PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute Institutional Review Board**
PELI-IRB SOP 06-09-2026	
Version No. 9	**SOP 06 Expedited Review**
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SOP 06 Expedited Review

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) adopts expedited review as a legitimate and ethically appropriate review mechanism for research activities that involve no more than minimal risk to participants and do not raise complex ethical issues requiring deliberation by the full board.

1. Expedited review shall be applied only to research protocols and post-approval submissions that meet established criteria for minimal risk, do not involve vulnerable populations, and do not introduce new or significant ethical concerns.
2. The determination that a protocol or submission qualifies for expedited review shall be made by the PELI-IRB through its designated authority, based on a documented assessment of risk, study population, and research procedures.
3. Expedited review shall not compromise the ethical rigor, independence, or scientific and ethical standards applied to full board review. Protocols reviewed under the expedited process shall be evaluated using the same ethical principles and assessment standards as those reviewed by the full board.
4. Expedited review may be used for:
    a. initial review of minimal-risk research protocols;
    b. continuing review, minor amendments, and other post-approval submissions that do not adversely affect participant safety, rights, or welfare; and
    c. protocol modifications required to protect participant safety, provided that such changes do not introduce additional risks.
5. Protocols involving vulnerable populations, more than minimal risk, or significant ethical complexity shall not be eligible for expedited review and shall be referred for full board review.

6. All expedited review decisions shall be properly documented, communicated to the investigator, and reported to the full board for information, to ensure transparency, accountability, and institutional oversight.
7. The PELI-IRB reserves the right to refer any protocol or submission initially considered for expedited review to the full board at any stage, should new information or ethical concerns arise.

II. Purpose

To describe the procedures for the review of protocols that qualify for expedited review.

III. Scope

This SOP applies to the review and approval of study protocols and post approval submissions with minimal risk to study participants, whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise.

The following are types of protocols that can be subjected to expedited review:

a. Research methodologies that involve no more than minimal risk to the participants.
b. Protocols of a non-confidential nature, not likely to harm the status or interests of the study participants and not likely to offend sensibilities or cause psychological stress to the individuals involved.
c. Protocols not involving vulnerable participants (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in the case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).
d. Protocols that involve collection of anonymized biological specimens for research purposes by non-invasive means (e.g. collection of small amounts of blood, body fluids, or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
e. Research involving data, documents, or specimens that have already been collected or will be collected for ongoing medical treatment or diagnosis.

The following post approval submissions are qualified for expedited review:

a. Proposed continuing reviews, protocol amendments, and end of study reports that have minor modifications and no significant risk to the study participants.
b. Minor amendments to previously approved research where such amendment

c. Do not affect the substance of the original protocol and where no major new ethical issues are raised.
d. Protocol amendments for safety reasons, that is, in order to protect the welfare of the participants.
e. Request for extension for an approved project with no modification of the protocol.
f. Approval of recruitment and publicity material for approved projects.
g. Change of associate or co-investigators.
h. Provision of a retrospective statement that the quality assurance study has been conducted in an ethical manner to assist journal editors to assess articles presented for publications.

IV. Responsibility

In conducting an expedited review, the IRB must demonstrate due diligence in the protection of human participants. Expedited review is the responsibility of Primary Reviewers appointed to assess any protocol that qualifies for the expedited process. The same assessment forms used for full board review shall be used to evaluate the scientific and ethical merits of the protocol. Expedited reviews shall be carried out within four (4) weeks of submission of documents.

V. Process Flow/ Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Review protocol/ post- approval submission and submit findings/recommendations to the Staff Secretary	Primary Reviewers /Independent Consultants	7-14 calendar days
2	Finalization of review results	Chair	1-3 calendar days
3	Notify PI of review results	Chair and Staff Secretary	1 calendar day
4	File documents in the protocol file folder and update database	Staff Secretary	1 calendar day
5	Include expedited review results in the next meeting agenda	Chair and Staff Secretary	at least 14 calendar days before meeting

VI. Detailed Instructions

1. **Expedited Review Proper**

Step 1 Step 1. The Primary Reviewers carry out the expedited review of the protocol and related documents within 7–14 calendar days from receipt of documents. The medical Member/Primary Reviewer reviews the subject of the research protocol to evaluate the scientific soundness and ethics of the study. The lay Member/Primary Reviewer assesses the intelligibility and thoroughness of the informed consent.

For expedited reviews of post-approval submissions, the assigned reviewers ensure that there is no change in the risk/benefit ratio to study participants before approving the submission. Reviewers may request clarifications or revisions of the protocol by the PI before recommending approval.

The assigned reviewers complete the assessment forms in a comprehensive and informative manner. Correspondences among the Chair, Staff Secretary, and the assigned reviewers for expedited reviews shall be conducted through e-mail. The Staff Secretary collates the correspondences, assessment forms, other post approval forms, notification letters, and decision letters used in the review.

a. Form 4.3 Study Protocol Assessment Form for Ethical Review
b. Form 4.5 Informed Consent Assessment Form
c. For the forms used in post -approval submissions (amendment, protocol deviations, application for continuing review), refer to the specific SOP.

Step 2 The Chair reviews the collated correspondence of the reviewers, consolidates the findings, and finalizes the review results within 1–3 calendar days. If the two (2) reviewers differ significantly in opinion about the study, the Chair shall have the final decision.

Step 3 The Staff Secretary prepares a notification or decision letter in Form 4.6, Form 4.7, Form 4.8, Form 4.9 to be checked and signed by Chair and sends this to the PI. SOP 26 Communicating IRB Decisions.

Step 4 The Staff Secretary files the documents related to the expedited review in the protocol file and updates the database. See SOP 27 Management of Active Files.

Step 5 The Chair and Staff Secretary include the Expedited Review and final results in the next meeting agenda. See SOP 21 Preparing the Meeting Agenda

VII. Forms

1. Form 4.3 Study Protocol Assessment Form for Ethical Review
2. Form 4.5 Informed Consent Assessment Form
3. Form 4.6 Notification of IRB Decision
4. Form 4.7 Document Decision Form
5. Form 4.8 Request Information for Post-Approval Procedures
6. Form 4.9 Approval Letter for Post-Approval Procedures

VIII. References

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

IX. Revisions 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 2.3 of version 7 Chapter 2 Initial Review Procedures of PELI IRB SOP • Add references within the SOP • Add in the scope that this SOP applies also to post approval submissions (aside from initial review of protocols) and the phrase "whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise" • Add "expedited reviews should be carried out within 4 weeks of submission of documents" • Remove steps 1-6 and start the SOP with the actual expedited review ; refer to initial steps for protocol submissions, post approval submissions OR review of a medical device Include citing of initial steps for post approval submissions (protocol deviations, etc) since these can also be for expedited review. • Change timeline for review by Primary Reviewers from 2-4 weeks to 1-2 weeks upon receipt of documents • Change procedure for finalization of decision/result of the review if there is no consensus between the 2 assigned reviewers from including in the full board agenda to the Chair having the final say (as written in 2020 PHREB Workbook SOP 4 expedite review Step 5) • Add step to include the expedited review and results in the next meeting agenda • Add "forms" to include forms used in the SOP
9	March 9, 2026	Revised and reclassified as SOP 6 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