

Storage of Inactive Clinical Research Records Policy

Classification Information Management	Table of Contents 1 Purpose 1 2 Scope 1 3 Definitions 1 4 Policy Statement 1 5 Special Situations 2 6 Responsibilities..... 2 7 Related Policies 3 8 Related Procedures 3 9 References..... 3 10 History 3
Approval Authority Vice-President (Research)	
Implementation Authority Associate Dean (Clinical Research), Cumming School of Medicine	
Effective Date May 25, 2011	
Last Revision N/A	

1 Purpose

The purpose of this policy is to ensure:

- a) that Inactive Clinical Research Records are stored properly;
- b) compliance with grant terms and conditions;
- c) compliance with contract terms and conditions;
- d) compliance with relevant legislation; and
- e) sound stewardship of financial resources.

2 Scope

This policy applies to clinical researchers at the University of Calgary.

3 Definitions

In this policy:

- a) “CCCR” refers to the Calgary Centre for Clinical Research.
- b) “Inactive Clinical Research Records” refers to paper or hard copy records:
 - i. that were created or collected by the researcher to support clinical research; and
 - ii. that are no longer needed by the researcher to carry out the research; but
 - iii. which must be retained for a period of time in accordance with contractual or regulatory requirements.
- c) “University” means the University of Calgary.

4 Policy Statement

Storage Facility

4.1 Researchers will store Inactive Clinical Research Records in accordance with procedures established by the University Archives under the Information Management Program.

- 4.2** Storage of Inactive Clinical Research Records in a facility other than one designated by the University Archives is prohibited.

Storage Fees

- 4.3** Researchers will either:
- a) budget for the long-term storage costs of Inactive Clinical Research Records; or
 - b) invoice the sponsor for storage fees when the study is closed.
- 4.4** CCCR will establish procedures for the collection of revenue to pay for storage of Inactive Clinical Research Records and will manage the collection process.
- 4.5** CCCR will pay University Archives for storage costs accrued by researchers at year-end upon presentation of an invoice.

Retention Period

- 4.6** Researcher will provide University Archives with information relating to record retention requirements when the project or study is closed and records are transferred to inactive storage.
- 4.7** University Archives will facilitate destruction of the records when the retention period expires.

Violations

- 4.8** Violators of this policy may be subject to penalties under University policy, collective agreements, and under provincial and federal law.

- 5 Special Situations** A flat storage rate may be applied if CCCR is unable to collect storage fees before a project is closed or transferred.

- 6 Responsibilities**
- 6.1** Approval Authority
- a) ensure appropriate rigour and due diligence in the development or revision of this policy.
- 6.2** Calgary Centre for Clinical Research
- a) establish procedures for the collection of storage fees;
 - b) manage the collection process; and
 - c) reimburse University Archives for storage fees.
- 6.3** Implementation Authority
- a) ensure that University staff are aware of and understand the implications of this policy and related procedures;
 - b) monitor compliance with the policy and related procedures;
 - c) regularly review the policy and related procedures to ensure consistency in practice; and
 - d) sponsor the revision of this policy and related procedures when necessary.
- 6.4** Researcher
- a) ensure funds are allocated for storage of records.
- 6.5** University Archives

- a) facilitate the transfer of records to the storage facility;
- b) respond to requests for access to records;
- c) facilitate the destruction of records when the retention period expires; and
- d) invoice CCCR for storage costs.

7	Related Policies	Information Asset Management Policy
8	Related Procedures	Storage of Inactive Clinical Research Records Procedure
9	References	Health Canada
10	History	May 25, 2011 Approved and Effective. January 1, 2020 Editorial Revision. Updated format and links.