PEREGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 29/05-0-2022	
Version No. 5	**SOP 29** **Management of Active Study Files**
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 29 Management of Active Study Files

1. **Purpose**

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

2. **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.

3. **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.

4. **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	Every week
5	Keep the active study files in the PELI-IRB office	Staff Secretary	

5. 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.

Purple-colored side labels indicate Principal Investigator- initiated studies while;
Blue-colored side labels indicate Sponsored-initiated studies

Step 2 The Staff Secretary under the supervision of the Member Secretary classifies the active files
as follows:
- Initial submission
- Resubmission
- Progress report
- Amendment
- Protocol deviation
- Protocol violation
- SAE
- SUSAR
- Early termination
- Continuing review
- 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:
- Protocol Code - Study Title -Proponent's Family Name - Sponsor or Funding Agency.

A Protocol Index is attached on the inside front cover and indicates the contents of the folder as follows:
- All versions of study protocol
- Protocol-related documents
- Principal investigator and co-investigator's CVs and other similar documents.
- Reviewer's assessment forms
- Amendment reports

- Continuing review applications
- Serious Adverse Event Reports or Safety Notifications
- Non-compliance (Deviation or Violation)
- Participating Queries
- Site Visit Reports
- Approval letters
- Notifications of IRB Decision
- Miscellaneous communication
- 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:

- Protocol Code
- Protocol Title
- Department
- Principal Investigator
- Submission date
- Full board or Expedited Review date
- Reviewers
- Review decision
- Board meeting date
- Approval date
- 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