PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute Institutional Review Board**
PELI-IRB-SOP-07-10-2026	
Version No. 10	**SOP 7 Full Board Review**
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SOP 07 Full Board Review

I. Policy

A. The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall conduct full board review of research protocols that involve more than minimal risk, vulnerable populations, novel or high-risk interventions or devices, or other ethical considerations requiring deliberation by the convened IRB. Vulnerable participants are persons who may be relatively or absolutely incapable of protecting their own interests due to limitations in decision-making capacity, power relationships, education, or resources, and therefore require additional protections when participating in research.

1. Full board review shall be conducted at a convened IRB meeting with quorum present, in accordance with applicable ethical guidelines and institutional requirements.
2. Protocols undergoing full board review shall be subject to independent, multidisciplinary evaluation and collective deliberation by IRB members to ensure adequate protection of the rights, safety, and welfare of research participants.
3. The IRB shall review, discuss, and decide on protocols based on:
    a. scientific and ethical justification;
    b. risk–benefit assessment;
    c. adequacy of the informed consent process;
    d. safeguards for vulnerable populations, when applicable; and
    e. compliance with applicable ethical and regulatory standards.
4. Decisions of the IRB during full board review shall be made through documented deliberation and voting, and may include approval, approval with conditions, deferral pending modifications, or disapproval
5. All protocols undergoing full board review shall be evaluated using the appropriate PELI-IRB study assessment forms, completed by designated primary and secondary reviewers prior to the convened meeting.

6. Study assessment forms shall be used to ensure a structured, consistent, and comprehensive review of ethical, scientific, and regulatory aspects of the protocol, including but not limited to;
    a. scientific validity and study design
    b. risk–benefit assessment;
    c. participant selection and protections;
    d. informed consent process; and
    e. data safety and monitoring considerations
7. Completed assessment forms shall serve as reference documents during full board deliberations and shall inform IRB discussion, decisions, and required modifications
8. The use of assessment forms shall support but not replace collective IRB deliberation, professional judgment, and decision-making by the convened Board
9. Completed assessment forms shall form part of the official IRB record for each protocol reviewed and shall be maintained in accordance with SOPs on documentation, records management, and archiving

B. Policy on Suspension or Termination of IRB Approval

The PELI-IRB may suspend or terminate IRB approval of a research protocol when continuation of the study poses unacceptable risk to participants, involves serious or continuing non-compliance, or fails to meet ethical or regulatory requirements.

Decisions to suspend or terminate approval shall be made by the IRB in accordance with applicable SOPs, documented in the meeting minutes, and communicated to the investigator and relevant authorities as required.

C. Recruitment Practices and Advertisements in Full Board Review

1. In the conduct of full board review, the Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall evaluate participant recruitment practices and advertisements as an integral component of the ethical review of research protocols.
2. Reviewers shall assess recruitment practices and advertisements to ensure:
    a. voluntary participation;
    b. absence of coercion;
    c. accurate and non-misleading information;
    d. appropriate compensation.

D. Recruitment methods shall be reviewed for equitable selection of participants, consistent with the scientific objectives of the study and ethical principles of justice.

E. When recruitment involves vulnerable populations, the IRB shall require additional safeguards to ensure protection of participant rights and welfare.

F. Compensation, reimbursement, or incentives related to participation shall be evaluated to ensure that they do not unduly influence the decision to participate in the research.

G. All recruitment materials, including advertisements, scripts, posters, and other participant-facing communications, shall require IRB approval prior to use.

H. Any changes to approved recruitment practices or advertisements shall require prior IRB review and approval before implementation.

I. Approved recruitment materials shall form part of the official IRB record and shall be maintained in accordance with documentation and archiving SOPs.

I. Purpose

To describe the full board review for protocol and post approval submissions.

II. Scope

This SOP applies to initial, resubmissions, and post-approval submissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups.

