authorized to sign documents)
- Informed Consent Form(s) and any written information provided to participants
- Signed Informed Consent Documents (from participants)
- Advertisements for Participant Recruitment
- Participant Screening Log
- Participant Enrollment Log
- Participant Identification Code List (linking study ID to participant identity, kept confidential)
- Sample Labels for investigational product containers
- Instructions for Handling Investigational Products and related materials
- Shipping Records and Certificates of Analysis for investigational products and trial-related materials
- Investigational Product Accountability Records (dispensing logs, return/destruction documentation)
- Documentation of Investigational Product Destruction (if applicable)
- Pre-Trial and Trial Monitoring Reports (e.g., Pre-Study Qualification, Site Initiation Visit)
- Monitoring Visit Reports (ongoing oversight)
- Relevant Communications (e.g., emails, meeting notes, protocol clarifications)
- Source Documents (e.g., participant medical records, lab results)
- Signed, Dated, and Completed Case Report Forms (CRFs)
- Documentation of CRF Corrections (audit trail for data changes)
- Serious Adverse Event (SAE) Reports to the Sponsor
- Unexpected Serious Adverse Drug Reaction (SADR) Reports to regulatory authorities and IRB/IEC
- Sponsor Notifications of new safety information to investigators
- Interim or Annual Safety Reports submitted to IRB/IEC and regulatory authorities
- Completed Participant Identification Code List (for follow-up, if needed)
- Record of Retained Body Fluids/Tissue Samples (if applicable)
- Audit Certificate (if applicable)
- Final Trial Close-Out Monitoring Report
- Treatment Allocation and Decoding Documentation (for blinded trials)
- Final Report by Investigator to IRB/IEC (if required)
- Clinical Study Report (summary and interpretation of trial results)

4. PROCESS

Maintenance of all study-related, non-clinical records and essential records should adhere to the following procedures:

A. A regulatory file or binder will be maintained for each managed research study or managed by regulatory teams in order to be quickly accessed per study.

B. Regulatory files and binders may be maintained in electronic or hardcopy format. The final format will be determined by sponsor/investigator requirements.

C. All electronic regulatory files are to be kept confidential and maintained on the VCU or VCU Health secured shared drive or secured electronic (eRegulatory) software platform, which is maintained by and adheres to the policies of VCU or VCU Health Information Technology. Binders maintained in electronic format must be maintained in a 21 CFR 11 compliant system for FDA-regulated studies; shared drives at VCU/VCU Health are not 21 CFR 11 compliant.

D. All hardcopy regulatory binders are to be kept confidential and stored in a secure location with controlled, limited access.

E. Prior to study initiation, a regulatory file or binder will be created and organized in a manner that is inspection-ready.

F. Regulatory binders will be filed in a timely manner and will be updated as new records are generated, received, or become available.

G. Contents of regulatory files or binders will be reviewed for completeness and accuracy prior to inspection by scheduled monitors and/or auditors.

H. All regulatory binders or files will be readily available for audit/inspection by auditors, study monitors, regulatory officials, and others who might require access to study-related documentation.

I. Upon final closure/termination of a study, electronic regulatory files will be archived following the appropriate SOP for the system being utilized.

J. Upon final closure/termination of a study, hardcopy regulatory binders will be maintained following the Record Retention and Archiving SOP.

K. Destruction of regulatory records will follow the Records Management institutional policy and the Research Data Ownership, Retention, Access, and Security policy.

5. REFERENCES

A. US Code of Federal Regulations

- 21 CFR Part 312 – Investigational New Drug Application
  - 312.50 – General Responsibilities of Sponsors
  - 312.60 – General Responsibilities of Investigators
  - 312.62 – Investigator Recordkeeping and Record Retention
  - 312.68 – Inspection of Investigator's Records and Reports

- 21 CFR Part 812 - Investigational Device Exemption
  - 812.140(a)(d) & (e) – Records

B. Good Clinical Practice
- ICH Harmonised Guideline Guideline For Good Clinical Practice E6(R3)

C. VCU Policy
- VCU Information Technology Policies and Standards
- Records Management
- Research Data Ownership, Retention, Access, and Security Policy
- Essential Records Guidance
- Veeva Compliance Notice

D. VCU HRPP Policies and Guidance; HRPP Toolkit
- HRP-103 Investigator Manual
- HRP-430 Checklist - Investigator Quality Improvement Assessment

Review/Revision History CR-CO-540

Version No.	Effective Date	Description
CR-CO-540.3		● Clarified essential record definition ● Revised/updated list of essential record ● Aligned with ICH E6(R3) ● Aligned with HRPP toolkit ● Biennial review performed ● Minor formatting edits ● Reference links updated ● Updated references
CR-CO-540.2a	06-01-2021	● Links updated
CR-CO-540.2	07-01-2020	● Biennial review performed ● Section 4.3 - added security requirement for electronic regulatory files (eRegulatory) ● Reference links updated

CR-CO-540.1	06-01-2018	● Original