

	<b>Peregrine Eye and Laser Institute Institutional Review Board</b>
PELI-IRB-SOP-17-02-2026	<b>SOP 17 Management of Appeals</b>
Version No. 2	
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## SOP 17 Management of Appeals

### **I. Policy**

The PELI-IRB shall provide a mechanism for investigators or stakeholders to appeal IRB decisions they believe were improperly reached. Appeals shall be reviewed and resolved fairly, transparently, and expeditiously, ensuring respect for IRB authority while providing a mechanism for reconsideration based on additional information or procedural concerns.

### **II. Purpose**

To describe the IRB procedures related to researchers' appeals regarding the feasibility and acceptability of IRB recommendations including its disapproval.

### **III. Scope**

This SOP covers procedures that begin with receipt of the appeal and end with communication of the IRB's action to the researcher and updating of the protocol database, to be completed within 3 months upon receipt of the appeal.

### **IV. Responsibility**

The IRB shall consider the perspective of the researcher regarding the feasibility and acceptability of IRB recommendations including its disapproval to ensure fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher. Appeals shall undergo full review and shall be resolved within three (3) months upon receipt of the fully documented appeal.

## V. Process Flow/ Steps Workflow

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive the appeal from the researcher	Staff Secretary	1 calendar day
2	Retrieve pertinent protocol file	Staff Secretary	1 calendar day
3	Notify Chair and Primary Reviewer/s	Staff Secretary	1-3 calendar days
4	Include in Agenda of the next regular meeting	Chair and Staff Secretary	7 calendar days
5	Discuss and deliberate on the appeal	Chair and IRB Members	must be done during the forthcoming board meeting after receipt of the appeal
6	Communicate PELI-IRB action	Chair	30 calendar days
7	File documents and update the protocol database	Staff Secretary	1 calendar day after meeting

## VI. Detailed Instructions

**Step 1** The Staff Secretary receives the letter of appeal and enters the pertinent information into the logbook.

**Step 2** The Staff Secretary retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, ICF, research tools and other related documents.

**Step 3** The Staff Secretary notifies the Chair and the primary reviewers about the letter of appeal and awaits further instructions.

**Step 4** The Chair instructs the Staff Secretary to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.

**Step 5** The primary reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal. The Chair presents the contents of the appeal and leads discussion. The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification. The committee then decides by consensus whether to accept any or all of the points raised in the appeal.

**Step 6:** Based on the deliberations, the Chair summarizes the decision points and instructs the Staff Secretary to prepare the draft decision letter using Form 17 Decision Letter Template for finalization and forwarding to the researcher (see SOP 27).

**Step 7** The Staff Secretary files all documents in the appropriate protocol folder and updates the protocol database.

## VII. Forms

1. Form 17 Decision Letter for Management of Appeals

## VIII. Reference

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

## IX. Revision Index

Version	Date	Reasons For Revision
1	July 16, 2022	Initial Release
2	March 9, 2026	<ul style="list-style-type: none"><li>•Revised and reclassified as SOP 11 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>