

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB-SOP-26-06-2026	SOP 26 Preparation of Communication Records
Version No. 6	
Approval Date: March 9, 2026	
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SOP 26 Preparation of Communication Records

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall ensure that all official communications related to IRB review, decisions, requirements, and oversight activities are accurately prepared, documented, and maintained as part of the permanent IRB record.

1. Communication records shall include all written correspondence and official notifications between the PELI-IRB and investigators, sponsors, institutional officials, and other relevant stakeholders concerning research protocols and IRB actions.
2. Preparation of communication records shall ensure that IRB decisions, conditions, and required actions are conveyed in a clear, timely, and unambiguous manner, consistent with approved SOPs and ethical review outcomes.
3. All communication records shall be traceable to the corresponding protocol, IRB review, or administrative action, ensuring continuity and accountability throughout the lifecycle of the study.
4. Communication records shall be prepared and maintained in a manner that supports:
 - a. verification of investigator compliance with IRB requirements;
 - b. monitoring of response timelines and follow-up actions; and
 - c. transparency of IRB oversight activities.
5. Confidentiality and data protection shall be maintained in all IRB communications, in accordance with institutional policies and applicable ethical and regulatory standards.
6. Communication records shall form part of the official IRB documentation, retained and archived in accordance with records management and archiving SOPs.

II. Purpose

To describe the procedures for the management of incoming and outgoing communications by the IRB and filing of such records.

III. Scope

This SOP covers the procedures related to the management of receiving, processing and filing of IRB communications. This SOP starts with the sorting of incoming and outgoing communications and ends in the filing and storing of such communications

IV. Responsibility

It is the responsibility of the Staff Secretary, under the supervision of the Vice-Chair, to document all communications in a logbook or electronic database, separating protocol-related communications from administrative communications to ensure accountability and efficient filing for tracking and retrieval.

Incoming communications shall be acted upon promptly by the Chair or Vice-Chair

V. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Sort all incoming and outgoing communications	Staff Secretary	Upon receipt
2	Record the details of the incoming and outgoing communications	Staff Secretary	Upon receipt
3	Act on incoming communications	Chair or Member-Secretary	1-2 calendar days
4	File communication documents to corresponding binders	Staff Secretary	Upon receipt

VI. Detailed Instructions

Step 1 IRB communications refer to documented communications and can be in the form of hard copy communications or emails. Upon receipt of the communications, the Staff Secretary sorts these incoming and outgoing communications into:

- a. Protocol and protocol-related communications
- b. Administrative communications

Step 2 The Staff Secretary organizes a log of incoming and outgoing communications. This log should have at least the following elements:

- a. Date of incoming and outgoing communications
- b. Name of IRB party contacted
- c. Content of outgoing communication or incoming communication

- d. Notation of any follow-up if necessary
- e. Contact information of sending party
- f. Name and signature of individual who received the communication and completed the record

Step 3 Upon receipt of the communication from the Staff Secretary, the Chair or Member-Secretary acts on this incoming communication within 1-2 calendar days to avoid delay. The Chair signs these communications.

Step 4 Copies of incoming and outgoing communications are filed in their respective folders. The Staff Secretary files the protocol-related communications in the protocol file folder while the administrative communications are filed in the IRB communications folder.

- a. Protocol file folder
- b. IRB Communications folder
- c. Additional folder if needed

VII. Forms

1. Logbook for Incoming Communications
2. Logbook for Outgoing Communications

VIII. References

1. National Ethical Guidelines for Health and Health -related Research 2017
2. Philippine Health Research Ethics Board SOP 2020
3. PELI-IRB SOP 2017

IX. Revision Index

Version	Date	Reasons For Revision
01	August 30, 2013	Patterned SOP after the SOP drafted by the DOH SOP Team (based on the FERCAP template)
02	April 1, 2014	Added Section 4.7 Conduct of Meeting
03	Jan 26, 2016	Changed logo of “Pacific Eye and Laser Institute” to “Peregrine Eye and Laser Institute” in the document header

04	June 15, 2017	<p>The following major revisions of both SOP and forms 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.11, 3.12 made in compliance with PHREB recommendations of official finding report last June 8, 2017:</p> <p>Clarify the following and state specific procedures on the following:</p> <ul style="list-style-type: none"> ○ Invitation of “guest” (SOP 4.7.2), ensure confidentiality ○ Attendance by video or teleconference SOP 6.5 ○ Decision via consensus or voting page 15 #1 ○ abstention of member page 15 #1 confidentiality clause SOP 4.6.9 ○ Follow the standard agenda and minutes format <ul style="list-style-type: none"> ▪ Call to order ▪ Declaration of quorum ▪ Declaration of COI ▪ Approval of previous minutes ▪ Business arising from the previous minutes ▪ Review of new protocols ▪ Review of resubmitted protocols ▪ Progress Reports ▪ Amendment/s ▪ PD/PV and Noncompliance ▪ SAE/SUSARS ▪ Early Study Termination, close out reports, Final Reports ▪ Site visits ▪ Reports of expedited reviews ▪ Other matters <p>The above items should always be part of the agenda and minutes, whether a report on any of the items will be discussed in the meeting. If there are no reports for a specific item, then it should be indicated as NONE.</p> <p>Invite PI only to the IRB meeting for clarificatory purposes</p> <p>Use PELI IRB Protocol No., full title of protocol and name of PI to identify protocols in the meeting agenda</p> <p>Ensure the agenda is complete following the template suggested in the SOP</p> <p>Ensure that the IRB deals with the PI directly and not with the sponsor</p> <p>Indicate type of review in the agenda and minutes of the meeting (expedited or full board)</p> <p>Document in the SOP current practices of the Staff Secretary on filing of documents</p> <p>Prepare an SOP on the disposal of archives</p> <p>Ensure that the archiving color coding scheme of the Staff Secretary be formalized in the SOP</p> <p>Ensure adequate space for archiving for future protocols</p> <p>Improve the database to track timelines of critical points in the review process and that can generate data useful for the IRB</p>
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5	July 16, 2022	<p>Reformat numbering to conform to 2020 PHREB SOP Workbook</p> <p>Refer to SOP 4.3 of version 4 of PELI-IRB</p> <p>Add references within the SOP</p> <p>Revise “Purpose”</p> <p>Revise “Scope” to indicate specific coverage</p> <p>Revise “Responsibility”</p> <p>Revise “Process Flow/Steps”</p> <p>Make “Process Flow/Steps” and “Detailed Instructions” consistent</p> <p>Add “Forms” to include forms to be used in the SOP</p>
6	March 9, 2026	<p>Revised and reclassified as SOP 25 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics</p> <p>Added a Policy section to define the governing principles and general guidelines of the SOP.</p> <p>Convert all timelines to calendar days</p> <p>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</p>