**Statement of Policy**

Files of studies which have been terminated or completed or declared inactive shall be kept in a separate storage for 3 years. Studies of Researchers who have not resubmitted their proposals within 3 months after receiving the Decision Letter (SOP 21 Form 008) shall be considered inactive.

**Objectives of the SOP**

Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.

**Scope/Applicability**

This SOP includes procedures related to storage and retrieval of protocols that are classified as inactive, terminated or completed. This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.

**Flowchart**

|  |  |  |
| --- | --- | --- |
| **ACTIVITY** | **RESPONSIBILITY** | **TIMELINE** |
| Step 1: Acceptance of Final or Early Termination Reports (SOP # 13 on Review of Final Reports, SOP # 14 Review of Early Termination Reports, and Identification of a Protocol as Inactive. | REC Members, Chair | 1 day |
| Step 2: Updating of corresponding protocol folder | REC Staff | 1-2 days |
| Step 3: Transfer of the protocol folder in the archives and Update of the Protocol Database | REC Staff | 1-2 days |

**Description of Procedures**

Step 1 - Acceptance of Final or Early Termination Reports and Identification of an Inactive File: *The Committee members approve or accept the final report or early termination report during a meeting (SOP# 13 Review of Final, Report; SOP # 14 Review of an Early Termination Report). In the identification of an Inactive File, the staff informs the Member Secretary of the failure of a concerned researcher/ proponent/ investigator to respond to the recommendations of the REC in the last 3 months during which time the researcher/proponent/investigator has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the protocol is declared inactive.*

Step 2 - Updating of the corresponding active file: *The staff files the Final or Early termination report in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.* When a protocol is inactivated, add a provision to append the year of inactivation as the last digits of the protocol code. This will help in archiving and tracking inactivated protocols. For example: If a protocol code is PROT-123, and the protocol was inactivated in 2025, the archived code would become PROT-123-25.

Step 3 - Transfer of the Protocol Folder in the Archives and Update of the Protocol Database: *The* staff checks whether the documents listed in the protocol file index are complete and removes extraneous documents. Thence, the staff transfers the folder to the archive section and updates the protocol database.

**Forms:**

SOP 24 Form 028 Borrower’s Log

**History of SOP**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Authors** | **Main Change** |
| 01 | 02/28/2017 |  |  |
| 02 | 06/21/2019 | krva | Coding of protocol |
| 03 | 09/26/2022 | krva | Revision of SOP |
| 04 | 02/20/2025 | krva | Revision of Step 2 |