

	Peregrine Eye and Laser Institute Institutional Review Board
	SOP 18 Management of Appeals
	PELI-IRB SOP 18/01-0-2022
	Version No. 1
	Approval Date: July 16, 2022 Effective Date: July 16, 2022 Supersedes: Not Applicable

SOP 18 Management of Appeals

1. Purpose

To describe the IRB procedures related to researcher’s appeals regarding the feasibility and acceptability of IRB recommendations including its disapproval.

2. Scope

The SOP on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the committee’s action to the researcher and updating of the protocol, to be completed within 3 months upon of receipt of appeal.

3. 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 of researchers shall undergo full review and shall be resolved within three (3) months upon receipt of the fully documented appeal.

4. Process Flow/ Steps Workflow

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive the appeal from the researcher	Staff Secretary	1 day upon receipt
2	Retrieve pertinent protocol file	Staff Secretary	1 day upon receipt
3	Notify Chair and Primary Reviewer/s	Staff Secretary	1-3 days upon receipt
4	Include in Agenda of the next regular meeting	Chair and Staff Secretary	1 week upon receipt
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 committee action	Chair	within 3 months upon receipt of the appeal

7	File documents and update the protocol database	Staff Secretary	within the day of receipt of appeal and decision making by the IRB
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5. 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 IRB staff secretary to prepare the draft decision letter **Form 3.10** Decision Letter Template for his/her finalization and forwarding to the researcher. See SOP 28 Communicating IRB Decisions

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