

	<b>Peregrine Eye and Laser Institute Institutional Review Board</b>
PELI-IRB-SOP-27-02-2026	<b>SOP 27 Communicating IRB Decisions</b>
Version No. 2	
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## SOP 27 Communicating IRB Decisions

### I. Policy

IRB decisions shall be communicated clearly, promptly, and accurately to investigators and relevant stakeholders, specifying required actions, conditions, and timelines for compliance

### II. Purpose

To manage the communication of IRB decisions to ensure that all stakeholders are appropriately, accurately and promptly informed of the results of the deliberations of the IRB.

### III. Scope

The scope of this SOP covers procedures and special requirements for notification of researchers/investigators of the decisions or actions of the IRB. The IRB uses either a Notification Form to summarize required modifications in the protocol or an Approval Form to indicate its approval. This SOP begins with the finalization of recommendations of the IRB or reviewers and ends with the filing of the decision document in the protocol file.

### IV. Responsibility

It is the responsibility of the IRB to communicate its decisions to the researcher within two (2) weeks after the review of the complete set of submission documents. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the IRB and signed by the Chair.

## V. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Finalize recommendations made by the committee during the full board review and recommendations made by the reviewers during the expedited review	Chair	After the meeting
2	Transfer the information from minutes of meeting to IRB decision forms or templates	Staff Secretary Member-Secretary	After the Chair finalized the recommendations
3	Approve the IRB decision document	Chair	2 calendar days
4	Transmit IRB decision to researcher	Staff Secretary	2 calendar days after approval
5	File the decision document in the protocol file and update the Protocol Database	Staff Secretary	1 calendar day

## VI. Detailed Instructions

**Step 1** For finalization of Committee's Recommendations See SOP 7 on Full Review and for finalization of Reviewers' Recommendations, see SOP 6 Expedited Review).

**Step 2** Upon approval of the draft minutes, or finalization of the reviewers' recommendations, the Staff Secretary drafts the decision letter using Form 4.6 or Form 4.7 for initial review and Form 4.8 or Form 4.9 for post-approval review.

**Step 3** The Chair reviews and approves the decision documents within two (2) calendar days

**Step 4** The notification or approval letter is sent to the researchers within two (2) calendar days after the approval of the decision document.

**Step 5** The Staff Secretary files decision documents within the day of transmitting the decision. The Staff Secretary also maintains all protocol related decisions or actions in the protocol folder to facilitate retrieval. This action is also noted in the protocol database The protocol file folders are stored securely in locked cabinets in the PELI-IRB office.

## VII. Forms

1. Form 4.6 Notification of IRB Decision
2. Form 4.7 Document Decision Form
3. Form 4.8 Request for Information for Post Approval Procedures
4. Form 4.9 Approval Letter for Post-Approval Procedure

### VIII. References

1. National Ethical Guidelines for Health and Health-related Research 2017
2. Philippine Health Research Ethics Board Standard Operating Procedures 2020

### IX. Revisions Index

<b>Version</b>	<b>Date</b>	<b>Reasons For Revision</b>
1	July 16, 2022	Initial Release
2	March 9, 2026	Revised and reclassified as SOP 11 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics  Added a Policy section to define the governing principles and general guidelines of the SOP.  Convert all timelines to calendar days  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