

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB-SOP-29-06-2026	SOP 29 Archiving of Terminates, Inactive or Complete Studies
Version No. 6	
Approval Date: March 9, 2026	
Effective Date: March 9, 2026	
Supersedes: SOP 30 v.5 July 16, 2022	

SOP 29 Archiving of Terminated, Inactive or Completed Studies

I. Policy

Upon study closure, the IRB shall archive all essential documents in a manner that ensures long-term retrievability, confidentiality, and compliance with retention requirements.

II. Purpose

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

III. 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.

IV. 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of the Member-Secretary and Chair to have an archive of all protocol files that have been terminated, completed or are no longer active to ensure accessibility, easy retrieval of information from the files for reference and compliance with national and international guidelines .They are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.

V. 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 under the supervision of Vice Chair	Vice Chair/Staff Secretary	After updating the protocol folder

VI. 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.

VII. Form

1. Protocol Index

VIII. References

1. National Ethical Guidelines for Health and Health -related Research 2017
2. Philippine Health Research Ethics Board Workbook 2020
3. PELI-IRB SOP 2017

IX. Revision Index

Version	Date	Reasons For Revision
01	August 30, 2013	Patterned SOP after the SOP drafted by the DOH SOP Team (based on the FERCAP template)
02	April 1, 2014	Added Section 4.7 Conduct of Meeting
03	Jan 26, 2016	Changed logo of “Pacific Eye and Laser Institute” to “Peregrine Eye and Laser Institute” in the document header
04	June 15, 2017	<p>The following major revisions of both SOP and forms 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.11, 3.12 made in compliance with PHREB recommendations of official finding report last June 8, 2017:</p> <p>Clarify the following and state specific procedures on the following: Invitation of “guest” (SOP 4.7.2), ensure confidentiality Attendance by video or teleconference SOP 6.5 Decision via consensus or voting page 15 #1 abstention of member page 15 #1 confidentiality clause SOP 4.6.9 Follow the standard agenda and minutes format</p> <ul style="list-style-type: none"> ▪ Call to order ▪ Declaration of quorum ▪ Declaration of COI ▪ Approval of previous minutes ▪ Business arising from the previous minutes ▪ Review of new protocols ▪ Review of resubmitted protocols ▪ Progress Reports ▪ Amendment/s ▪ PD/PV and Noncompliance ▪ SAE/SUSARS ▪ Early Study Termination, close out reports, Final Reports ▪ Site visits ▪ Reports of expedited reviews ▪ Other matters <p>The above items should always be part of the agenda and minutes, whether a report on any of the items will be discussed in the meeting. If there are no reports for a specific item, then it should be indicated as NONE. Invite PI only to the IRB meeting for clarificatory purposes Use PELI IRB Protocol No., full title of protocol and name of PI to identify protocols in the meeting agenda Ensure the agenda is complete following the template suggested in the SOP Ensure that the IRB deals with the PI directly and not with the sponsor Indicate type of review in the agenda and minutes of the meeting (expedited or full board)</p>

		<p>Document in the SOP current practices of the Staff Secretary on filing of documents</p> <p>Prepare an SOP on the disposal of archives</p> <p>Ensure that the archiving color coding scheme of the Staff Secretary be formalized in the SOP</p> <p>Ensure adequate space for archiving for future protocols</p> <p>Improve the database to track timelines of critical points in the review process and that can generate data useful for the IRB</p>
5	July 16, 2022	<p>Reformat numbering to conform to 2020 PHREB SOP Workbook</p> <p>Refer to SOP 4.5 of version 4 of PELI -IRB</p> <p>Add references within the SOP</p> <p>Revise "Scope" to indicate specific coverage</p> <p>Revise "Process Flow/Steps"</p> <p>Make "Detailed Instructions" and "Process Flow/Steps" consistent</p> <p>Add "Forms" to include form used in this SOP</p>
6	March 9, 2026	<p>Revised and reclassified as SOP 28 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics</p> <p>Added a Policy section to define the governing principles and general guidelines of the SOP.</p> <p>Convert all timelines to calendar days</p> <p>Forms were re-numbered to correspond with the SOP in which they are used to ensure consistency, traceability, and proper document control. All form numbers mentioned in the SOP were updated accordingly to align with the revised numbering system</p> <p>Step 3 of SOP 28 was revised to include the Vice Chair (Supervisor) as a responsible person to ensure proper oversight in the transfer and archiving of protocol files</p>