PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute Institutional Review Board**
PELI-IRB SOP-01-06-2026	
Version No. 6	**SOP 01 Appointment of the IRB Members and Employment of Staff Secretary**
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SOP 01 Appointment of the IRB Members and Employment of Staff Secretary

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall be composed of qualified IRB members supported by appropriate administrative staff to ensure independent, efficient, and ethical review of research involving human participants.

1. IRB members and officers shall be appointed through a transparent, documented, and systematic process based on qualifications, expertise, and the need for appropriate scientific, non-scientific, and lay representation, in accordance with PHREB and international guidelines.
2. Membership composition shall ensure:
    a. Appropriate medical, scientific, and methodological expertise relevant to the research reviewed,
    b. Representation of community perspectives through non-medical or lay members,
    c. Independence through inclusion of non-affiliated members; and
    d. Sensitivity to gender, age, and community representation.
3. The IRB shall comply with quorum requirements and ensure appropriate expertise during meetings, including specialists when reviewing vulnerable populations or complex studies.
4. Appointment, reappointment, term of office, rotation, resignation, disqualification, and replacement of IRB members and officers shall be conducted in a transparent and documented manner, balancing continuity of expertise with opportunities for renewal.
5. All IRB members and officers shall:
    a. possess appropriate ethical, scientific, or professional competence;

b. undergo initial and continuing training in research ethics, Good Clinical Practice, and research methodology;
c. disclose and manage conflicts of interest; and
d. maintain strict confidentiality of IRB documents, deliberations, and research-related information.

6. The PELI-IRB may designate specific reviewer roles, including scientific reviewers, non-scientific reviewers, non-affiliated members, Technical Reviewers, and an SAE Reviewer, whose defined responsibilities support rigorous scientific and ethical review without compromising IRB independence.
7. Technical review of research protocols shall be conducted to ensure that studies submitted for ethical review are scientifically sound, including assessment of:
    a. study objectives and rationale;
    b. research design and methodology;
    c. sampling design and sample size;
    d. data collection and analysis plans;
    e. statistical and biostatistical considerations; and
    f. epidemiologic and analytical validity, as applicable.
8. The PELI-IRB shall be supported by administrative personnel, including a full-time Staff Secretary, appointed by the institution to provide administrative and operational support necessary for effective IRB functioning.

    The IRB Vice-Chair shall have primary responsibility for supervising the Staff Secretary and all administrative staff in all IRB-related functions, including protocol tracking, document management, communication, and compliance with SOPs.
9. The Staff Secretary shall perform administrative functions only and shall not participate in IRB deliberations, ethical decision-making, or voting.
10. While administratively employed and compensated by the institution, the Staff Secretary shall function under the technical and operational supervision of the IRB Vice-Chair in matters relating to IRB functions. The Vice-Chair shall oversee day-to-day workflow, documentation standards, protocol tracking, and compliance with IRB procedures.

11. All IRB members and administrative staff shall be required to sign Confidentiality and Conflict of Interest Agreements prior to performing their functions. Failure to comply may constitute grounds for disqualification.
12. Documentation related to appointments, qualifications, training, confidentiality agreements, and conflicts of interest shall be maintained as part of the official IRB records.

II. Purpose

To define the policies, requirements, and procedures governing the appointment, composition, roles, and responsibilities of Institutional Review Board (IRB) members, officers, and administrative staff, including the full-time Staff Secretary, to ensure independent, competent, and ethical review of health research involving human participants.

III. Scope

The process begins with the identification and nomination of potential members and ends with the completion, termination, or expiration of their term of service, including proper documentation and archiving of records.

IV. Process Flow/Steps

STEP	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Identify need for appointment or staffing	IRB Chair/ Member-Secretary	3 calendar days
2	Recruitment of candidates	Human Resources Department	30 calendar days
3	Review of qualifications	HR/IRB Officers/ Managing Director	7 calendar days
4	Appointment and contract signing	Managing Director	5 calendar days
5	Orientation and endorsement	IRB Officers/ Incumbent Staff	3 calendar days
6	Execution of Confidentiality and COI Agreements	Appointee/Staff Secretary	2 calendar days
7	Filing and updating of CVs and Records	Staff Secretary	2 calendar days

Detailed procedures supporting the above process flow are implemented in accordance with relevant PELI-IRB SOPs, institutional human resource policies, and applicable national and international research ethics guidelines.

1. **Requirements for Membership**

    a. The IRB shall be composed of at least 5 members
    b. Its membership shall be multidisciplinary and multi-sectoral, with diverse backgrounds and experience to foster a comprehensive and efficient review of research activities conducted by the PELI staff and non-affiliated organizations.
    c. The membership shall include individuals whose primary concerns are in the medical sciences, at least one lay/non-medical/non-scientific member, and at least two (2) non-affiliated members, one of whom shall be an Ophthalmologist.
    d. Relevant expertise may include medicine and research, social and behavioral sciences, law, philosophy, environmental science, and public health.
    e. The IRB shall aim for gender representation and inclusion of both older and younger generations to promote sensitivity and balance in review procedures.
    f. The IRB shall have representatives from both the older and younger generations.
    g. The IRB shall have an office and adequate support staff for carrying out its responsibilities.
    h. The IRB shall adhere to quorum requirements as defined in national and international guidelines. When reviewing clinical trials involving children, a pediatrician or child development specialist shall be present during the meeting.

