

	Peregrine Eye and Laser Institute Institutional Review Board
	SOP 28 Communicating IRB Decisions
	PELI-IRB SOP 28/01-0-2022
	Version No. 1
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SOP 28 Communicating IRB Decisions

1. 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.

2. 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.

3. 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.

4. 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	Within 2 days
4	Transmit IRB decision to researcher	Staff Secretary	Within 2 days after approval
5	File the decision document in the protocol file and update the Protocol Database	Staff Secretary	Within the day of transmittal to researcher

5. Detailed Instructions

Step 1 For finalization of Committee's Recommendations See SOP 10 on Full Review and for finalization of Reviewers' Recommendations, see SOP 9 Expedited Review).

Step 2 Upon approval of the draft minutes, or finalization of the reviewers' recommendations, the Staff Secretart drafts the decision letter using **Form 2.5** or **Form 2.6** for initial review and **Form 2.7** or **Form 2.8** for post-approval review.

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

Step 4 The notification or approval letter is sent to the researchers within two (2) 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.