PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 6A/08-0-2022	
Version No. 8	**SOP 6A** **Management of Protocol Submissions**
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 6A Management of Protocol Submissions

1. Purpose

To describe the IRB procedures in the management of protocol submissions for initial review.

2. Scope

This SOP begins with the receipt of study documents for initial review and ends with update of all protocol information in the database.

The PELI-IRB accepts the following protocols for review:

- PELI funded researches
- Researches done in PELI
- Ophthalmologic protocols done by non-affiliated organizations in areas outside the eye center premises.,
- Non-ophthalmologic studies provided that there is a competent primary reviewer or independent consultant (e.g. Dermatologist) of that specialization.
- Researches referred from the PNHRS, PHREB, DOH, industry organizations, etc. on the condition that the host hospital/institution where the protocol will be done accepts the review of PELI-IRB and agrees to abide by the rules and regulations that the PELI-IRB follows. The other research sites also agree to provide the necessary environment to ensure safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/institutions that accept the IRB review.

3. Responsibility

The IRB shall ensure that study documents submitted for review are complete, properly recorded, and properly evaluated to determine appropriate action or type of review. The IRB Staff Secretary assists in all protocol submissions to the IRB under direct supervision of the Member Secretary. IRB shall ensure that all protocols undergo technical

review and approval prior to ethical review. The IRB is responsible for ensuring that any study protocol that is submitted for review is evaluated by a medical expert with expertise to the study protocol.

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive, check completeness, stamp application form, log protocol submission , notify Chair of submission	Staff Secretary	on day of receipt
2	Assign code and enter into database	Staff Secretary	
3	Forward copy of protocol package to Chair	Staff Secretary	1-2 days upon receipt
4	Determine type of review, assign reviewers and instruct Staff Secretary	Chair	1-3 days upon receipt
5	Distribute received files and assessment form for technical review to Technical Reviewer	Staff Secretary	1-2 days upon instruction by Chair
6	Review protocol and accomplish assessment form	Technical Reviewer	1- 2 weeks upon receipt
7	Receive and forward technical approval of protocol to Chair and PI	Staff Secretary	1 day upon receipt
8	If for exemption from review, proceed to SOP 7	Staff Secretary	1-3 days upon receipt of technical approval
9	If for expedited and full board reviews, distribute protocol package and assessment forms to assigned reviewers		1-3 days upon receipt of technical review
10	• For expedited review (see SOP 9) or • For full board include in agenda and discuss at Full Board (see SOP 24; SOP 10)		
11	Communicate IRB Decision	Chair and Staff Secretary	1-3 days after final decision

12	File original package in a properly coded Protocol File Folder and update database with names of Primary Reviewers	Staff Secretary	1 day upon receipt

5. Detailed Instructions

Step 1 The Staff Secretary ensures correctness and completeness of submitted forms and documents according to the checklist in **Form 2.1** Application Form for Protocol Review and puts a receiving stamp with the date received and name on each copy of the application **Form 2.1** on the same day. Incomplete or incorrect submissions will not be accepted and will be returned to the Principal Investigator. The Staff Secretary keeps the original copy of the **Form 2.1** for the IRB files, gives the duplicate (receiving copy) to the PI on the same day and enters the submission in the database and logbook. The Chair is informed of the new protocol submission on the same day as receipt.

Step 2 The Staff Secretary assigns an IRB protocol code indicating the year and the order in which the protocol was received. The IRB Code is assigned as follows:

<YYYY-NN>

YYYY Represents the year submitted (i.e. 2020)

NN Represents sequential number as issued by the staff secretary (i.e. 01)

This code is the ID number of the protocol and cannot be assigned to any other protocol. The code will be communicated to the PI in subsequent communications regarding the protocol on the same day. The Staff Secretary logs and encodes the submission using the database and logbook.

Step 3 The Staff Secretary forwards a copy of the protocol package to the Chair within 1-2 days of receipt of submission.

Step 4 The Chair, or in the absence of the former, the Vice-Chair determines the type of review for the protocol: Exempted from review, expedited review or for full board review.
For the Criteria for exemption from review, see SOP 7.
For protocols undergoing expedited or full board review, the Chair also assigns two (2) Primary Reviewers from among the IRB Members:

- a medical IRB Member or scientist with expertise on the subject of the research protocol to evaluate the scientific soundness and ethics of the study methods and
- a non-medical person/lay IRB Member to assess the intelligibility and thoroughness of the informed consent. An Independent Consultant with needed expertise related to the protocol may also be appointed.

The Chair instructs the Staff Secretary accordingly within 1-3 days of receipt of the protocol package.

Step 5 The Staff Secretary distributes the protocol package and **Form 2.2.1** Study Protocol Assessment Form for Technical Reviewer to the technical reviewer 1-2 days from submission.

Step 6 The technical reviewer reviews the protocol and accomplishes **Form 2.2.1** within 1- 2 weeks upon receipt. See SOP 8 Use of Study Assessment Forms. The Staff Secretary assists the technical reviewer in corresponding with the PI for any clarifications on the protocol and recommended modifications or revisions in research design, sampling design, sample size, statistical analysis plan and data analysis plan. The final approval on the assessment form is given only once any and all suggested revisions by the technical reviewer are done by the PI. The technical reviewer then forwards the approval in **Form 2.5** Notification of IRB Decision to the Staff Secretary for communicating to the Chair and the PI.

Step 7 The Staff Secretary forwards the accomplished **Form 2.2.1** and a copy of **Form 2.5** with technical reviewer's approval to the Chair and the **Form 2.5** to the PI.

Step 8 If the study is exempt from review, proceed to SOP 7.

Step 9 For protocol submissions undergoing full board review, the Staff Secretary distributes the following to the Primary Reviewers and Independent Consultants (if needed):

- Protocol package as hard copies and soft copies with access to the electronic files
- **Form 2.2.2** Study Protocol Assessment Form for Ethical Review to the medical member Primary Reviewer
- **Form 2.3** Informed Consent Evaluation Form to the lay member Primary Reviewer.

The Primary Reviewers and Independent Consultant if needed, review the protocol and accomplish the assessment forms (see SOP 8 Use of Study Assessment Forms), and make their recommendations.

Step 10 For expedited review, the Primary Reviewers and Independent Consultants (if needed) then proceed to do an expedited review (see SOP 9). For full board review, the Chair and Staff Secretary include the review in the next meeting agenda and the IRB discusses and decides at Full Board (see SOP 24; SOP 10).

Step 11 The Staff Secretary collates the comments and recommendations, prepares the **Form 2.6** Document Decision Form or **Form 2.5** Notification of IRB Decision and sends it to the PI. (See SOP 28 Communicating IRB Decisions).

Step 12 The Staff Secretary files the original package in a properly coded Protocol File Folder and updates the database with the names of the assigned Primary Reviewers and type of Review. The Member Secretary shall check and oversee compliance done or will be made by the staff secretary and members to the SOP and timelines set in the process flow chart.