PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB-SOP-12-07-2026	
Version No. 7	**SOP 12** **Review of Amendments**
Approval Date: March 9, 2026	
Effective Date: March 9, 2026	
Supersedes: SOP 14 V.6 July 16, 2022	

SOP 12 Review of Amendments

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) requires that all proposed amendments to approved research protocols and related study documents undergo prior review and approval to ensure continued protection of research participants and compliance with ethical and regulatory standards.

1. No amendment to an approved protocol or related study document shall be implemented without prior IRB approval, except when necessary to eliminate immediate hazards to participants, in which case the amendment shall be reported to the IRB as soon as possible.
2. Amendments subject to IRB review include, but are not limited to, changes in:
    a. study design, procedures, or interventions;
    b. inclusion or exclusion criteria
    c. study population or sample size
    d. informed consent documents or recruitment materials
    e. study personnel or study sites; and
    f. use, handling, or storage of biological specimens or data
3. All proposed amendments shall be documented, tracked, and linked to the originally approved protocol, ensuring traceability and continuity of ethical oversight.
4. The level of review for amendments shall be determined based on the nature and impact of the proposed changes.
    a. Minor amendments that do not alter the risk–benefit ratio or introduce new ethical issues may undergo expedited review;
    b. Major amendments that affect participant safety, scientific validity, or ethical acceptability shall undergo full board review
5. Review of amendments shall focus on assessing whether the proposed changes.
    a. maintain or improve participant safety and welfare

b. preserve the scientific integrity of the study; and

c. require revisions to informed consent or additional participant protections

6. The PELI-IRB shall clearly document its decisions on amendments and may require additional information, re-consent of participants, or other safeguards, as appropriate.
7. The PELI-IRB reserves the authority to disapprove proposed amendments or to require reclassification of the level of review if new risks or ethical concerns are identified.

II. Purpose

To describe the IRB review procedures for amendments of the protocol and related documents**.**

III. Scope

This SOP applies to approved study protocols and related documents that are being amended and submitted for approval by the PELI-IRB.

As stated in Form 4.8 Document Decision Form, no amendment of study-related documents shall be implemented until reviewed and approved by the IRB.

The SOP begins with the submission of an application for a protocol amendment receipt and ends with filing of the amendments and committee decision in the protocol file.

IV. Responsibility

The IRB shall require the submission of proposed amendments for review and approval before their implementation to ensure that the conduct of the study complies with the approved protocol such that any change such as amendments does not impact safety and welfare of study participants. The IRB should properly inform the PI to submit an amendment application whenever there is any change regarding the composition of the study team, the study site and the protocol related documents for approvals previously granted by the IRB.

V. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive application for Protocol Amendment to IRB	Staff Secretary	as needed
2	Check completeness and enter application into logbook	Staff Secretary	1 calendar day
3	Retrieve pertinent protocol file	Staff Secretary	1 calendar day

4	Notify Chair	Staff Secretary	1 calendar day
5	Classify amendment	Chair	1-3 calendar days
6	Distribute amendment packet	Staff Secretary	1 calendar day
7	Review Amendments	Technical and Primary Reviewers	7-14 calendar days
8	Forward recommendation to Chair	Staff Secretary	upon receipt
9	Review recommendations	Chair	7 calendar days
10	Communicate IRB Decision	Staff Secretary	1-3 calendar days
11	File Amendment documents and committee decision and update the database	Staff Secretary	1 calendar day after meeting

VI. Detailed Instructions

Step 1 The Staff Secretary receives the application for protocol amendment from the Principal Investigator through submission of a properly accomplished Form 12 Protocol Amendment Review Form.

Step 2 The Staff Secretary checks the completeness of the amendment packet submitted by the PI composed of the following:

a. Cover Letter
b. **Form 12** Protocol Amendment Form
c. clean protocol
d. tracked protocol

The Staff Secretary enters the amendment into the logbook within 1 calendar day upon receipt (see SOP 28).

Step 3 The Staff Secretary retrieves the corresponding protocol file for reference by the Chair and reviewers within 1 calendar day upon receipt.

Step 4 The Staff Secretary notifies the Chair of the application and forwards the amendment packet.

Step 5 The Chair classifies the amendment as expedited or full board (see SOP 06 or SOP 07). When necessary, a Technical Reviewer may be assigned within 1–3 calendar days upon receipt of the amendment documents.

The Primary Reviewers who conducted the initial review shall also be assigned to ensure continuity of ethical and scientific assessment..

Step 6 Within 1 calendar day after receipt of instruction from the Chair, the Staff Secretary distributes the amendment packet to the designated reviewers.

Step 7 The designated amendment reviewers check the amended protocol (clean and tracked) and compare them with the previously IRB approved documents in the protocol files. If needed, the Technical Reviewer shall evaluate the amendment first before the Primary Reviewers. The Technical Reviewer determines if the amendment will not alter the scientific soundness of the study. The Primary Reviewers determine if the amendments will alter the risk/benefit ratio of the study.

