VCU Office of the Vice President for Research and Innovation

Veeva eTMF: Records Retention Guideline

CONTENTS

1. PURPOSE

The purpose of this document is to describe the policy for the retention and disposition of GxP (nonclinical, clinical, manufacturing, laboratory, regulatory, and pharmacovigilance) controlled records at VCU.

2. SCOPE

This policy applies to GxP documentation supporting nonclinical, clinical, manufacturing, laboratory, pharmacovigilance operations, and regulatory submissions.

This policy works in collaboration with the following VCU policies and does not supersede either of these policies:

- Records Management Policy
- Research Data Ownership, Retention, Access, and Security Policy

3. DEFINITIONS

Archived Records - Protecting records from the ability to be further altered or deleted and storing these records under the control of dedicated data management personnel throughout the required records retention period.

Records Retention Period – The time period for which a record will be maintained in any format (e.g. paper or electronic).

Source Documents – Original records, and certified copies of original records, of clinical findings, observations, or other activities related to a clinical trial necessary for the reconstruction and evaluation of the trial.

GxP – Good "x" Practice. "x" stands for the various fields.

GxP Record - Information related to an activity subject to GxP regulations and required to be retained as historical evidence of the activity.

Essential Documents - Documents which individually and collectively permit evaluation of the conduct of a clinical trial and the quality of the data produced.

4. RESPONSIBILITIES

Role	Responsibilities
Project Manager (Archivist)	● Securely stores and maintains records that fall under the scope of this Records Retention Policy on behalf of VCU. ● Authorizes access to record retention areas (physical or digital) and maintains list of personnel with access to stored records. ● Contributes to the department-specific records retention log(s) and identifies records that are near the end of the retention period. ● Approves disposition of records.
Record Owner	● Provides finalized records to Project Manager in a timely manner for document retention.
Policy Owner	● Owns this policy and assures it meets global regulatory expectations, including defining what records to retain, where, how, and the retention period.

5. POLICY

5.1. Records Retention Timeframe

5.1.1. Archived records are to be maintained by the Project Manager (Archivist) for the retention period defined in Appendix A – Records Retention Schedule.

5.1.2. GxP records may be identified for retention for a period which may exceed the retention period defined in Appendix A – Records Retention Schedule and cannot be destroyed until no longer identified for retention. (e.g. Legal Hold).

5.2. Location of Records

5.2.1. Source Documents are to be maintained in the applicable document management system (electronic) or records retention site (physical records) per the department-specific records retention log(s).

5.3. Storage Conditions of Records

5.3.1. Original GxP records in print format and physical copies identified for retention are to be stored in a suitable fireproof storage container within a secure space to prevent theft, damage, or deterioration.

5.3.2. Completed records and documentation identified in Appendix A – Records Retention Schedule are to be stored in a secure location that allows for easy and timely retrieval. Access is limited to authorized personnel only.

5.3.3. Physical records may be periodically inventoried, boxed, and sent to a qualified, secure, offsite storage location, as appropriate. A log of such records should be maintained to facilitate retrieval as necessary.

5.3.4. At the discretion of the Project Manager (Archivist), records may be retained beyond their specified retention term.

5.4. Records Disposition

5.4.1. The Project Manager (Archivist) shall be responsible for authorizing, overseeing, and ensuring that records are destroyed pursuant to this policy.

6. REFERENCES

- Guideline on Good Pharmacovigilance Practices (GVP) Module 1 – Pharmacovigilance Systems and Their Quality Systems
- Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) - EMA Good Clinical Practice Inspectors Working Group
- ICH E6 Good Clinical Practice (GCP): Consolidated Guidance (R2)
- OECD Series on principles of Good Laboratory Practice, Number 1
- Guideline - TMF Closeout and Archival

APPENDIX A – RECORDS RETENTION SCHEDULE

Compliance Area	Category	Record Type	Retention Period
GLP	Nonclinical	Records for non-clinical studies that are part of a regulatory agency submission for an investigational drug (e.g., Investigational New Drug [IND], Investigational Medicinal Product [IMP])	At least 5 years following the date of the regulatory submission
GLP	Nonclinical	Records for non-clinical studies that are part of a regulatory agency submission for a marketed product (e.g., Biologics License Application [BLA], Marketing Authorization Applications [MAA], New Drug Submission [NDS])	At least 2 years following the approval date of the relevant regulatory agency submission for marketed product
GLP	Nonclinical	Records for non-clinical studies that are not part of a regulatory agency submission	At least 2 years after the date on which the study is completed, terminated, or discontinue
GCP	Essential Document	Records related to the conduct of a clinical trial. This retention period will allow for patient follow-up throughout the subsequent stages of drug development, assessment, and marketing as well as provide the ability to assess the impact on second generation. This includes the Trial Master File	Essential Documents will be retained for at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or 5 years post completion of clinical trials of the investigational product, whichever is longer. Unless otherwise requested by a regulatory agency, or as required per court order or pending legal action
PVG	Adverse Events	Pharmacovigilance records relating to products will be retained for the life of the product	25 years if a global organization. If not global, default to local jurisdictional requirement(s)
Regulatory	Investigational	Application or related amendment/variation or	2 years after the last approval of a marketing

Compliance Area	Category	Record Type	Retention Period
	New Drug/ Clinical Trial Application	documents included in an investigation submission to health authority including related correspondence	application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product
Regulatory	Application for Market Approval (NDA, BLA, MAA, NDS, etc.)	Application or related amendment/supplement/variation or documents included in submission to health authority in support of a market approval including related correspondence	25 years if a global organization. If not global, default to local jurisdictional requirement(s)
GxP	Audits	Audit Reports	Life of the trial +X years (X equals the applicable retention period for each Compliance Area/Category)
GxP	Computer System Validation	All records classified under this category	30 years after life of system
GxP	Training	All records classified under this category	25 years after employment ends
GxP	Organizational	Organizational charts	7 years after superseded or obsolete
GxP	Quality Systems	Standard Operating Procedures, Forms, Products Specification Files including Test Methods, Master Batch Records (MBR's), Specifications, Change Controls, Deviations, CAPAs	Permanent. Subject to periodic review

CONTACT

Please contact either of the following for questions regarding this document:

Lauren Wallace, MS
Director of Clinical Research Regulatory Affairs

kanigherl@vcu.edu

Jim Ward, MS, MBA
Assistant Vice President of Research Computing
jhward@vcu.edu

DOCUMENT HISTORY

Version	Effective Date	Brief Description of Change
1.0	01/05/2023	Initial Version