

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB SOP 15/05-0-2022	SOP 15 Review of Progress/ Final Report
Version No. 5	
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 15 Review of Progress/ Final Report

1. Purpose

To describe the IRB review procedures for progress report/final report.

2. Scope

This SOP provides instructions for the review of progress/final reports that are required by the PELI-IRB to be submitted by the PI to monitor the safety of participants enrolled in the study. This SOP also aims to provide instructions for the review of final reports that are submitted by the PI after completion of subject enrollment and all follow-up procedures.

This SOP applies to conducting any continuing review of study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the studies, and the vulnerability of the study participants and duration of the study, the IRB may choose to review or monitor the protocols more frequently.

This SOP describes the follow up of progress and final report by the IRB secretary and the review of such reports submitted by the PI by designated members of the IRB and /or technical review committee (as necessary) in compliance with ICH-GCP requirements.

3. Responsibility

It is the responsibility of the PELI-IRB to remind investigators to submit progress and final reports before due date, to forward the reports to its primary and or technical reviewers for assessments, to communicate with the investigators if there is a need for further information or action and release notification letter to the PI of IRB's decision to the report.

It is the responsibility of the primary and technical reviewers to evaluate the reports to check completeness of information and to ensure that the date is in accordance with the protocols and other related documents approved by the IRB.

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Track timeline for due dates of progress and final reports and remind PI of deadline of report	Staff Secretary	One month before due date of the report
2	Receive, Check completeness of report and forward to the primary reviewers for assessment/comments	Staff Secretary	One day upon receipt
3	Notify Chair	Staff Secretary	One day upon receipt
4	Instruct Staff Secretary	Chair	1-3 days from notification
5	Review progress or final report and recommend action	Primary and technical Reviewers	1 week each group upon receipt
6	Discuss at full board and make a decision	Members	
7	Communicate IRB decision to PI	Staff secretary	1-3 days upon finalization of decision
8	Update protocol post-approval submission database	Staff secretary	On the day of receipt

5. 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 addressed to the PI one month before the due date of the report with signature of member-secretary and chair.

Step 2 The Staff Secretary reviews the completeness of submitted report based on the items in **Form 3.3** Progress Report / **Form 3.4** Final Report and forwards these to the primary reviewers for evaluation one day upon receipt of the reports.

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

Step 4 The Chair instructs the Staff Secretary whether the Technical Reviewer will also review a progress report aside from the Primary Reviewers. Chair will also instruct Staff Secretary to include the report in the agenda of the next Full Board meeting. Chair confirms that the primary reviewers and the Technical Reviewer if needed are given the necessary documents. The chair has a timeline of 1-3 days upon notification by the staff secretary to give instructions.

Step 5 The Primary and/or Technical reviewers review of progress report if they are in accordance with the protocol and related documents approved by the IRB. They shall have 1 week each group to evaluate the stated report.

The primary and/or technical reviewers refer to the protocol file to check compliance with approval given by the IRB during initial review and upon submission of amendments. The primary and/or technical reviewers may recommend approval of the progress report. If there is any deviation or violation of approvals given by the IRB, the primary and/or technical reviewers may recommend that appropriate action be taken by the PI: amendment of the protocol or consent form, explanation of deviation or violation for final reports.

Step 6 The primary and/or technical reviewers of progress/final report discuss the report and their recommended action during the full board meeting and a decision is made for the report. See SOP 10: Full Board Review

Step 7 See SOP 28 Communicating IRB Decisions. For progress reports, the committee action may be approved, additional information requires, specific action/s required from the researcher. Approval by the IRB enables the continuance of the research. Staff Secretary prepares a draft of the committee decision based on either an expedited review report or minutes of a meeting.

The Chair signs the decision letter as follows:

- Notation
- Request for additional information or specific action/s including amendment of protocol or consent form

The IRB accepts final reports and considers the study as completed.

Staff secretary checks that the response letter is signed by the chair and member-secretary before giving it to the PI within 1-3 days after decision for progress report is final.

Step 8 IRB Staff Secretary keeps a copy in the protocol files of the progress/final report signed by the primary and or technical reviewers and the Chair. See SOP 29 Management of Active Study Files

For Final Reports, the IRB Staff secretary marks the folder of the completed protocol and archives the entire study protocol. See SOP 30 Archiving of Terminated, Inactive or Completed Studies. The Staff secretary updates the database.