

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB SOP 30/05-0-2022	SOP 30 Archiving of Terminated, Inactive or Completed Studies
Version No. 5	
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 30 Archiving of Terminated, Inactive or Completed Studies

1. Purpose

To describe procedures related to archiving of terminated, inactive or completed studies.

2. Scope

This SOP includes procedures on identifying documents to be archived, securing their storage and retrieval. The SOP starts from the time of 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.

3. Responsibility

It is the responsibility of the Staff Secretary, under the supervision of the Member Secretary and Chair to have an archive of all protocol files that have been terminated, completed or are no longer active to ensure accessibility, easy retrieval of information from the files for reference and compliance with national and international guidelines. They are securely kept together in a designated place in the IRB office where confidentiality and security of the documents can be maintained.

4. Process Flow/ Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Accept Final or Early Termination Reports and identification of a protocol as inactive	Chair members	Upon submission of documents
2	Update corresponding protocol folder	Staff Secretary	After identifying the documents
3	Transfer the protocol folder in the archives and update protocol database	Staff Secretary	After updating the protocol folder

5. Detailed Procedures

Step 1 The IRB members approve or accept the final report or early termination report during the meeting. For identifying the inactive file, the Staff Secretary informs the Member Secretary of the failure of the concerned researcher to respond to the recommendation of the IRB in the last 3 months during which time the researcher has been reminded of the requirement. This is indicated in the agenda of the next meeting where the protocol is declared inactive.

Step 2 The Staff secretary files the Final or Early Termination report in the corresponding protocol file, including the excerpts of the minutes that approved the report or declared the protocol as inactive. An archive number is assigned to the protocol by adding the year of archiving as a suffix to the original protocol code.

For example, if the Final Report of Protocol PELI IRB 2010-02 is approved in 2012, the archiving code is PELI IRB 2010-02/2012.

Step 3 The Staff Secretary checks whether the documents filed in the protocol file index are complete and removes extraneous documents, after which the Staff Secretary transfers the folder to the archive section and updates the protocol database. The archiving data as described in Step 2 should be entered accordingly in the protocol database. Archived protocols are retained for at least three (3) years after completion of the research and can be retrieved within the 3 -year archiving period in accordance with the SOP on Maintaining Confidentiality of Study Files and IRB documents. All archived files are destroyed after three(3) years leaving only a soft copy for the IRB.