

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB SOP 32/03-2022	SOP 32 Writing SOPs
Version No. 3	
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 32 Writing SOPs

1. Purpose

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

2. Scope

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

3. 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.

4. Process Flows/Steps for Writing SOPs

STEP	ACTIVITY	RESPONSIBILITY
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

5. 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 An SOP is written according to the following format:

- Header
- SOP Number
- Title
- Purpose of the SOP
- Scope which includes description and purpose of the SOP
- Responsibility
- Process Flow/Steps
- Detailed Instructions
- Forms
- References
- Revision index
- Page number at the footer

SOP uses a header/footer which contains the following elements:

- Identifier
- Institutional Logo
- Name of Institution
- SOP Number
- SOP Title
- Version Number
- Name of Author(s)
- Name of Editor(s)
- Approval Date
- Approved by
- Signature (of PELI Managing Director)
- Effective Date

Step 5 The SOP Team submits completed draft to the Chair.

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.

6. Regular update of SOP

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