

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB-SOP-10-01-2026	SOP 10 Use of Protocol Resubmission Form
Version No. 1	
Approval Date: March 9, 2026	
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Supersedes: Not Applicable	

SOP 10 Use of Protocol Resubmission Form

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall require the systematic use of a standardized protocol resubmission form to ensure that investigator responses to IRB-required modifications are complete, transparent, and adequately reviewed prior to final IRB determination.

1. The protocol resubmission form shall serve as the primary tool for documenting investigator responses to IRB comments, conditions, and required modifications.
2. Use of the resubmission form shall ensure:
 - a. clear correspondence between IRB comments and investigator responses;
 - b. consistent and efficient review of revised submissions; and
 - c. transparent documentation of the basis for IRB decisions.
3. Resubmission forms shall be reviewed at the same level of review as required by the original IRB decision, unless otherwise determined by the IRB Chair in accordance with applicable SOPs.
4. Completion and review of the resubmission form shall support but not replace IRB deliberation, professional judgment, and decision-making.
5. Completed resubmission forms shall form part of the official IRB record and shall be retained in accordance with records management and archiving SOPs.
6. The Principal Investigator shall submit the completed protocol resubmission form and revised documents within 90 calendar days from receipt of the IRB decision requiring resubmission.

II. Purpose

To define the policy and procedures governing the use of protocol resubmission forms in the review of investigator responses to IRB decisions requiring modifications, clarifications, or additional information prior to final approval.

III.Scope

To define the policy and procedures governing the use of protocol resubmission forms in the review of investigator responses to IRB decisions requiring modifications, clarifications, or additional information prior to final approval.

VI. Responsibility

1. Principal Investigator (PI)

- a. Completes the protocol resubmission form in response to IRB comments
- b. Provides clear, point-by-point responses and identifies all changes made
- c. Submits revised documents together with the completed resubmission form

2. IRB Chair/Vice-Chair

- a. Determines the appropriate level of review for the resubmission
- b. Assigns reviewers, as applicable

3. IRB Reviewers

- a. Review the completed resubmission form and revised documents
- b. Assess whether IRB-required modifications have been adequately addressed
- c. Provide recommendations for approval, further modification, or referral to full board review

4. Staff Secretary

- a. Receives and logs resubmission forms and accompanying documents
- b. Verifies completeness of resubmission packages
- c. Distributes resubmission materials to assigned reviewers
- d. Maintains resubmission documentation in the IRB files

V. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	IRB issues decision requiring resubmission	IRB	During full-board meeting
2	Staff Secretary checks completeness of resubmission	Staff Secretary	1 calendar day
3	Chair determines review pathway	Chair	3 calendar days
4	Reviewers evaluate resubmission using resubmission form	Assigned Reviewers	14 calendar days
5	IRB decision on resubmission	Chair/IRB	3 calendar days
6	Communicate decision to PI	Staff Secretary	3 calendar days
7	File resubmission form and decision	Staff Secretary	1 calendar day

VI. Detailed Instructions

Step 1 The protocol resubmission form shall require the PI to:

- (1) list each IRB comment or condition;
- (2) describe the corresponding response or modification; and
- (3) indicate where changes appear in the revised documents.

Revised documents submitted without a completed resubmission form shall be considered incomplete and shall not be reviewed.

Step 2 Reviewers shall use the resubmission form to verify that:

- (1) all IRB comments have been addressed
- (2) revisions are consistent with ethical and scientific requirements; and
- (3) no new issues requiring additional review have been introduced

Step 3 The Chair determines whether the resubmission shall undergo expedited or full board review.

Step 4 Reviewers shall use the resubmission form to verify that:

- (1) all IRB comments have been addressed;
- (2) revisions are consistent with ethical and scientific requirements; and
- (3) no new issues requiring additional review have been introduced.

Step 5 If reviewer’s assessment identifies unresolved issues or new concerns, the resubmission may:

- (1) be returned to further modification; or
- (2) be referred for full board review, as appropriate

Step 6 The Staff Secretary communicates the IRB decision to the PI within 3 calendar days.

Step 7 The Staff Secretary files the resubmission form and IRB decision and updates the database.

VII. Forms

- 2. Form 9 Protocol Resubmission

VIII. References

- 1. PELI-IRB SOP 9 v. 2 March 9, 2026– Management of Protocol Resubmission
- 2. PELI-IRB SOP 7 v. 10 March 9, 2026– Full Board Review
- 3. National Ethical Guidelines for Health and Health-Related Research

IX. Revision Index

Version	Date	Reasons For Revision
1	March 9, 2026	Initial Release