VCU Office of the Vice President for Research and Innovation

Veeva EDC: Record Retention

Table of Contents

1. Purpose

The purpose of this document is to describe the policy for the retention and disposition of GCP controlled records at VCU.

2. Scope

This policy applies to research data supporting clinical 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.

GCP: Good clinical practice

GCP record: Information related to an activity subject to GCP regulations and required to be retained as historical evidence of the activity.

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

4. Responsibilities

Role	Responsibilities
Study team	• 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 study team 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

- Archived records are to be maintained by study team for the retention period defined in Appendix A – Records Retention Schedule.
- 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

- 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

- 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.
- 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.

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

5.4. Records Disposition

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

6. Contact

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

Lauren Wallace, MS
Director of Clinical Research Regulatory Affairs
kanigherl@vcu.edu

Liz Kissell, MPH
Clinical Research Monitor/FDA Program Admin
kisselle@vcu.edu

7. References

- ICH Good clinical practice E6(R3)
- 21 CFR 312.57 and 21 CFR 312.62(b)
- 21 CFR 812.140

8. Document History

Version	Effective Date	Brief Description of Change
1.0	8/27/25	Initial Version

9. Appendix A – Records Retention Schedule

Compliance Area	Category	Record Type	Retention Period
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
Regulatory	Investigational New Drug/ Clinical Trial Application	Application or related amendment/variation or documents included in an investigation submission to health authority including related correspondence	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 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)