

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB SOP 01/05-0-2022	SOP 01 Ethical Framework and Constitution of the IRB
Version No. 5	
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 1 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 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 subjects 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:

- PELI patients, done within the eye center premises by its staff and non-affiliated organizations,
- Ophthalmologic protocols done by PELI staff in areas outside the eye center premises,
- Ophthalmologic protocols done by non-affiliated organizations in areas outside the eye center premises,
- Non-ophthalmologic studies provided that there is a competent primary reviewer or independent consultant (e.g. Dermatologist) of that specialization.

This SOP 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.

3. Ethical Basis

- a. 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:
 - Declaration of Helsinki 2008 and subsequent revisions
 - CIOMS 2002, 2009 and subsequent revisions
- b. The PELI-IRB will function in accordance with PHREB's Policy for Specialty Clinics and other national laws, regulations, and guidelines.
 - Memorandum of Agreement with Makati Medical Center was made last 15 Jan 2015 to able to ensure accessibility of a health facility that offers general medical services to research participants, if needed.
- c. The PELI-IRB provides its own standard operating procedures based on:
 - PHREB Committee on Standard and Accreditation Policies that also included the requirements for Specialty Clinics
 - Operational Guidelines for Ethics Committees That Review Biomedical Research (2011) by the World Health Organization
 - Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization
 - International Conference on the Harmonization of Good Clinical Practice (ICH-GCP), ICH-GCP E6 (R2), 2017
 - National Ethical Guidelines for Health Research (2012) by the Philippine Health Research Ethics Board (PHREB)
 - Philippine Food and Drug Authority regulations and other relevant laws and regulations
- d. 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.
- e. 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.
- f. 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.

- g.** 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 that it approved.