PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 02/05-0-2022	
Version No. 5	**SOP 02** **Appointment of the IRB Members**
Approval Date: July 16, 2022	
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 2 Appointment of the IRB Members

1. Purpose

To describe the appointment procedures, identify the roles and responsibilities of the IRB officers and members.

2. Scope

While the PELI-IRB remains under authority of the Managing Director, it has to maintain its independence and develop its competence related to decision making as defined in international and national guidelines. The membership SOPs cover the nomination and appointment procedures of the IRB members, officers and independent consultants.

3. Responsibility

It is the responsibility of the PELI-IRB Managing Director to formally appoint the members and officers of the IRB after due consultation with the current members of the IRB.

4. Process Flow/Steps

STEP	ACTIVITY	RESPONSIBILITY
1	Ask the IRB members to nominate potential new members	Chair/Secretary
2	Submit names of potential members to the Chair	Member/Secretary
3	The Chair discusses the qualifications of the nominees and submits the list to the Managing Director	Chair/Secretary
4	Appoint new IRB members and consultants	Managing Director
5	Receive appointment letter, sign confidentiality and conflict of interest agreements, and submit updated CVs	New members/consultants

5. Detailed Instructions

Step 1 Chair asks the IRB members to nominate potential new members/potential officers.

Step 2 Current IRB members shall nominate candidates for new members/officers to the Chair.

Step 3 The Chair discusses the qualifications of the nominees and submits the list to the Managing Director

Step 4 The Managing Director selects from a list of nominees for IRB members and consultants and issues an appointment letter.

Step 5 The nominated member receives an appointment letter, signs a confidentiality and conflict of interest agreement, and submits updated CV

6. Requirements for Membership

- IRB Membership
- The IRB shall be composed of at least 5 members
- Its membership shall be multidisciplinary and multi-sectoral. The IRB members should have diverse background and experience and foster a comprehensive and efficient review of research activities commonly conducted by the PELI staff and non-affiliated organizations.
- The membership shall include persons whose primary concerns are in the medical science, at least one member who is in a lay/non-medical/non-scientific area, and at least two members who are non-affiliated, one of which is an Ophthalmologist.
- Relevant expertise may include medicine and research, social and behavioral science, law, philosophy, environmental science and public health. It is recommended that the IRB should include a person who will represent the interest and concerns of the community such as lay/non-medical/non-scientific.
- The IRB shall aim for gender representation in its membership in order to promote gender sensitivity in its review procedures.
- The IRB shall have representatives from both the older and younger generations.
- The IRB shall have an office and adequate support staff for carrying out its responsibilities.
- The IRB shall adhere to quorum requirements as defined in international and national guidelines for ERCS that review health research. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its board meeting.

7. Term of Office

- The appointing authority shall indicate in the appointment letter **(Form 1.2)** 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 3 years, unless subjected to change as agreed upon between the member and the managing director.
- Their appointments may be renewed by the Appointing Authority.

- The IRB shall adopt some mechanism for its rotation of its membership roster, to enable participation of new members with fresh outlook and approaches, but it shall also strive to ensure continuity, the development and maintenance of expertise.

8. Qualifications/Appointment of Members

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

- Members are selected based on their good moral character and personal capacities, their ethical and/or scientific knowledge and expertise, as well as their willingness to volunteer their time and effort to perform their functions in the IRB.
- Members shall have prior training in Good Clinical Practice, research methodology and research ethics, or should be willing to undergo such training during their membership.
- Members shall disclose in writing any financial, professional or personal interest or involvement in a project or proposal under consideration, which is in conflict with their function as a reviewer.
- Members shall submit their curriculum vitae, properly signed and dated and update them at least once every two (2) years.
- Members will be required to sign a confidentiality/conflict of interest agreement at the start of their term. The agreement should cover all applications, meeting deliberations, information on research participants and related matters.
- The IRB shall decide on how to manage specific conflicts of interests of members related to their participation in committee deliberations/actions regarding a particular protocol covered by the provisions.
- The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IRB in the course of its work.

9. Conditions of Appointment of Members

All prospective IRB members shall be willing:

- To make public his/her full name, profession and affiliation as an IRB member.
- Disclose all financial accountability, reimbursement for work and expenses, related to their work in the PELI-IRB that shall record and publicly disclose its financial report upon request.
- All IRB members shall sign the Confidentiality and Conflict of Interest Agreements (**Form1.1)** regarding meeting deliberations, applications, information on research participants and related matters.

