Ethical Framework and Constitution of the IRB

1. Purpose

To describe the composition and structure of the Peregrine Eye and Laser Institute-Institutional Review Board (PELI-IRB) in compliance with national and international guidelines or policies in ethical research specifically with Philippine Health Research Ethics Board's (PHREB) Policy on Specialty Clinics.

2. Scope

The PELI-IRB is an independent body created by the Peregrine Eye and Laser Institute under the Managing Director, whose responsibility is to ensure the protection of the rights, safety, and well-being of human participants involved in health-related research and to provide public assurance of that protection. In accordance with PHREB's Policy for Specialty Clinics and other applicable national/international regulations, the PELI-IRB has the authority to approve, require modifications to, or disapprove research protocols and related documents as well as ensure compliance with its relevant procedures after approval.

The PELI-IRB reviews and monitors health researches that involve:

a. PELI patients, done within the eye center premises by its staff and non-affiliated organizations,
b. Ophthalmologic protocols done by PELI staff in areas outside the eye center premises,
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.

This provides the Terms of Reference (TOR) that describe the framework for the constitution of the PELI-IRB, the responsibilities and activities of its officers, members, staff and consultants.

3. Responsibility

It is the responsibility of the IRB members, officers and staff to understand, implement and follow the SOPs of the PELI-IRB.

4. Protection of IRB Members and Chairs

Members and officers of the PELI-IRB shall serve for the full term specified in the IRB constitution and may not be removed prior to the expiration of their term except for good cause, as determined by the IRB in accordance with institutional policies. This ensures independence, impartiality, and continuity in the review of research protocols.

5. Ethical Basis

1.1 The PELI-IRB is guided in its reflection, advice, and decision by the ethical principles and procedures expressed in the following international policies, guidelines and documents:

a. Declaration of Helsinki 2008 and subsequent revision
b. CIOMS 2002, 2009 and subsequent revisions

1.2 The PELI-IRB will function in accordance with PHREB's Policy for Specialty Clinics and other national laws, regulations, and guidelines.

1.3 The PELI-IRB provides its own standard operating procedures based on:

a. PHREB Committee on Standard and Accreditation Policies that also included the requirements for Specialty Clinics
b. Operational Guidelines for Ethics Committees That Review Biomedical Research (2011) by the World Health Organization
c. Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization
d. International Conference on the Harmonization of Good Clinical Practice (ICH-GCP), ICH-GCP E6 (R2), 2017
e. National Ethical Guidelines for Health Research (2012) by the Philippine Health Research Ethics Board (PHREB)
f. Philippine Food and Drug Authority regulations and other relevant laws and regulations

1.4 The PELI-IRB adheres to national and international ethical standards and recognizes that the protocols it approves may also be approved by national and/or local ethics committees prior to their implementation in specific localities.

1.5 In evaluating protocols and ethical issues, the IRB is cognizant of the diversity of laws, cultures, and practices governing health research in various countries around the world.

1.6 In attempts to inform itself, whenever possible, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed PELI research is being considered.

1.7 The PELI-IRB will take the initiative to be informed, as appropriate, by national/local ethics committees and researches of the impact of the research it approved.

2. Mandatory Researcher Training

All researchers conducting studies under the authority of the Peregrine Eye and Laser Institute are required to undergo training on the ethical conduct of research and their responsibilities toward human participants. Certification of training completion must be submitted prior to the initiation of any research activity and updated as required by PHREB guidelines and institutional policies.

3. Care for Research- Related Injury

The Peregrine Eye and Laser Institute and all investigators conducting research under its authority share responsibility for ensuring that appropriate mechanisms are in place to provide timely and adequate medical care and management for research participants who may suffer research-related injuries or adverse events. Research protocols reviewed by the PELI-IRB shall clearly describe provisions for the treatment, referral, and management of such injuries, including responsibilities of the investigator and the institution, in accordance with applicable ethical and regulatory standards.

To support this obligation, the Peregrine Eye and Laser Institute has entered into formal Memoranda of Agreement with Makati Medical Center (15 January 2015) and Adventist Medical Center (02 February 2023) to ensure the availability and accessibility of general medical services for research participants when necessary.

4. Institutional Oversight and Accountability

The PELI-IRB develops, adopts, and implements its own Standard Operating Procedures to operationalize its ethical mandate. These procedures are informed by national and international reference documents, including PHREB standards and accreditation policies for specialty clinics, World Health Organization operational and standards guidance for ethics review committees, the International Council for Harmonisation – Good Clinical Practice (ICH-GCP), National Ethical Guidelines for Health Research, and relevant Philippine Food and Drug Administration regulations and laws.