2. **Term of Office**

    a. The appointing authority shall indicate in the appointment letter the IRB's functions, terms of office, scope of work, conditions of appointment, system of replacement or recall, and compensation, if any. Members are appointed for a period of three (3) years, unless otherwise agreed upon between the member and the Managing Director.
    b. Appointments may be renewed by the appointing authority.
    c. The IRB shall adopt mechanisms for membership rotation to enable participation of new members while ensuring continuity and maintenance of expertise.

3. **Qualifications/Appointment of Members**

The Managing Director is responsible for appointing/renewal of appointment of IRB members upon the recommendation of the IRB Chair.

a. Members are selected based on good moral character, ethical and/or scientific competence, and willingness to perform IRB functions.
b. Members shall have prior training in Good Clinical Practice, research methodology and research ethics, or should be willing to undergo such training.
c. Members shall disclose in writing any financial, professional or personal interest
d. Members shall submit a signed and dated curriculum vitae and update it at least once every two (2) years.
e. Members shall be required to sign a Confidentiality and Conflict of Interest agreement at the start of their term.
f. The IRB shall determine appropriate management of conflicts of interest.
g. The confidentiality agreement protects the privacy and confidentiality of all parties involved.

4. **Conditions of Appointment of Members**

All prospective IRB members shall be willing to:

a. Make public their full name, profession and affiliation as an IRB member.
b. Disclose financial accountability, reimbursement and expenses, related to IRB work.
c. Sign the Confidentiality and Conflict of Interest Agreements covering, applications, deliberations, and participant - related information.

5. **Resignation, Disqualification and Replacement of Members**

a. Members may resign their position by submitting a letter of resignation to the Chair and endorsed to the Managing Director.
b. Members may be disqualified for valid reasons by majority vote of the IRB
c. Vacancies shall be filled following established nomination and appointment procedures.
d. Replacement terms shall be limited to the remaining term of the replaced member

6. **IRB Officers**

The following officers through the exercise of the respective responsibilities contribute to efficient IRB operations:

a. **Chair**

- Presides over IRB meeting
- Is accountable to the Managing Director
- Prepares annual IRB report
- Ensures administrative and financial support of the IRB operations
- Represents the IRB internally and externally
- Determines eligibility of expedited review
- Assigns reviewers
- Ensures compliance with GCP

b. **Vice-Chair**

- Presides over meetings and other responsibilities in the absence of the Chair
- Performs other duties as designated by the Chair
- Supervises the Staff Secretary
- Ensures good IRB Documentation

c. **Member-Secretary**

- Ensures the preparation and maintenance of meeting agenda and minutes
- Organizes the preparation, review, revision and distribution of SOPs and guidelines
- Provides updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the IRB members.
- Ensures proper maintenance and accessible library of relevant resource materials and references

7. **Roles and Responsibilities of IRB Members**

a. **General Roles and Responsibilities**

- Participate in IRB meetings
- Review and evaluate research proposals
- Assess serious adverse event reports
- Monitor ongoing studies

- Review final reports
- Maintain confidentiality of the documents and deliberations during IRB meetings
- Declare any conflict of interest
- Participate in continuing education

b. **Specific Roles**

- Scientific Member - Technically qualified experts
- Lay Member - Represents community interests and evaluates informed consent
- Non-Affiliated Member - Ensures independence
- SAE Reviewer - Review serious adverse event
- Technical Reviewer – Ensures scientific soundness of the protocols

8. **Staff Secretary**

The Staff Secretary provides administrative support including documentation, tracking, safekeeping and filing of approved agendas and minutes, communication, training coordination, SOP management, maintenance of resource materials, and budget assistance under the supervision of the Vice-Chair.

9. **Confidentiality and Conflict of Interest Agreement**

a. All IRB members shall read, understand, and sign the Confidentiality and Conflict of Interest Agreement prior to performing IRB functions. Refusal to sign may result in disqualification. Signed agreements shall be properly filed by the Staff Secretary

b. The members keep a copy for their records. The Vice-Chair shall ensure that the Staff Secretary keeps proper filing of a copy of the signed Agreement in the membership files.

V. Forms

1. Form 1.1 Confidentiality and Conflict of Interest Agreement
2. Form 1.2 Membership Appointment Letter

VI. References

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

VII. Revision index

Version	Date	Reasons For Revision
02	Jan 26, 2016	Changed logo of "Pacific Eye and Laser Institute" to "Peregrine Eye and Laser Institute" in the document header
03	June 15, 2017	• 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)
04	Oct 17, 2017	• 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.

05	July 16, 2022	○ 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 ○ Made Process Flow/Steps and detailed instructions consistent
06	March 6, 2026	○ Revised and reclassified as SOP 1 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics ○ Designated the Vice Chair as the primary person responsible for supervising staff ○ Expanded the Scope section to clearly define the beginning and end of the activities covered by this SOP. ○ Added a Policy section to define the governing principles and general guidelines of the SOP. ○ Incorporated the appointment of IRB staff and detailed delineation of responsibilities to ensure alignment with current operational procedures. ○ Specify who has the primary task of supervising the staff and harmonize across SOPs