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|  | Peregrine Eye and Laser Institute Institutional Review Board |
| PELI-IRB-SOP-28-06-2026 | SOP 28 Management of Active Study Files |
| Version No. 6 | |
| Approval Date: March 9, 2026 | |
| Effective Date: March 9, 2026 | |
| Supersedes: SOP 29 v.5 July 16, 2022 | |

SOP 28 Management of Active Study Files

I. Policy

Active study files shall be maintained in a secure, organized manner that permits retrieval of submissions, decisions, correspondence, and oversight documentation throughout the lifecycle of the study

II. Purpose

To describe the procedures related to the management of active study files.

III. Scope

This SOP provides instructions for the management of active files from protocols accepted for review, undergoing review and have been approved. This SOP starts with the classification and coding of active files and ends with the periodic updating of such files.

IV. Responsibility

It is the responsibility of the Staff Secretary under the supervision of the Chair and Member-Secretary to organize, orderly file and store all active files after classifying them to ensure easy identification and retrieval.

V. Process Flow/Step

| STEP | ACTIVITY | PERSON RESPONSIBLE | TIMELINE |
|------|---|-------------------------------------|--------------------------|
| 1 | Design a standard coding system for all protocols submitted to the IRB for review | Staff Secretary | |
| 2 | Classify and code the active files | Staff Secretary Member-Secretary | Upon receipt of document |
| 3 | Prepare the protocol folder | Staff Secretary | Upon receipt of document |
| 4 | Update the active study files regularly in the database | Staff Secretary | Weekly |
| 5 | Keep the active study files in the PELI-IRB office | Staff Secretary | |

VI. Detailed Instructions

Step 1 Protocol files of approved protocols are considered active from the moment the protocol files are received for review until such time they are inactivated either by completion or termination. For efficient file management, the Staff Secretary creates a standard coding system to use for these active files.

The Staff Secretary codes the active study files as follows:

PELI-IRB-yyyy-(year)-number (chronological number based on order of receipt)

For example, the first protocol received in 2022 is coded PELI-IRB 2022-01.

Step 2 The Staff Secretary under the supervision of the Vice-Chair classifies the active files as follows:

- a. Initial submission
- b. Resubmission
- c. Progress report
- d. Amendment
- e. Protocol deviation
- f. Protocol violation
- g. SAE
- h. SUSAR
- i. Early termination

- j. Continuing review
- k. Final report/ Close out report

After classifying the active files, the Staff Secretary then codes them using the coding system explained in Step 1. The Staff Secretary assigns a code to the initial submission and the same code to all submissions related to that initial submission.

Step 3 The Staff Secretary files all documents pertaining to a specific study to a vertical folder that is labelled on the front cover and along the spine with:

- a. Protocol Code - Study Title -Principal Investigator - Sponsor or Funding Agency.
- b. A Protocol Index is attached on the inside front cover and indicates the contents of the folder as follows:
- c. All versions of study protocol
- d. Protocol-related documents
- e. Principal investigator and co-investigator's CVs and other similar documents.
- f. Reviewer's assessment forms
- g. Amendment reports
- h. Continuing review applications
- i. Serious Adverse Event Reports or Safety Notifications
- j. Non-compliance (Deviation or Violation)
- k. Participating Queries
- l. Site Visit Reports
- m. Approval letters
- n. Notifications of IRB Decision
- o. Miscellaneous communication
- p. Final report

Step 4 The Staff Secretary creates a secure protocol database which can be paper-based (a logbook secured in a locked cabinet) or electronic (password-protected files in a device) to facilitate protocol monitoring. The database should have at least the following fields:

- a. Protocol Code
- b. Protocol Title

- c. Department
- d. Principal Investigator
- e. Submission date
- f. Full board or Expedited Review date
- g. Reviewers
- h. Review decision
- i. Board meeting date
- j. Approval date
- k. Date of progress report

The active files, records and documents should be properly maintained and updated weekly.

Step 5 The Staff Secretary keeps all active study files in a secure well-identified filing cabinet, which are accessed only by identified personnel who will be entrusted to keep the lock and key. Active files can be accessed outside of regular protocol review in accordance with the SOP on Maintenance of Confidentiality of Study Files and IRB Documents

VII. Form

- 1. Protocol Index
- 2. Folder Label

VIII. References

- 1. National Ethical Guidelines for Health and Health -related Research 2017
- 2. Philippine Health Research Ethics Board SOP 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 |

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| 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:</p> <ul style="list-style-type: none"> ○ 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 <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.</p> <p>Invite PI only to the IRB meeting for clarificatory purposes</p> <p>Use PELI IRB Protocol No., full title of protocol and name of PI to identify protocols in the meeting agenda</p> <p>Ensure the agenda is complete following the template suggested in the SOP</p> <p>Ensure that the IRB deals with the PI directly and not with the sponsor</p> <p>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> |
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| 5 | July 16, 2022 | <p>Reformat numbering to conform to 2020 PHREB SOP Workbook</p> <p>Refer to SOP 4.4 of version 4 of PELI-IRB</p> <p>Add references within the SOP</p> <p>Revise “Scope” to indicate specific coverage</p> <p>Revise “Responsibility” to be more concise</p> <p>Revise “Process Flow/Steps “</p> <p>Make “Detailed Instructions” and “Process Flow/Steps” consistent</p> <p>Add Forms within the SOP</p> |
| 6 | March 9, 2026 | <p>Revised and reclassified as SOP 27 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> |