

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB SOP 33/03-0-2022	SOP 33 Revising SOPs
Version No. 3	
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 33 Revising 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.

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.

3. 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 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.

4. 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

5. 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, indicate the previous SOP identifier and the main changes in the Revision Index. The SOP identifier reflects the chronological number and date of the revision. SOP identifier format is: PELI-IRB SOP XX/YY-W-ZZZ, where

XX is a two-digit number corresponding to the SOP number, YY is a two-digit number identifying the version of the SOP, and W is a one-digit number identifying the version of SOP with changes in the SOP, and ZZZZ refers to the year the SOP was drafted.

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 Prior to archiving, the Secretary marks the superseded SOP with “superseded” and the year of archiving.

6. Regular update of SOP

The SOP should be reviewed and updated every 3 years.