1. The following types of protocols should undergo full board review after initial submission:
    a. Clinical trials about investigational new drugs, biologics, or device in various phases (Phase 1, 2,3)
    b. Phase 4 intervention research involving drugs, biologics, or device
    c. Protocols including questionnaires and social interventions that are confidential in nature that may cause psychological, legal, economic and other social harm
    d. Protocols involving vulnerable participants that require additional protection from the IRB during review.
    e. Protocols that involve collection of identifiable biologic specimens for research
2. Criteria for Full Board Review of post approval submissions:
    a. Major revisions of the protocol and informed consent after initial review
    b. Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/exclusion criteria, safety issues, etc.)
    c. Major amendments that change the risk/benefit ratio
    d. Major protocol violations are those, which affect the safety of the patient or the integrity of data or study being conducted.
    e. Progress/Final reports that deviate from original approval given by the IRB

f. Onsite SAE or SUSARs that may require protocol amendment or re-consent of participants

III. Responsibility

It is the responsibility of the IRB to conduct full board reviews of study protocols and post approval submissions to ensure compliance with technical and ethical standards in the conduct of research involving human participants and identifiable human data and materials.

Only protocols submitted for at least 4 weeks before a scheduled meeting shall be included in the agenda for full review. The IRB holds its regular full board meetings on the 3rd week of January, April, July and October. If the day is a holiday, the meeting shall be held on Thursday of the following week. Special meetings may be held upon the discretion of the board. The decision shall be communicated to the proponent within six (6) weeks after submission of required documents.

The Staff Secretary is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version of the submitted protocol package.

In addition, the Staff Secretary should create a specific protocol file, make copies of the file and then distribute the copies to the PELI-IRB reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated. The Vice-Chair shall ensure compliance of the Staff Secretary with this SOP.

Designated reviewers shall thoroughly review assigned protocols and document findings, observations, comments, and recommendations in the Study Assessment Forms before submission to the Staff Secretary.

IV. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Distribute documents	Staff Secretary	at least 7 calendar days before the meeting
2	Review protocol and submit recommendation	Primary Reviewers /Independent Consultants	7 – 14 calendar days
3	Submit assessment forms to Chair	Staff Secretary	1 calendar day
4	Include in meeting agenda	Chair Staff Secretary	at least 14 calendar days before the next meeting
5	Presentation of findings	Primary Reviewers	During meeting
6	Discussion	IRB Members	During meeting
7	Summary of issues	Chair	During meeting
8	IRB decision	Chair and IRB Members	During meeting
9	Documentation deliberation	Member-Secretary and Staff Secretary	1 calendar day
10	Communicate decision to PI	Chair and Staff Secretary	1-3 calendar days after final decision
11	File documents and update database	Staff Secretary	1 calendar day after final decision

VI. Detailed Instructions

Full Board Review Proper

Step 1 The Staff Secretary distributes the protocol package to the IRB members by granting access to electronic files at least 7 calendar days before the full board meeting. **Step 2** The assigned reviewers review the protocol or post-approval report, properly accomplish the assessment forms, and submit them to the Staff Secretary once completed within 7 to 14 calendar days from receipt of the documents.

1. The Primary Reviewers shall:
    a. Use the Protocol Evaluation Form for the protocol and the Informed Consent Evaluation Form to review the protocol and consent form and write relevant comments

b. Check the CV or information of the investigators (including GCP training for clinical trials), the study sites and other protocol-related documents, including advertisements.
c. Consider whether the study and training background of the PI are related to the study.
d. Look for disclosure or declaration of potential conflicts of interest.
e. Non-physician PI should be advised by a physician when necessary.
f. Determine if the facilities and infrastructure at the study sites can accommodate the study.
g. Check the "Assent Form" if the protocol involves children or other vulnerable participants as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedures to be done should be explained to the child or vulnerable participant separately).

