PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
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Version No. 9	**SOP 04** **Management of Protocol Submissions**
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SOP 04 Management of Protocol Submissions

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall manage all protocol submissions for initial review in a manner that ensures ethical rigor, scientific validity, transparency, consistency, and regulatory compliance, in accordance with applicable national and international ethical guidelines.

1. The PELI-IRB shall review only those research protocols that fall within its approved scope of authority and for which adequate institutional and ethical assurances are in place.
2. All protocol submissions shall be complete, accurate, and formally documented prior to acceptance for review. Submissions that do not meet established requirements shall not proceed until deficiencies are corrected.
3. Each accepted protocol shall be assigned a unique identification code and recorded in an official IRB tracking system to ensure traceability throughout the review process.
4. All protocols shall undergo appropriate technical or scientific review, as applicable, prior to ethical review to ensure methodological soundness and feasibility.
5. The PELI-IRB shall determine the appropriate level of review—exempt, expedited, or full board—based on the nature of the research and applicable ethical criteria.
6. Protocols shall be reviewed by qualified IRB members or independent consultants with relevant expertise. When necessary, external expertise shall be sought to ensure competent evaluation.
7. The management of protocol submissions shall be conducted in a manner that ensures fairness, independence, confidentiality, and timely processing, without undue influence from investigators, sponsors, or institutional authorities.
8. The PELI-IRB shall maintain oversight and quality assurance mechanisms to ensure compliance with approved SOPs and continuous improvement of the review process.

II. Purpose

To describe the IRB procedures in the management of protocol submissions for initial review.

III. Scope

This SOP begins with the receipt of study documents for initial review and ends with the update of all protocol information in the database.

1. The PELI-IRB accepts the following protocols for review:
    a. PELI funded research;
    b. Research conducted in PELI
    c. Ophthalmologic protocols done by non-affiliated organizations in areas outside the eye center premises;
    d. Non-ophthalmologic studies provided that there is a competent primary reviewer or Independent Consultant (e.g. Dermatologist) of that specialization.
    e. Researches referred from the PNHRS, PHREB, DOH, industry organizations, etc. on the condition that the host hospital/institution where the protocol will be done accepts the review of PELI-IRB and agrees to abide by the rules and regulations that the PELI-IRB follows. The other research sites also agree to provide the necessary environment to ensure safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the Committee may deem necessary. These conditions should be written in a document and signed by other hospitals/institutions that accept the IRB review.

IV. Responsibility

The IRB shall ensure that study documents submitted for review are complete, properly recorded, and properly evaluated to determine appropriate action or type of review.
The IRB Staff Secretary assists in all protocol submissions to the IRB under direct supervision of the Vice-Chair. IRB shall ensure that all protocols undergo technical review and approval prior to ethical review. The IRB is responsible for ensuring that any study protocol that is submitted for review is evaluated by a medical expert with expertise to the study protocol.

V. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive, check completeness, stamp application form, log protocol submission, notify Chair of submission	Staff Secretary	1 calendar day
2	Assign code and enter into database	Staff Secretary	
3	Forward copy of protocol package to Chair	Staff Secretary	1-2 calendar days
4	Determine type of review, assign reviewers and instruct Staff Secretary	Chair	1-3 calendar days
5	Distribute received files and assessment forms for technical review to Technical Reviewer	Staff Secretary	1-2 calendar days
6	Review protocol and accomplish assessment form	Technical Reviewer	7-14 calendar days
7	Receive and forward technical approval of protocol to Chair and PI	Staff Secretary	1 calendar day
8	If except from review, proceed to SOP 5	Staff Secretary	1-3 calendar days
9	If for expedited and full board reviews, distribute protocol package and assessment forms to assigned reviewers		1-3 calendar days
10	• For expedited review (see SOP 6) or • For full board include in agenda and discuss at Full Board (see SOP 21; SOP 7)		
11	Communicate IRB decision	Chair and Staff Secretary	1-3 calendar days
12	File original package in a properly coded Protocol File Folder and update database with names of Primary Reviewers	Staff Secretary	1 calendar day

VI. Detailed Instructions

Step 1 The Staff Secretary ensures the correctness and completeness of the submitted forms and documents according to the checklist in Form 4.1 – Application Form for Protocol Review and places a receiving stamp indicating the date received and name on each copy of Form 4.1 on the same day. Incomplete or incorrect submissions will not be accepted and will be returned to the Principal Investigator. The Staff Secretary keeps the original copy of Form 4.1 for the IRB files, gives the duplicate (receiving copy) to the PI on the same day, and enters the submission in the database and logbook. The Chair is informed of the new protocol submission on the same day of receipt.

An Initial Submission, consisting of two (2) hard copies, one (1) receiving copy, and electronic copy, shall include the following; (Form 4.1 Checklist)

- Completely filled out Form 4.2, Form 4.3, Form 4.4, Form 4.5
- Full protocol
- Investigator's brochure
- Declaration of Conflict of Interest, if applicable
- Terms of reference / Clinical Trial Agreement

*Note: Non-disclosure/concealment of specific study budget allocation may be allowed for purposes of confidentiality between site and sponsor.