The PELI-IRB recognizes that research protocols it reviews may also be subject to review and approval by other national or local ethics committees prior to implementation in specific localities. In evaluating protocols and ethical issues, the PELI-IRB remains cognizant of the diversity of laws, cultures, and practices governing health research across different jurisdictions. Where applicable, it endeavors to be informed of the regulatory requirements of sponsor countries conducting global research in the Philippines, as well as the conditions and requirements of local communities where PELI-related research is proposed.

5. Allegations of Unethical Conduct

The PELI-IRB acknowledges the responsibility of the institution to maintain mechanisms for receiving, investigating, and addressing allegations of unethical conduct, non-compliance, or misconduct by researchers involved in studies under its oversight. Such mechanisms shall ensure due process, confidentiality, and appropriate institutional action.

Where allegations of unethical conduct are substantiated, the institution, in coordination with the PELI-IRB and appropriate authorities, shall impose corrective actions or sanctions consistent with institutional policies, applicable laws, and regulatory requirements. The PELI-IRB may recommend suspension, modification, or termination of IRB approval as part of its mandate to protect research participants.

Through this ethical framework and institutional mandate, the PELI-IRB seeks to ensure that all research under its oversight is conducted in a manner that is scientifically sound, ethically robust, accountable, and respectful of the rights, welfare, and dignity of human research participants.

6. Revision Index

Version	Date	Reasons For Revision

<table>
<tr><td>02</td><td>Jan 26, 2016</td><td>Changed logo of “Pacific Eye and Laser Institute” to “Peregrine Eye and Laser Institute” in the document header</td></tr>
<tr><td>03</td><td>June 15, 2017</td><td>The following major revisions made in compliance with PHREB recommendations of official finding report last June 8, 2017:
Exception clause revision in 3 year appointment period
Create and implement a plan for training for IRB officers and members on SOP, use of assessment forms, Advance Ethics Research Training which are case based, Technical Research Review Workshop, and Scientific Writing Workshop for PELI consultants
Ensure that CVs of IRB members and Independent Consultants are updated every 2 years as per SOP
State in the SOP 1 that the IRB is compliant with the PHREB Policy on Specialty Clinics and describe why it is compliant. State relevant MOAs with a general hospital.
Clarify and define scientific, non-scientific members in the SOP
Define tenure of IRB officers in the TOR and in the SOP
Clarify the role of the Technical Review Committee;
Ensure consistency of the flow chart with the detailed instructions (e.g. person responsible for a particular process)</td></tr>
<tr><td>04</td><td>Oct 17, 2017</td><td>The following major revisions made in compliance with PHREB recommendations stated in the provisional letter dated last July 31, 2017 and email communication from PHREB dated Aug 14, 2017:
There should be at least 2 non-affiliated members one non-affiliated members one of which is an ophthalmologist.
Limit protocol review to ophthalmologic studies only, provided that, if there is presence of non-ophthalmologic competent primary reviewers or Independent Consultants (e.g. Dermatologic Study) PELI-IRB may review that certain study (e.g. Dermatologic Study).
· Clearly state the role of the Technical Reviewer and primary reviewer and provide specific timelines regarding technical review and ethics review.</td></tr>
<tr><td>05</td><td>July 16, 2022</td><td>Reformatted numbering to conform to 2020 PHREB SOP workbook
Refer to SOP Chapter 1 of version 4 of PELI IRB
Added references within the SOP
Added revision index within the SOP</td></tr>
<tr><td>06</td><td>March 9, 2026</td><td>Ethical Framework and Constitution of the IRB (originally SOP 1)– Removed from the SOP Section; reclassified as institutional IRB Policy
Include institutional policies required by the 2024 PHREB Accreditation Policies and Guidelines
<table>
<tr><th>PHREB Requirement</th><th>Section in PELI-IRB Constitution</th><th>Notes</th></tr>
<tr><td>2.1 Ethics review for all human research</td><td>Sections 2, 5, 8</td><td>Scope explicitly states all research requires IRB review</td></tr>
</table></td></tr>
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		2.2 Protection of REC members and Chairs	Section 4	Full term and removal only for good cause
		2.3 Researcher training requirement	Section 6	Mandatory training and certification required
		2.4 Care for research-related injuries	Section 7	Includes MOAs and protocol requirements
		2.5 Mechanism to handle unethical conduct	Section 9	Mechanism for investigation, due process, and sanctions