2. The primary reviewers take note of the following Review Guidelines:

a. The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness.

b. In assessing the degree of risk against benefit, determine whether the risks are reasonable in relation to the anticipated benefits, and/or if the risks can be minimized.

c. Study participants are selected equitably especially if randomization is not to be used. Study participant's information sheet should be clear, complete and written in understandable language.

d. There is voluntary, non-coercive recruitment of study participants.

e. The Informed Consent is adequate, easy to understand and properly documented.

f. There should be a translation of the Informed Consent document into the local dialect which should be comprehensible by the general public.

g. The procedure of getting the informed consent is clear and unbiased.

h. The persons who are responsible for getting the informed consent are named and they introduce themselves to the study participants.

i. The informed consent process entails use of adequate, complete and understandable written and oral information that are given to the research participant and, when appropriate, their legally acceptable representatives.

j. If applicable, the informed consent process has clear justification for the intention to include in the research individuals who cannot consent, and a full account of the

arrangement for obtaining consent or authorization for the participation of such individuals.

k. The research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.

l. There is provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support; treatment for study related injuries, as well as compensation for participation to cover expenses like transport and loss of wages because of participation.

m. The compensation for study participation should not unduly influence potential participants to participate in the research study.

n. There are appropriate safeguards included to protect vulnerable study participants.

o. Contact persons with address and phone numbers are included in the informed consent.

p. There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.

q. There are appropriate measures to ensure confidentiality and security of personal information concerning research participants.

r. There is a description of the persons who will have access to personal data of the research participants, including medical records and biological samples.

s. There are appropriate contracts or memoranda of understanding especially in collaborative studies.

t. The medical care provided to research participants during and after the course of the research should be clearly stated.

u. The steps to be taken if research participants voluntarily withdraw during the course of the research should be clearly stated.

v. There should be provisions for compensation/treatment in the case of injury/disability/death of a research participant attributable to participation in the research.

w. If applicable, there should be a description of the plan to make the study product available to research participants following the research.

x. Examine community involvement and impact/benefit of the study to the community and/or the institution.

If relevant, the reviewer looks for the following in the protocol:

- Community consultation
- Impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn
- The influence of the community on the consent of individuals
- Involvement of local researches and institutions in the protocol design, analysis and publication of the results
- Contribution to development of local capacity for research and treatment in benefit to local communities
- Sharing study results with the participants/community
- A description of the availability and affordability of any successful study product to the concerned communities following the research
- After reviewing the protocol and the documents, the reviewer recommends a decision:
- Record the decision by marking the appropriate block in the assessment form: Approved, Minor revision, Major revision for resubmission or Disapproved Include comments and reasons for disapproval.
- Check the completeness and correctness of marked items in the assessment forms. Indicate the date and affix the reviewer's signature in the decision form.

Once completed, the reviewers submit the assessment forms completed forms to the Staff Secretary together with the protocol documents.

Step 3 The Staff Secretary sends the hard and soft copies of the assessment forms to the Chair upon receipt from the reviewers.

Step 4 The protocol or post-approval submission review is included in the next meeting agenda at least 14 calendar days before the next full board meeting. See SOP 22 Preparation and Distribution of Meeting Agenda.

Step 5 The assigned reviewers present their findings and recommendations during the full board meeting.

- Form 4.3 and Form 4.5 for initial approval
- Forms 11, 12, 13,14,15,19, and 20,for the corresponding post approval submission

If a Primary Reviewer for a protocol or an assigned reviewer for a post approval submission cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.

Step 6 The Chair leads the discussion of the ethical issues using Form 4.3 Study Protocol Assessment Form for Ethical Review and the Form 4.5 Informed Consent Assessment Form and the assessment of the primary reviewers as guides for an orderly exchange of ideas.

During the discussion, the following considerations should be observed:

- A member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the Chairperson prior to the review of the application and recorded in the minutes;
- A decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g. investigators, representatives of sponsor, Independent Consultants) from the meeting, with the exception of EC staff;
- The decisions should only be made at meetings where a quorum is present;
- The documents required for a full review of the application should be complete and relevant elements should be considered before a decision is made;
- Decisions should be arrived at through consensus when possible; when a consensus is unlikely, the PELI- IRB members vote by raising of hands.
- Advice that is non-binding may be appended to the decision;
- In cases of conditional decisions, clear suggestions for revision and procedure for having the application re-reviewed should be specified;
- A negative decision should be supported by clearly stated reasons.

