

	<b>Peregrine Eye and Laser Institute Institutional Review Board</b>
PELI-IRB-SOP-09-02-2026	<b>SOP 09 Management of Protocol Resubmissions</b>
Version No. 2	
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## SOP 09 Management of Protocol Resubmissions

### I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) requires that all protocol resubmissions be managed in a systematic, timely, and transparent manner to ensure that required modifications are adequately addressed before approval is granted.

1. Protocol resubmissions shall consist only of revised or modified versions of protocols previously reviewed by the PELI-IRB, submitted in response to IRB-required modifications or clarifications. All revised documents shall be clearly labeled with the corresponding version number and date.
2. Investigators shall address all conditions, comments, and required modifications specified in the IRB decision letter prior to resubmission. Partial or incomplete responses shall not be considered sufficient for approval.
3. Each resubmission shall be formally documented, linked to the original protocol identification number, and tracked in the IRB database to ensure continuity, traceability, and accountability.
4. The level of review for a resubmitted protocol shall be determined based on the nature and extent of the modifications:
  - a. Minor modifications that do not alter the risk–benefit ratio or raise new ethical issues may undergo expedited review
  - b. Major modifications that affect participant safety, study design, or ethical considerations shall undergo full board review.
5. Review of resubmissions shall focus on determining whether the IRB-required modifications have been satisfactorily addressed, and whether the revised protocol continues to meet applicable scientific and ethical standards.

6. No resubmitted protocol shall be approved unless the PELI-IRB is satisfied that all required modifications have been adequately incorporated and that the protocol complies with applicable ethical guidelines.
7. Decisions on protocol resubmissions shall be clearly documented and communicated to the investigator in writing, with explicit reference to the outcome of the review.
8. The PELI-IRB reserves the authority to require additional review, clarifications, or referral to full board review if new information or unresolved ethical concerns arise during evaluation of the resubmission.

**II. Purpose**

To describe the review procedures for protocol resubmissions.

**III. Scope**

This SOP pertains to the resubmission of revised or modified protocols that have been previously reviewed by the IRB.

The procedure begins with the receipt of protocol resubmission and ends with the communication of IRB decision, documentation, and updating of the IRB database.

**IV. Responsibility**

The IRB shall ensure that the researcher addresses the required modifications prior to approval, within 30 calendar days after receipt of the decision letter.

Modifications may be minor or major. Minor modifications shall undergo expedited review, while major modifications shall undergo full board review.

**V. Process Flow/Steps**

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive resubmission and log	Staff Secretary	1 calendar day
2	Notify Chair and classify resubmission (Type of Review)	Chair Staff Secretary	1 calendar day
3	Review resubmission (All Documents)	Reviewers	3 calendar days
4	Communicate IRB Decision	Chair and Staff Secretary	3 calendar days
5	File the documents in the Protocol File Folder and update the database	Staff Secretary	1 calendar day after meeting

**VI. Detailed Instructions**

**Step 1** The Staff Secretary receives the study document, checks the nature of the document

and ensures that the submission is properly logged.

**Step 2** The Staff Secretary retrieves Form 4.7 Notification of IRB Decision that pertains to the original protocol and informs the Chair about the resubmission and about the nature of the modifications required from the researcher. Given the necessary information, the Chair either evaluates the resubmitted protocol as expedited or full board. Staff Secretary distributes documents to reviewers.

**Step 3** The assigned reviewers conduct review of the resubmitted protocol by noting the different recommendations made by the IRB and evaluating whether these were satisfactorily addressed in the resubmitted protocol. The reviewers submit their report and recommendations in Form 9 Protocol Resubmission to the Chair for inclusion in the next regular meeting if for full board review, see SOP 7. If for Expedited Review, see SOP 6.

**Step 4** For Resubmissions approved at the level of the Chair: The Chair dictates his/her decision to staff secretary for preparation of the draft approval letter Form 4.8 Document Decision Form, finalization and sending to the Principal Investigator. For the resubmissions that underwent Full Review, refer to SOP 27 Communicating IRB Decisions.

**Step 5** The Staff Secretary gathers all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter) and enters the relevant information on resubmission in the appropriate protocol database.

## **VII. Forms**

1. Form 4.7 Notification of IRB Decision
2. Form 4.8 Document Decision Form
3. Form 9 Protocol Resubmission

## **VIII. References**

1. 2020 PHREB SOP Workbook
2. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
3. WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011
4. National Ethical Guidelines for Health and Health-related Research (NEGHHR) 2017

## **IX. Revision Index**

<b>Version</b>	<b>Date</b>	<b>Reasons For Revision</b>
1	July 16, 2022	Initial Release

2	March 9, 2026	<ul style="list-style-type: none"><li>• Revised and reclassified as SOP 9 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics</li><li>• Added a Policy section to define the governing principles and general guidelines of the SOP.</li><li>• Convert all timelines to calendar days</li><li>• Forms were re-numbered to correspond with the SOP in which they are used to ensure consistency, traceability, and proper document control. All form numbers mentioned in the SOP were updated accordingly to align with the revised numbering system</li></ul>
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