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| PERIGRINE EYE AND LASER INSTITUTE | **Peregrine Eye and Laser Institute**<br>**Institutional Review Board** |
| PELI-IRB-SOP-13-06 2026 | |
| Version No. 6 | **SOP 13**<br>**Review of Progress Report** |
| Approval Date: March 9, 2026 | |
| Effective Date: March 9, 2026 | |
| Supersedes: SOP 15 v.5 July 16, 2022 | |

# SOP 13 Review of Progress Report

## I. Policy

The PELI-IRB requires the regular submission and review of Progress Reports for all ongoing approved studies to ensure continuing ethical oversight of research involving human participants.

Progress Reports shall be reviewed to monitor:

- Participant safety and welfare
- Compliance with the approved protocol and informed consent process
- Occurrence of adverse events, protocol deviations, and violations
- Adequacy of the risk–benefit balance during study implementation

Approval or acknowledgment of a Progress Report constitutes authorization for the continued implementation of the study for the specified approval period.

## I. Purpose

To define the procedures for the review of Progress Reports submitted by investigators to ensure continued protection of research participants.

## II. Scope

This SOP applies to all **ongoing IRB-approved studies** requiring periodic progress reporting.

The process begins with **tracking of submission timelines** and ends with **communication of IRB decision and database update**.

## III. Responsibility

1. PELI-IRB
   a. Monitor submission timelines
   b. Ensure ethical and technical review
   c. Approve or require action
2. Primary Reviewer
   a. Assess ethical compliance and participant protection
   b. Recommend IRB action
3. Technical Reviewer
   a. Conduct scientific and technical assessment when require

4. Staff Secretary
    a. Track due dates and send reminders to investigators
    b. Receive, log, and screen submitted reports for completeness
    c. Distribute reports to reviewers
    d. Prepare decision letters
    e. Update protocol database and files

**IV.** Process Flow/Steps

| STEP | ACTIVITY | PERSON RESPONSIBLE | TIMELINE |
|---|---|---|---|
| 1 | Track due dates of Progress Reports | Staff Secretary | 30 calendar days before due date |
| 2 | Receive and check completeness | Staff Secretary | 1 calendar day |
| 3 | Notify Chair | Staff Secretary | 1 calendar day |
| 4 | Instruct Staff Secretary | Chair | 1–3 calendar days |
| 5 | Review progress | Primary and Technical Reviewers | 7 calendar days |
| 6 | Discuss at full board and make a decision | Members | During scheduled meeting |
| 7 | Communicate IRB decision to PI | Staff Secretary | 1-3 calendar days upon finalization of decision |
| 8 | Update protocol post-approval submission database | Staff Secretary | 1calendar day after decision |

**V.** Detailed Instructions

**Step 1** The Staff Secretary checks the database and tracks the due dates of progress or final reports of Study Protocols approved by the PELI IRB. Staff Secretary shall ensure to keep track of such timelines. The Staff Secretary prepares and sends a reminder letter to the PI one month before the due date, with signature of the Chair.

**Step 2** The Staff Secretary reviews the completeness of submitted reports based on Form 13 Progress Report and forwards these to the Primary Reviewers within 1 calendar day upon receipt.

**Step 3** The Staff Secretary refers the submission to the Chair within 1 calendar day upon receipt and awaits further instructions.

**Step 4** The Chair instructs the Staff Secretary whether the Technical Reviewer will review the report in addition to the Primary Reviewers. The Chair also instructs inclusion of the report in the next Full Board meeting agenda. The Chair provides instructions within 1–3 calendar days upon notification.

**Step 5** Review of progress report shall include participant safety, protocol compliance, adverse events and deviations and continued favorable risk-benefit ratio. The Primary Reviewer shall evaluate the report within 7 calendar days.

The primary reviewers may take note of the progress report. If issues affecting participant safety or protocol compliance are identified, IRB actions may include: (1) request for clarification (2) request for amendment (3) suspension or termination of the study.

**Step 6** The primary and/or technical reviewers of progress discuss the report and their recommended action during the full board meeting and a decision is made for the report. See SOP 7: Full Board Review

**Step 7** See SOP 27 Communicating IRB Decisions.

For progress reports, the Committee may take one of the following actions:

a. Notation/Acknowledgment of the progress report, allowing the research to continue as approved.
b. Request for additional information from the researcher.
c. Request for specific action(s) from the researcher, which may include amendments to the protocol or informed consent form.

Approval or acknowledgment of the progress report by the IRB enables the continuation of the research study.

The Staff Secretary prepares the decision based on reviewer report or meeting minutes.

The signed response letter shall be released to the PI within 1–3 calendar days after IRB decision.

**Step 8** IRB Staff Secretary keeps a copy in the protocol files of the progress report signed by the primary and or technical reviewers and the Chair. See SOP 28 Management of Active Study Files

**VI.** Forms

1. Form 13 Progress Report
2. Form 4.11 Reminder Letter
3. Form 4.8 Request Information for Post-Approval Procedures
4. Form 4.9 Approval Letter for Post -Approval Procedures

**VII.** References

**1.** 2020 PHREB SOP Workbook

**2.** PELI-IRB SOP 2017

**VIII.** 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:<br>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)<br>Ensure that Protocol violations and deviations are categorized accordingly<br>Define major and minor violations<br>Organize the sequence of discussion of the protocol (i.e. Scientific, then ethical issues, ICF; include the PDPVs and reasons for that)<br>Ensure appropriate timelines for SAE reporting are incorporated in the SOP AND communicated to the PI<br>Ensure timely review of the continuing reports<br>Indicate reviewers of SAEs in the minutes<br>Ensure that SAE reviewer is a medical doctor<br>Categorize protocol deviations into major or minor and how deviations will affect risk<br>Reflect recommended actions required of PI on deviations/violations in the meeting minutes<br>Consistently require Final reports for all studies<br>Communicate to the PI the results of review of final report.<br>Ensure consistency of the flow chart with the detailed instructions (e.g. person responsible for a particular process). |

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| 5 | July 16, 2022 | Reformat numbering to conform to 2020 PHREB SOP workbook<br>Refer to SOP 3.3 of version 4 of PELI IRB<br>Add references within the SOP and transfer all cited ones to this item<br>Remove submission of progress report by PI from workflow<br>Make process flow and steps consistent<br>Add "forms" to include forms used in the SOP |
| 6 | March 9, 2026 | Revised and reclassified as SOP 11 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics<br><br>Added a Policy section to define the governing principles and general guidelines of the SOP.<br><br>Convert all timelines to calendar days<br><br>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 |