Step 7 The Chair summarizes the technical and ethical issues that were identified, the issues that were resolved /not resolved, including the recommendations for the issues that were not resolved.

Step 8 The Members in attendance arrive at a decision on the protocol or post approval submission.

3. The following are the possible decisions/ actions for full board reviews:

a. **For protocol submissions /resubmissions:**

(1) Approval

(2) Minor revisions required

(3) Major revisions require

(4) Disapproval

(5) Pending, Clarification needed before decision can be made

b. **For SAEs/SUSARs:**

(1) Notation with no further action required

(2) Further information or action required

(3) Pending, Clarification needed before decision can be made

c. **For Protocol amendments:**

(1) Approved,

(2) Additional justification/information required,

(3) Re-consent required

(4) Disapproved

(5) Clarification or Minor Modification subject to expedited review at the level of the Chair

d. **For Progress/Final Reports:**

(1) Take note and no further action required

(2) Request further information

(3) Recommend further action

(4) Pending, if major clarifications are required before a decision can be made

(5) For Protocol Déviations /Violations :

(6) Take note and no further action required

(7) Request an amendment to the protocol

(8) Request an amendment to the informed consent form

(9) Suspend or Terminate the Study

(10) Pending, if major clarifications are required before a decision can be made

e. **For Early termination report:**

(1) Approve with no further action

(2) Request information

(3) Recommend further action

f. **For continuing review:**

(1) Uphold original approval with no further action

(2) Request for further information

(3) Recommend further action

(4) Pending, if major clarifications are required before a decision can be made

(5) Disapproval

If the study is approved, the IRB determines the duration of validity of approval and frequency of continuing review.

Step 9 The Staff Secretary documents the committee deliberation and action during the meeting and the Member-Secretary ensures that the important points during the discussion are reflected in the minutes of the meeting. See SOP 25 Preparation of the Minutes of the Meeting

Step 10 The Staff Secretary communicates the decision of the IRB to the PI 1-3 calendar days after full board decision. See SOP 27 Communicating IRB Decisions.

For protocol reviews: Form 4.6 Notification of IRB Decision and/or Form 4.7 Approval Letter are prepared by the Staff Secretary, checked and signed by the Chair and sent to the PI. The letter contains identification of the document approved with version numbers and dates, the frequency of continuing review and the responsibilities of the PI throughout the course of the study.

For post-approval submissions, Form 4.8 Request Information for Post Approval Procedures or Form 4.9 Approval Letter for Post Approval Procedures is prepared by the Staff Secretary, checked and signed by the Chair and sent to the PI.

Step 11 The Staff Secretary files copies of the assessment forms in the Protocol File Folder and updates the database.

V. Forms

1. Form 4.3 Protocol Evaluation Form for Ethical Review
2. Form 4.5 Informed Consent Evaluation Form
3. Form 4.6 Notification of IRB Decision
4. Form 4.9 Approval Letter
5. Form 4.8 Request Information for Post Approval Procedures
6. Form 4.10 Approval Letter for Post Approval Procedures
7. Forms 12 Protocol Amendment Review form
8. Form 13 Progress Report
9. Form 14 Final Report
10. Form 15 Deviation /Non-compliance / Violation Report
10. Form 19 Early Study Termination Form
11. Form 20 Continuing Review Application

