

	<p style="text-align: center;">Peregrine Eye and Laser Institute Institutional Review Board</p>
<p>PELI-IRB-SOP-32-04-2026</p>	
<p>Version No. 4</p>	<p>SOP 32 Revising SOPs</p>
<p>Approval Date: July 16, 2022</p>	
<p>Effective Date: July 16, 2022</p>	
<p>Supersedes: SOP 34 V.3 JULY 16, 2022</p>	

SOP 32 Revising SOPs

I. Policy

The PELI-IRB shall periodically review and update its SOPs to reflect changes in ethical standards, regulations, and institutional needs. Revisions shall be documented, approved by the IRB, and implemented in a controlled manner.

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II. Purpose

To define the process for writing SOPs (Standard Operating Procedures) used by the IRB.

III. Scope

This SOP provides instructions on how the IRB SOPs are prepared, approved and distributed.

As the IRB sees fit, an existing SOP may be revised. A revision should be substantial (correction of grammatical errors is not considered substantial; a change in the identifier of an SOP is considered substantial). Minor changes refer to editorial, grammatical, or administrative changes that have no substantial effect on procedures. Major changes on the other hand, are those that have a substantial effect of procedures, definitions, requirements and similar considerations.

When an SOP is difficult to understand or does not cover what is should, a revision may become necessary.

IV. Responsibility

It is the responsibility of the Chair of the IRB to appoint an SOP team to revise the SOPs of the IRB. The Chair designates the members of the team, initiate approval processing of final version of SOPs, and submits the SOP to the PELI Managing Director for final approval.

The SOP Team is an ad hoc committee composed of appointed IRB members with invited resource persons. The team is responsible for reviewing and revising existing SOPs when necessary.

The team must follow existing procedures, format, and coding system of the eye center when drafting or editing any SOPs of the eye center, and consults the Secretary and Chair about the need for new or revised version of the SOPs. The team submits SOP drafts to the Chair for approval processing.

The Staff Secretary is responsible for coordinating the revision of the SOPs, maintains current SOPs with a complete SOP list, ensures that all IRB members have access to the SOPs and are working according to the current version of the SOPs.

V. Process Flow/Steps for Revising SOPs

STEP	ACTIVITY	RESPONSIBILITY
1	Propose to revise an SOP	IRB Members
2	Once SOP revision has been agreed on, assign an IRB member or ad hoc SOP Team to draft the revised SOP.	IRB Chair
3	Write draft of revised SOP	Designated IRB member or ad hoc SOP Team
4	Discuss proposed draft during full board meeting	IRB Members
5	Indicate main changes in the Revision Index	Designated IRB member or ad hoc SOP Team
6	Once approved during full board meeting, IRB Chair submits draft to Managing Director for final approval	IRB Chair/Managing Director
7	Final approval of SOP	Managing Director
8	Implement approved SOP	Staff Secretary
9	File/distribute SOP	Staff Secretary
10	Retain copy of original signed SOP	Staff Secretary
11	Archive superseded SOPs	Staff Secretary

VI. Detailed Instructions

Step 1 Any member of the IRB may propose a revision of an SOP.

Step 2 When the need for a revision of SOP has been identified and agreed on, the IRB Chair will designate an IRB member or ad hoc SOP Team to draft the revised SOP.

Step 3 A draft will be written by a designated member of the IRB or ad hoc SOP Team.

Step 4 The proposed draft of the revised SOP is discussed and acted upon through full board meeting among the IRB members.

Step 5 If an SOP supersedes a previous version, the Revision Index shall indicate the previous SOP identifier and provide a summary of the main changes or updates made in the new version.

The SOP identifier shall follow the format:

PELI-IRB-SOP-XX- ZZ-YYYY

where:

XX – Two-digit SOP number

ZZ – Revision version number of the SOP

YYYY – Year when the SOP was drafted or revised

Example:

PELI-IRB-SOP-13-01-2026

Step 6 Upon full board approval, the Chair submits the approved draft to the PELI Managing Director for final approval.

Step 7 PELI Managing Director approves the SOP by signing in the appropriate section in the header/footer.

Step 8 The approved SOPs will be implemented from the date of approval by the Managing Director.

Step 9 The Staff Secretary files and distributes the SOP to IRB members and updates the SOP manual published on the eye center website.

Step 10 The Staff Secretary retains one complete originally signed SOP copy.

Step 11 Archive the superseded SOP. Prior to archiving, the Secretary marks the superseded SOP with “superseded” and the year of archiving.

VII. Regular update of SOP

The SOP should be reviewed and updated every 3 years.

VIII. References

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

IX. Revision Index

Version	Date	Reasons For Revision
02	January 26, 2016	Changed logo of “Pacific Eye and Laser Institute” to “Peregrine Eye and Laser Institute” in the document header
03	July 16, 2022	Reformatted numbering to conform to 2020 PHREB SOP workbook Refer to SOP Chapter 5 of Version 2 January 2016 of PELI-IRB Added references within the SOP Added revision index Revised overall SOP header layout Removed page number in SOP header and added it to footer Removed cover page and added elements from it to header Added "Regular update of SOP" Made Process Flow/Steps and detailed instructions consistent
4	March 9, 2026	Revised and reclassified as SOP 31 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.