

	<b>Peregrine Eye and Laser Institute Institutional Review Board</b>
PELI-IRB-SOP-31-04-2026	<b>SOP 31 Writing SOPs</b>
Version No. 4	
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## SOP 31 Writing SOPs

### I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall develop, maintain, and implement written Standard Operating Procedures (SOPs) that govern its structure, functions, and review processes in accordance with applicable national and international ethical and regulatory standards.

1. All SOPs shall be prepared using a systematic, documented, and controlled process to ensure consistency, clarity, regulatory compliance, and operational effectiveness in the protection of research participants.
2. SOPs shall be developed and revised in alignment with:
  - a. Philippine Health Research Ethics Board (PHREB) requirements and accreditation standards;
  - b. National Ethical Guidelines for Health and Health-Related Research;
  - c. International Council for Harmonisation – Good Clinical Practice (ICH-GCP);
  - d. World Health Organization (WHO) Standards and Operational Guidance for Ethics Review Committees; and
  - e. other applicable regulatory or institutional policies.
2. SOPs shall accurately reflect current IRB practices and shall define responsibilities, procedures, documentation requirements, and decision-making processes necessary for ethical review and oversight of research.
3. SOP development and revision shall involve appropriate consultation with IRB officers, members, administrative staff, and subject matter experts, as necessary, to ensure scientific, ethical, and operational adequacy.

4. All SOPs and subsequent revisions shall undergo:
  - a. review and approval by the IRB through appropriate deliberative processes; and
  - b. final institutional approval by the Managing Director or authorized institutional official.
5. Approved SOPs shall be implemented only after formal approval and shall be made accessible to IRB members and relevant personnel. The IRB shall ensure that personnel are trained and operate in accordance with the current approved versions.
6. SOPs shall be subject to periodic review, at least every three (3) years or more frequently when regulatory changes, organizational modifications, or operational needs require revision.
7. The IRB shall maintain version control and archival records of all SOPs to ensure traceability, historical documentation, and regulatory accountability.

## **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.

## **IV. Responsibility**

It is the responsibility of the Chair of the IRB to appoint an SOP team to formulate or 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 proposing and formulating new SOPs, and 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 Secretary is responsible for coordinating the writing and revising 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.

IRB members are responsible for reviewing and approving the drafts of new or revised SOPs in a full board meeting, keeping a copy of complete SOPs and performing their functions according to current SOPs.

The PELI Managing Director is responsible for final approval of all SOPs.

**V. Process Flows/Steps**

STEP	ACTIVITY	PERSON RESPONSIBLE
1	Chair designates members of SOP Team	IRB Chair
2	SOP Team orientation of duties and responsibilities	IRB Chair
3	Organize SOP Team workshops as needed	IRB Chair
4	Write SOP according to designated format	Designated IRB member or SOP Team
5	Submit completed draft to IRB Chair	Designated IRB member or SOP Team
6	Review and deliberate draft during full board meeting	IRB Chair/ members
7	Submit approved full board approved draft to PELI Managing Director	IRB Chair/Managing Director
8	Final approval	Managing Director
9	Implement approved SOP	Staff Secretary
10	File and distribute SOP	Staff Secretary
11	Retain original signed SOP document	Staff Secretary

**VI. Detailed Instructions**

**Step 1** The Chair designates members and non-members as needed to be part of the SOP Team.

**Step 2** The SOP team receives an orientation from the Chair regarding duties and responsibilities.

**Step 3** The Chair may also organize SOP Team workshops to facilitate drafting of SOPs.

**Step 4** SOP Writing and Format

An SOP is written according to the following format:

- a. Header
- b. SOP Number
- c. Title
- d. Policy
- e. Purpose of the SOP
- f. Scope (including description and purpose of the SOP)
- g. Responsibility
- h. Process Flow/Steps
- i. Detailed Instructions
- j. Forms
- k. References
- l. Revision Index
- m. Page number (located in the footer )

The SOP shall utilize a header and footer containing the following elements:

- a. Identifier
- b. Institutional Logo
- c. Name of Institution
- d. SOP Number
- e. SOP Title
- f. Version Number
- g. Name of Author(s) and Editor(s)
- h. Approval Date and Effective date
- i. Approved by (Name and Signature of PELI-IRB Chair and Managing Director)

**Step 5** The SOP Team submits completed draft to the Chair for initial review.

**Step 6** The Chair submits the draft to full board review where the IRB members deliberate on the draft.

**Step 7** Upon full board approval, the Chair submits the approved draft to the PELI Managing Director for final approval.

**Step 8** The PELI Managing Director approves the SOP by signing in the appropriate section in the header/footer.

**Step 9** The approved SOPs will be implemented from the date of approval by the Managing Director.

**Step 10** The Staff Secretary distributes the printed or electronic copy of the approved SOPs to the IRB members and staff, with an electronic copy published through the eye center website.

**Step 11** The Staff Secretary retains one complete originally signed SOP copy.

**VII. Regular update of SOP**

The SOP should be reviewed and updated every 3 years or as needed.

**VIII. References**

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

**IX. Revision Index**

<b>Version</b>	<b>Date</b>	<b>Reasons For Revision</b>
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 30 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.