Protocol amendments, which increase the risk to study participants, may include but are not limited to the following:

a. change in study design
b. additional treatments or deletion of treatments
c. any change in the exclusion/inclusion criteria
d. change in method of drug intake or route of drug intake
e. significant change in the number of participants
f. significant decrease or increase in dosage amounts

The reviewers submit recommendations using Form 12 within 7–14 calendar days.

Step 8 The Staff Secretary forwards reviewer recommendations to the Chair upon receipt of Form 12.

Step 9 The Chair shall review the recommendations of the assigned amendment reviewers in Form 12 whether expedited or full board and the process proceeds accordingly. For expedited review, see SOP 6. For full board review, see SOP 7.

Amendments for expedited review are the following:

a. Do not affect the substance of the original protocol and where no major new ethical issues are raised.
b. Are protocol amendments for safety reasons, i.e., to protect the welfare of the participants.
c. Request for extension of an approved project with no modification of protocol.

d. Request for approval of recruitment and publicity materials for approved protocols.
e. Indicate change of associate or co-investigators.
f. Provides for a retrospective statement that the study has been conducted in an ethical manner to assist journal editors to assess articles presented for publications.
g. Amendments for protocols that underwent expedited reviews in its initial approval.

For the full board review, if only minor changes that do not affect risk-benefit ratio are involved, the reviewers' recommendation becomes the basis for the final decision of the IRB and the IRB Secretary prepares a letter granting approval, as instructed and signed by the Chair.

Step 10 Staff Secretary prepares a communication letter to inform the investigators about the board decision. For amendments, the IRB action may be any of the following:

a. Approved,
b. Additional justification/information required,
c. Re-consent required
d. Disapproved
e. Suspension or Termination of the Study
f. Clarification or Minor Modification subject to expedited review at the level of the Chair

The criteria for expediting a minor modification or clarification would be:

a. Lack of details or description in study protocol and ICF elements
b. Revisions to improve clarity and/or comprehension
c. Lack of training certificates, MOA etc.

The Staff Secretary shall release the decision within **1–3 calendar days** using appropriate forms (see SOP 27).

Step 11 The Staff Secretary files the amendment and a copy of the committee decision in the protocol folder and updates the database (see SOP 28).

VII. Forms

1. Form 12 Protocol Amendment Review Form
2. Form 4.9 Approval Letter for Post-Approval Procedures Form
3. Form 4.8 Request Information for Post-Approval Procedures

VIII. References

1. 2020 PHREB SOP Workbook
2. PELI-IRB SOP 2017

IX. Revision Index

Version	Date	Reasons For Revision
01	August 8, 2013	Patterned SOP after the SOP drafted by the DOH SOP Team (based on the FERCAP template)
02	February 3, 2014	Revised section 3.7 (additional requirements from the PI for premature suspension or termination of a research study), added section 3.8 suspension or termination of IRB approval, added Form 3.11 (Reminder Letter), added section 3.9 continuing review, added Form 3.12 Application for Continuing Review
03	January 26, 2016	Changed logo of "Pacific Eye and Laser Institute" to "Peregrine Eye and Laser Institute" in the document header and in the header of forms 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.11, 3.12
04	June 15, 2017	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: State in the SOP 3 that the IRB reviews by full board reports of onsite SAE/SUSARs and indicate timelines for reporting (SOP 3.1.5.2 SAE reporting timelines should comply with the ICH-GCP guidelines) Ensure that Protocol violations and deviations are categorized accordingly Define major and minor violations Organize the sequence of discussion of the protocol (i.e. Scientific, then ethical issues, ICF; include the PDPVs and reasons for that) Ensure appropriate timelines for SAE reporting are incorporated in the SOP AND communicated to the PI Ensure timely review of the continuing reports Indicate reviewers of SAEs in the minutes Ensure that SAE reviewer is a medical doctor Categorize protocol deviations into major or minor and how deviations will affect risk Reflect recommended actions required of PI on deviations/violations in the meeting minutes Consistently require Final reports for all studies Communicate to the PI the results of review of final report. Ensure consistency of the flow chart with the detailed instructions (e.g. person responsible for a particular process).
5	July 16, 2022	Reformat numbering to conform to 2020 PHREB SOP workbook Refer to SOP 3.2 of version 4 of PELI IRB Add references within the SOP and transfer all cited ones to this item Rewrite workflow activities for more conciseness Determination of type of review - expedited or full board - will be by the Chair upon the review of recommendations of assigned amendment reviewers of the protocol add "forms" to include forms used in the SOP

6	April 24, 2025	To include additional decision for protocol amendment: To include criteria for expediting a minor modification or clarification
7	March 9, 2026	Revised and reclassified as SOP 12 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics Added a Policy section to define the governing principles and general guidelines of the SOP. Convert all timelines to calendar days 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