VI. Références

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

VII. Revision Index

Version	Date	Reasons For Revision
2	August 8, 2013	Pattern SOP after the SOP drafted by the DOH SOP Team (based on the FERCAP template)
3	February 3, 2014	Added concise but detailed flowcharts as guides for PI/Research coordinators/PELI-IRB members/secretariat, changes made to IRB protocol submission checklist, changes to Form 2.1, added Form 2.9(Review of Protocol Modifications) (Statement of Agreement to Comply with Ethical Principles), changes to Form 2.3; considerations to decision-making during full-board review are added (based on WHO guidelines Section 7); added more elements to Review Guidelines following WHO Guidelines Section 6.2; revised Form 2.6, responsibilities of the PI, revised Form 2.1 (Application for Protocol Review); added section 2.6 SOP on Informed Consent Process; added Section 2.7 SOP on Assent of Children or Decisionally-Impaired Individuals, added Section 2.8 General Recruitment Practices and Advertisements
4	Sept 9, 2015	Added "Terms of Reference / Clinical Trial Agreement" to documents to be submitted under new protocol review
5	Jan 26, 2016	Changed logo of "Pacific Eye and Laser Institsitute" to "Peregrine Eye and Laser Institute" in the document header and in the header of forms 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9
6	June 15, 2017	The following major revisions of both SOP and forms 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 made in compliance with PHREB recommendations of official finding report last June 8, 2017: Ensure SOP 2.7 on classification of assent for children and decision impaired individuals is consistent with the NEGHR Ensure consistency of the flow chart with the detailed instructions (e.g. person responsible for a particular process) Clarify the role of the Technical Review Committee; Ensure consistency in the implementation of SOP 2.4.5.10 ● Ensure that sponsors submit SR/NSR assessment for medical devices ● Ensure that the IRB implements SOP 2.5 on risk assessment, i.e. Significant Risk [SR] vs No Significant Risk [NSR]) on type of review for medical devices ● Ask the PI to submit the required number of copies of protocol package and other documents for initial review (SOP 2.1.5.5) ● Include timelines for critical control points in the protocol review process to ensure efficiency of review submission and approval ● Revise the contents and format of the Protocol and ICF assessment forms to reflect the essential elements of a protocol and informed consent ● Require inclusion of Protocol and ICF Assessment form in the distribution of Protocol to IRB members prior to the IRB meeting ● Explain in detail the methodology in the protocol or describe the process of getting the Informed Consent (Who, When, How) ● Primary reviewer should present the summary or abstract of the

		protocol and the issues identified in the review of the protocol; invite Independent Consultant for risk assessment as needed. IRB should assess the R/B of the protocol not the PI ● Lay member/s should comment on the language used in the ICF ● Consider translating ICF in Chinese language, as needed ● Describe clearly how the IC will be taken considering that the patient-participants may have visual problems Follow the SOP that the Chair should summarize protocol points of discussion
7	Oct. 17, 2017	The following major revisions made in compliance with PHREB recommendations stated in the provisional letter dated last July 31, 2017: ● Clearly state the role of the Technical Reviewer and primary reviewer and provide specific timelines regarding technical review and ethics review. ● Assent for Children to follow 2017 NEGHR ●Change in Initial Submission Copies
8	July 16, 2022	• Reformat numbering to conform to 2020 PHREB SOP workbook • Refer to SOP 2.4 of version 7 of Chapter 2: Initial Review Procedures of PELI IRB SOP • Add references within the SOP • For Responsibility: add schedule of full board meetings and 6 week deadline for communicating IRB decision to the proponent • Make process flow and steps consistent • Remove steps 1-6 and start the SOP with the distribution of the protocol package to the rest of the IRB members ; refer to initial steps and timelines for protocol submissions, resubmissions , review of medical devices and post approval submissions. • Change timeline of review of protocol / post approval submission by assigned reviewer to 1-2 weeks upon receipt of protocol package or report • Change timeline of inclusion in full board agenda from 1 day upon being informed to at least 2 weeks from the full board meeting • Include “Presentation of review findings”; “Discussion”; “Summary of issues and resolutions”; and all possible “IRB actions” for full board reviews in the Steps. • Add “forms” to include forms used in the SOP

9	April 24, 2025	To include additional decision for protocol amendment • Clarification or Minor Modification subject to expedited review at the level of the Chair
10	March 9, 2026	Revised and reclassified as SOP 7 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