- Data collection forms or case report forms
- Informed consent form (English, Filipino, and Chinese, as applicable)
- Assent form (English, Filipino, and Chinese [Fukien], as applicable)
- CV of the PI and co-investigators and the GCP certificate (as necessary but mandatory for sponsor-initiated studies), updated, signed and dated
- Gantt Chart ,if applicable
- Clearance or permit from other regulatory agencies (e.g. FDA approval, Non-significant Risk (NSR)/Significant Risk (SR) rating for new IND and Medical Devices)
- Ads for recruitment, if applicable
- A description of the process used to obtain and document consent,
- A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants,
- A description of the arrangement for indemnity, if applicable
- A description of arrangements for insurance coverage for research participants
- A statement of agreement to comply with ethical principles set out in relevant guidelines
- All significant previous decisions by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere)

Step 2 The Staff Secretary assigns an IRB protocol code indicating the year and the order in which the protocol was received. The IRB Code is assigned as follows:

a. <YYYY-NN>
b. YYYY Represents the year submitted (i.e. 2020)
c. NN Represents sequential number as issued by the Staff Secretary (i.e. 01)

This code is the ID number of the protocol and cannot be assigned to any other protocol. The code will be communicated to the PI in subsequent communications regarding the protocol on the same day. The Staff Secretary logs and encodes the submission using the database and logbook.

Step 3 The Staff Secretary forwards a copy of the protocol package to the Chair within 1-2 calendar days of receipt of submission.

Step 4 The Chair, or in the absence of the former, the Vice-Chair determines the type of review for the protocol: Exempted from review, expedited review or for full board review.

a. For the Criteria for exemption from review, see SOP 5.
b. For protocols undergoing expedited or full board review, the Chair also assigns two (2) Primary Reviewers from among the IRB Members:
    - a medical IRB Member or scientist with expertise on the subject of the research protocol to evaluate the scientific soundness and ethics of the study methods and
    - a non-medical person/lay IRB Member to assess the intelligibility and thoroughness of the informed consent. An Independent Consultant with needed expertise related to the protocol may also be appointed.

    The Chair instructs the Staff Secretary accordingly within 1-3 calendar days of receipt of the protocol package.

Step 5 The Staff Secretary distributes the protocol package and Form 4.2 Study Protocol Assessment Form for Technical Reviewer to the Technical Reviewer 1-2 calendar days from submission.

Step 6 The Technical Reviewer reviews the protocol and accomplishes Form 4.2 within 7-14 calendar days upon receipt. The Staff Secretary assists the Technical Reviewer in corresponding with the PI for any clarifications on the protocol and recommended modifications or revisions in research design, sampling design, sample size, statistical analysis plan and data analysis plan. The final approval on the assessment form is given only once any and all suggested revisions by the Technical Reviewer are done by the PI.

The Technical Reviewer then forwards the approval in Form 4.6 Notification of IRB Decision to the Staff Secretary for communicating to the Chair and the PI.

Step 7 The Staff Secretary forwards the accomplished Form 4.2 and a copy of Form 4.6 with Technical Reviewer's approval to the Chair and the Form 4.6 to the PI.

Step 8 If the study is exempt from review, proceed to SOP 5.

Step 9 For protocol submissions undergoing full board review, the Staff Secretary distributes the following to the Primary Reviewers and Independent Consultants (if needed):

a. Protocol package as hard copies and soft copies with access to the electronic files
b. Form 4.3 Study Protocol Assessment Form for Ethical Review to the medical member Primary Reviewer
c. Form 4.4 Informed Consent Evaluation Form to the lay member Primary Reviewer.
d. The Primary Reviewers and Independent Consultant if needed, review the protocol and accomplish the assessment forms and make their recommendations.

Step 10 For expedited review, the Primary Reviewers and Independent Consultants (if needed) then proceed to do an expedited review (see SOP 6). For full board review, the Chair and Staff Secretary include the review in the next meeting agenda and the IRB discusses and decides at Full Board (see SOP 21; SOP 7).

Step 11 The Staff Secretary collates the comments and recommendations, prepares the Form 4.7 Document Decision Form or Form 4.6 Notification of IRB Decision and sends it to the PI. (See SOP 27 Communicating IRB Decisions).

Step 12 The Staff Secretary files the original package in a properly coded Protocol File Folder and updates the database with the names of the assigned Primary Reviewers and type of Review. The Vice-Chair shall check and oversee compliance done or will be made by the Staff Secretary and members to the SOP and timelines set in the process flow chart.

VII. Forms

1. Form 4.1 Application Form for Protocol Review
2. Form 4.2 Study Assessment Form for Technical Reviewer
3. Form 4.3 Study Protocol Assessment Form for Ethical Review
4. Form 4.4 Informed Consent Evaluation Form
5. Form 4.6 Notification of IRB Decision

6. Form 4.7 Document Decision Form

VIII. References

1. Philippine Health Research Ethics Board Standard Operating Procedures 2020
2. CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016
3. WHO Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants 2011
4. National Ethical Guidelines for Health and Health-related Research (NEGHHR) 2017
5. PELI-IRB SOP 2017

IX. 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 Version 7 Chapter 2 Initial Review Procedures 2.1 Management of Protocol Submissions of PELI IRB SOP

		• Add references within the SOP • Include determination of type of review by Chair after notification of a protocol submission ; to be done within 1-3 calendar days of receipt of the protocol • Make Process Flow and Steps consistent • Spell out how a code is assigned to a protocol package in Step 2 • Changed timeline of step 1/2 (receipt , coding, entry into database) to “on day of receipt” • Include “enters the submission in the database and logbook” in step 1 • Change timeline of delegation of primary reviewers by Chair to 1-3 calendar days upon receipt of technical approval • Include types of protocol that can be for expedited review • Add “forms” to include forms used in the SOP.
9	March 9, 2026	• Revised and reclassified as SOP 4 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics • Convert all timelines to calendar days • Added a Policy section to define the governing principles and general guidelines of the SOP • 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.