Research St. Joseph's – Hamilton (RSJ-H)		**Pages** 1 of 2	**Number** 018-RSJ-H
Policy Title Storage of Inactive Clinical Research Records		**Date** 03 March 2022	
Supersedes 09 May 2018	**Cross Reference**	**Issuing Authority** RSJ-H Scientific Director	
☑ Charlton Campus	☑ West 5th Campus	☑ King Campus	

Position responsible *for developing and maintaining the policy: RSJ-H Scientific Director*

1.0 PURPOSE

The purpose of this policy is to ensure that inactive clinical research records are stored properly in compliance with grant terms and conditions, contract terms and conditions, relevant legislation, ethical standards, federal regulations, and international guidelines.

2.0 SCOPE

This policy applies to all research and clinical research studies conducted at St. Joseph's Healthcare Hamilton.

3.0 DEFINITIONS

In this policy, "inactive clinical research records" refers to any hard or paper copy of documentation created or collected by a researcher and/or their staff for the purpose of supporting a clinical research study and are no longer needed to carry out the research but must be retained for a period of time in accordance with contractual, ethical, or regulatory requirements.

4.0 POLICY

Researchers will store inactive clinical research records in accordance with provisions established in ICH GCP Guidelines, Health Canada regulations, and Hamilton Integrated Research Ethics Board requirements.

4.1 Storage Facility

Researchers are permitted to store research records using a third party vendor that is qualified to securely store records for the duration of the retention period.

The Research Institute of St. Joe's Hamilton will not be responsible for providing dedicated on-site storage space for inactive clinical research records.

4.2 Storage Fees

Any fee associated with storing inactive clinical research records with a third party vendor are the sole responsibility of the researcher and should be provisioned for in the study budget. In the event that the budget does not account for this it is encouraged that researchers initially seek additional funding from the sponsor. If additional sponsor funding is unavailable, researchers are permitted to pay for storage fees with their discretionary account (if available), or seek funding from their department or affiliated Research Institute program lead. The Research Institute of St. Joe's Hamilton does not provide funding for storage fees.

4.3 Retention Period

Researchers are required to store research records in accordance with study-applicable regulations, guidelines, and approved ethics applications. For example, if the research study was conducted under a Health Canada Clinical Trial Application then those records must be maintained for a minimum of fifteen (15) years after submission of the final trial report. If the research study is not conducted under a Health Canada Clinical Trial Application then those records must be maintained for the period of time indicated in the application approved by the Hamilton Integrated Research Ethics Board.

5.0 REFERENCES

Health Canada: Guidance for Records Related to Clinical Trials (Guide-0068)

Health Canada: Food and Drug Regulations, Part C, Division 5

ICH GCP Guidelines (E6 R(2))