

	<b>Peregrine Eye and Laser Institute Institutional Review Board</b>
PELI-IRB-SOP-14-06 2026	<b>SOP 14 Review of Final Report</b>
Version No. 6	
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## SOP 14 Review of Final Report

### I. Policy

The PELI-IRB requires the submission and review of Final Reports for all approved studies upon completion, termination, or early closure.

Final Reports shall be reviewed to ensure:

- Appropriate ethical closure of the study
- Documentation of study conduct
- Resolution of participant safety issues
- Reporting of outcomes and deviations
- Proper disposition and archiving of records

Acceptance of the Final Report signifies closure of IRB oversight.

### I. Purpose

To define the procedures for the review and closure of completed or terminated research studies.

### II. Scope

This SOP applies to all studies that are:

- Completed
- Terminated
- Withdrawn

The process begins with submission of Final Report and ends with archiving of the protocol file.

### III. Responsibility

#### 1. PELI-IRB

- Monitor submission timelines
- Ensure ethical and technical review
- Approve or require action

#### 2. Primary Reviewer

- Assess ethical compliance and participant protection
- Recommend IRB action
- 3. Technical Reviewer
  - Conduct scientific and technical assessment when required
- 4. Staff Secretary
  - Track due dates and send reminders to investigators
  - Receive, log, and screen submitted reports for completeness
  - Distribute reports to reviewers
  - Prepare decision letters
  - Update protocol database and files

#### IV. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive Final Report	Staff Secretary	Upon submission
2	Check completeness	Staff Secretary	1 calendar day
3	Notify Chair and Primary Reviewer	Staff Secretary	1 calendar day
4	Review Final Report	Primary Reviewers	7 calendar days
5	Discuss at full board and make a decision	Members	During scheduled meeting
6	Communicate IRB decision to PI	Staff Secretary	1-3 calendar days upon finalization of decision
7	Update protocol post-approval submission database	Staff Secretary	1 calendar day after decision

#### V. Detailed Instructions

**Step 1** The Staff Secretary receives the Final Report submitted using Form 14 – Final Report.

**Step 2** The Staff Secretary reviews the completeness of submitted report based on the items in Form 14 Final Report

**Step 3** The Staff Secretary refers the submission to the Chair and Primary Reviewers within 1 calendar day upon receipt of the report.

**Step 4** The Primary Reviewers review the Final Report within 7 calendar days.

Reviewers assess:

- Completion status of the study
- Resolution of safety issues
- Protocol compliance and deviations
- Study outcomes and reporting

**Step 5** The Primary Reviewers discuss the report and their recommended action during the full board meeting, and a decision is made (see SOP 07).

**Step 6** (See SOP 27 Communicating IRB Decisions)

The IRB acknowledges receipt of the report and formally closes the study after confirming that there are no unresolved safety, ethical, or regulatory issues.

The Staff Secretary prepares the response letter based on the IRB decision and ensures that it is signed by the Chair.

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

**Step 7** The Staff Secretary marks the protocol as completed and archives the study file (see SOP 29).

The Staff Secretary updates the database.

**II. Forms**

1. Form 14 **Final Report**
2. Form 4.8 Request Information for Post-Approval Procedures
3. Form 4.9 Approval Letter for Post -Approval Procedures

**III. References**

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

**IV. Revision Index**

<b>Version</b>	<b>Date</b>	<b>Reasons For Revision</b>
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)

		<p>Ensure that Protocol violations and deviations are categorized accordingly</p> <p>Define major and minor violations</p> <p>Organize the sequence of discussion of the protocol (i.e. Scientific, then ethical issues, ICF; include the PDPVs and reasons for that)</p> <p>Ensure appropriate timelines for SAE reporting are incorporated in the SOP AND communicated to the PI</p> <p>Ensure timely review of the continuing reports</p> <p>Indicate reviewers of SAEs in the minutes</p> <p>Ensure that SAE reviewer is a medical doctor</p> <p>Categorize protocol deviations into major or minor and how deviations will affect risk</p> <p>Reflect recommended actions required of PI on deviations/violations in the meeting minutes</p> <p>Consistently require Final reports for all studies</p> <p>Communicate to the PI the results of review of final report.</p> <p>Ensure consistency of the flow chart with the detailed instructions (e.g. person responsible for a particular process).</p>
5	July 16, 2022	<p>Reformat numbering to conform to 2020 PHREB SOP workbook</p> <p>Refer to SOP 3.3 of version 4 of PELI IRB</p> <p>Add references within the SOP and transfer all cited ones to this item</p> <p>Remove submission of progress report by PI from workflow</p> <p>Make process flow and steps consistent</p> <p>Add “forms” to include forms used in the SOP</p>
6	March 9, 2026	<p>Revised and reclassified as SOP 11 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>