PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB-SOP-16-06-2026	
Version No. 6	**SOP 16** **Responding to Participant Queries and Complaints**
Approval Date: March 9, 2026	
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SOP 16 Responding to Participant Queries and Complaints

I. Policy

The PELI-IRB shall ensure that queries, concerns, and complaints from research participants, representatives, or the public regarding studies under IRB oversight are received, documented, investigated, and addressed in a timely and fair manner. Participant concerns shall be monitored for patterns that may indicate systemic issues requiring IRB action or study modification.

II. Purpose

To describe the IRB process in reviewing and addressing participants' queries and complaints.

III. Scope

This SOP is limited to queries and complaints of research participants, or their families, in studies that have been issued an ethical approval by the IRB. It begins with the receipt and recording of the query or complaint and ends with the logging of the response and inclusion in the agenda of the REC meeting.

IV. Responsibility

The IRB is responsible for attending to queries and complaints from clients, patients, or research participants promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the IRB staff or referred to the primary reviewers of the specific protocol. All complaints must be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion.

V. Process Flow/ Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive and record queries and complaints	Staff Secretary	1 calendar day
2	Refer query or complaint to competent authority.	Staff Secretary	1 calendar day
3	Formulate a response	Primary Reviewers Chair	7 calendar days
4	Include in the agenda of the next full board meeting	Staff Secretary and Chair	Not applicable
5	Summarize actions taken and Communicate response	Staff Secretary and Chair	1-3 calendar days

VI. Detailed Instructions

Step 1 The Staff Secretary receives the query or complaint, records it in Form 16 Query/Complaint Record including date, time, name and contact details of concerned party, specific study, starting date of participation, and concerns of the participant.

Step 2 The Staff Secretary refers queries related to specific protocols approved by the IRB to the Primary Reviewers and refers all complaints to the Chair, who determines the level of risk involved. Minimal risk complaints are referred to the primary reviewers of the concerned protocol. Complaints involving more than minimal risk are referred to the full board through a special meeting to be conducted within 48 hours. The Staff Secretary notifies the concerned Primary Reviewers that they will lead the discussion and provides relevant materials for reference.

Step 3 If study protocol-related query or complaint, accomplished Form 16 should be reviewed and signed by primary reviewer. For more than minimal risk, the committee may choose any of the following options:

a. Constitute a site visiting team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.
b. Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.

c. Formulate recommendation if satisfied with the adequacy of information. Possible recommendations are :

- Request for explanation/justification from researcher
- Accept request/demand of participant
- Suspension of further recruitment
- Amendment of protocol
- Re-consent of participants
- Others

Step 4 Complaints that involve more than minimal risk are included in the agenda of the next regular meeting. See SOP 7 Full Review.

Step 5 The Staff Secretary summarizes the actions taken and outcomes of the query/complaint in Form 15 Query/Complaint Record signed by the Chair and communicates the response. See SOP 27 Communicating IRB Decisions.

VII. Forms

1. Form 16 Query/Complaint Record

VIII. References

1. 2020 PHREB SOP Workbook
2. PELI-IRB SOP 2017

IX. Revision Index

Version	Date	Reasons For Revision
01	August 8, 2013	Patterned SOP after the SOP drafted by the DOH SOP Team (based on the FERCAP template)
02	February 3, 2014	Revised section 3.7 (additional requirements from the PI for premature suspension or termination of a research study), added section 3.8 suspension or termination of IRB approval, added Form 3.11 (Reminder Letter), added section 3.9 continuing review, added Form 3.12 Application for Continuing Review
03	January 26, 2016	Changed logo of "Pacific Eye and Laser Institute" to "Peregrine Eye and Laser Institute" in the document header and in the header of forms 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.11, 3.12

04	June 15, 2017	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: State in the SOP 3 that the IRB reviews by full board reports of onsite SAE/SUSARs and indicate timelines for reporting (SOP 3.1.5.2 SAE reporting timelines should comply with the ICH-GCP guidelines) Ensure that Protocol violations and deviations are categorized accordingly Define major and minor violations Organize the sequence of discussion of the protocol (i.e. Scientific, then ethical issues, ICF; include the PDPVs and reasons for that) Ensure appropriate timelines for SAE reporting are incorporated in the SOP AND communicated to the PI Ensure timely review of the continuing reports Indicate reviewers of SAEs in the minutes Ensure that SAE reviewer is a medical doctor Categorize protocol deviations into major or minor and how deviations will affect risk Reflect recommended actions required of PI on deviations/violations in the meeting minutes Consistently require Final reports for all studies Communicate to the PI the results of review of final report. Ensure consistency of the flow chart with the detailed instructions (e.g. person responsible for a particular process).
5	July 16, 2022	Reformat numbering to conform to 2020 PHREB SOP workbook Refer to SOP 3.5 of version 4 of PELI IRB Adapt 2020 PHREB SOP 26 Management of Queries/Complaints Add references within the SOP Make a more detailed workflow Add “forms” to include forms used in the SOP
6	March 9, 2026	Revised and reclassified as SOP 15 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