10. Resignation, Disqualification and Replacement of Members

- Members may resign their position by submitting a letter of resignation to the chair and endorsed to the Managing Director.

- Members may be separated from the committee by disqualification for valid reasons as determined by majority vote of the committee members.
- Members that have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.
- The terms of replacement shall be limited to the remaining term of the member that he/she has replaced.

11. IRB Officers

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

Chair:

- Presides over IRB meeting and is accountable to the Managing Director
- Prepares an annual report summarizing IRB activities and decision outcomes to the Managing Director
- Ensures sufficient financial and administrative support of the IRB operations
- Represents the IRB interests within the eye center administration
- Represents the IRB to the outside world
- Supervises the IRB staff
- Decides which protocols may be expedited
- Assigns primary reviewers
- Ensures that the protocol submitted for review have been approved by the technical review
- Ensures overall IRB compliance with GCP

Vice-Chair

- Presides over meetings and other responsibilities in the absence of the Chair
- Performs other duties as designated by the Chair

Member-Secretary

- Ensures good IRB documentation
- Ensures an effective and efficient tracking procedure for each proposal received
- Ensures efficient preparation, maintenance, and distribution of study files
- Ensures efficient and timely IRB meeting
- Ensures the preparation and maintenance of meeting agenda and minutes
- Communicates with IRB members and investigators
- Arranges training for personnel and IRB members

- Organizes the preparation, review, revision and distribution of SOPs and guidelines
- Ensure provision of necessary administrative support for IRB related activities to the Chair
- 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
- Supervises the Staff Secretary
- Assists in deciding the review type (expedited/full board) along with other IRB officers
- Assists in assigning reviewers
- Assists in planning annual training to be incorporated in the annual budget

12. Roles and Responsibilities of IRB Members

General Roles and Responsibilities

- Participate in IRB meetings
- Review, discuss and consider research proposals submitted for evaluation
- Assess serious adverse event reports and recommend appropriate action
- Review progress reports and monitor ongoing studies as appropriate
- Evaluate final reports
- Maintain confidentiality of the documents and deliberations during IRB meetings
- Declare any conflict of interest
- Participate in continuing education activities in health research and ethics

Specific Types of Members/Roles

a. **Scientific Member** - are technically qualified experts in their field, such as clinical medicine, engineering, biological sciences, physical sciences, biostatistics and many others. (US-FDA)
b. **Non-Medical or Non-Scientific or Lay Member** - A member who represents the interest and concerns of the community. This member's main responsibility is to evaluate the content of informed consent form and make sure that the said form is comprehensible, complete, and in of best interest for the subject.
c. **Non-Affiliated Member** - A member of the board not under direct employment by the institution where IRB is established. This is to make sure the unbiased preservation of the IRB's main roles in assuring patient safety and upholding the main ethical principles it follows.
d. **SAE Reviewer** - is a scientific reviewer that assesses serious adverse event reports and make sure that necessary actions were done to ensure patient safety.
e. **Technical Reviewer –** has varied expertise such as but not limited to the following:
    - Research methodology
    - Study Design
    - Sampling size
    - Statistical analysis

- Biostatistics
- Epidemiology
- Data analyst

Has the authority to review the technical aspect of the study and has the responsibility to ensure that proposed research for review is scientifically sound before proceeding with PELI-IRB's ethical review. Initially evaluate technicalities stated in the protocol such as but not limited to the following:

- Objectives/Expected output
- Literature review rationalizing the design
- Research design
- Sampling design, sample size
- Data collection plan
- Data analysis plan (including statistical basis for design, as applicable)

Confidentiality and Conflict of Interest Agreement

- The Staff Secretary provides a copy of the agreement form **(Form 1.1)** to each member of the PELI-IRB together with the appointment letter.
- It is the responsibility of all the IRB members to read, understand, accept and sign the agreement contained in the Confidentiality/Conflict of Interest form before beginning their ethical and technical review functions.
- If a member refuses to sign such agreement, this may be a ground for his/her disqualification to serve in the PELI-IRB.
- Newly-appointed members obtain 2 copies of the agreement form, read the text very carefully, fill in their names, sign and date the forms.
- Any members may ask questions, or ask a clarification from the Chair or Member-Secretary related to the contents of the document.
- The members keep a copy for their records. The Member secretary shall ensure that the Staff Secretary keeps proper filing of a copy of the signed Agreement in the membership files.