PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute Institutional Review Board**
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Version No. 6	**SOP 02 Selection and Engagement of Independent Consultants**
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SOP 02 Selection and Engagement of Independent Consultants

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall engage Independent Consultants when specialized scientific, medical, technical, or ethical expertise is required to ensure a thorough, competent, and ethically sound review of research protocols beyond the expertise of the sitting IRB members, in accordance with applicable national and international ethical guidelines and regulatory requirements.

1. Independent Consultants shall be engaged when the IRB Chair determines that a protocol involves procedures, interventions, devices, or methodologies that are not within the collective competence of the IRB membership. Nominations for Independent Consultants may be made by any IRB member and shall be evaluated by the IRB Chair.
2. The selection of Independent Consultants shall be based on:
    a. documented relevant expertise and qualifications;
    b. professional experience appropriate to the protocol under review;
    c. absence of conflicts of interest; and
    d. ability to provide an independent and objective assessment.
3. Independent Consultants shall serve in an advisory capacity only and shall not participate in IRB voting or final decision-making.
4. All Independent Consultants shall be required to:
    a. disclose any actual or potential conflicts of interest;
    b. maintain confidentiality of all study-related information; and
    c. formally agree to the terms of reference established by the PELI-IRB prior to performing any review activities.

5. The IRB Chair shall review all disclosed conflicts of interest prior to appointment and determine whether the consultant is eligible to participate in the review. In cases of significant conflict of interest, the consultant shall not be engaged.
6. The use of Independent Consultants shall enhance, but not replace, the responsibility of the PELI-IRB to ensure that all protocols receive appropriate ethical and scientific review in accordance with applicable ethical guidelines and regulatory requirements.
7. Documentation related to the selection, engagement, assessment reports, and termination of Independent Consultants shall be maintained as part of the official IRB records and subject to audit and accreditation review.

II. Purpose

To describe the procedures for identifying, selecting, appointing, engaging, documenting, and terminating Independent Consultants of the PELI-IRB.

III. Scope

This SOP describes the procedures for engaging the services of a professional/expert as a consultant to the PELI-IRB.

This SOP applies to initial review, continuing review, protocol amendments, and other research-related reviews requiring specialized scientific, medical, technical, or ethical expertise not available within the IRB.

If the Chair of the IRB determines that a study involves procedures that are not within the area of competence or expertise of the IRB members, the Chair may invite Independent Consultants with expertise in special areas to assist in the review of protocols that require such expertise in addition to those available within the IRB.

IV. Responsibility

Upon the advice or recommendation of the officers or any PELI-IRB member, it is the responsibility of all the IRB members to nominate and approve the name of the Independent Consultants to be endorsed by the IRB Chair.

IRB Members may nominate potential Independent Consultants. The IRB Chair assesses the need, evaluates qualifications, reviews conflict of interest disclosures, and endorses the consultant for appointment. The Managing Director formally appoints the Independent Consultant, while the

Staff Secretary handles all documentation, communication, record-keeping, and filing. The Member-Secretary records the Independent Consultant's participation in the IRB meeting minutes.

V. Process Flow/Steps

STEP	ACTIVITY	RESPONSIBILITY
1	Identify need for Independent Consultant	IRB Chair
2	Nominate and screen candidates	IRB Members / IRB Chair / Staff Secretary
3	Review qualifications and conflict of interest disclosures	IRB Chair
4	Endorse selected consultant to Managing Director	IRB Chair
5	Appointment of Independent Consultant	Managing Director
6	Completion of documentary requirements	Independent Consultant/Staff Secretary
7	Conduct protocol review and submit assessment	Independent Consultant/Staff Secretary
8	Document participation in IRB meeting minutes	Member-Secretary
9	Store documents in the Independent Consultant file	Staff Secretary

VI. Detailed Instructions

Step 1 The IRB Chair shall determine the need for an Independent Consultant when a submitted research protocol involves specialized procedures, interventions, devices, methodologies, or ethical concerns that are beyond the collective expertise of the IRB membership.

Step 2 IRB Members may nominate qualified individuals. The Staff Secretary compiles a list of nominees. The IRB Chair evaluates qualifications based on expertise and relevance to the protocol under review.

Step 3 The prospective consultant shall disclose any actual or potential conflicts of interest. The IRB Chair shall review the disclosure and determine eligibility prior to endorsement. If a significant conflict of interest exists, the consultant shall not be engaged.

Step 4 The IRB Chair submits the selected consultant's name to the Managing Director for formal appointment.

Step 5 The Managing Director shall formally appoint the Independent Consultant.

Step 6 The Independent Consultant shall sign the TOR, Confidentiality, and Conflict of Interest Agreements.

The IRB Staff Secretary shall contact the consultant and request submission of the following:

a. Curriculum vitae
b. A signed Term of Reference
c. A signed Confidentiality and Conflict of Interest Agreements

Step 7 Conduct of Protocol Review

a. The IRB Staff Secretary provides study protocol documents and assessment forms to the concerned consultant for review, after the latter has signed the TOR and the Confidentiality and Conflict of Interest Agreements (Form 1.1).
b. The consultant must complete the assessment form to be reviewed by the IRB at the time the study is reviewed.
c. The consultant may attend the IRB meeting, present his/her assessment, and participate in the discussion but without the right to vote. The report becomes a permanent part of the study file.

Step 8 The Member-Secretary shall document in the IRB meeting minutes:

a. Name of the Independent Consultant
b. Area of expertise
c. Nature of participation
d. Confirmation that the consultant did not vote
e. The consultant's written assessment shall be referenced in the minutes.

Step 9 The Staff Secretary shall keep the pertinent documents in a consultant's file.

VII. Termination of Services

The Consultant's services may be terminated by either the consultant or the officers of the PELI-IRB. Upon termination of the consultant's services, the Staff Secretary shall ensure that all the necessary documentation is filed with the other administrative documents. The Staff Secretary shall store the said documents in the IRB folders under the Independent Consultants File in alphabetical order.

VIII. Forms

1. Form 1.1 Confidentiality and Conflict of Interest Agreement

IX. 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. o Clarify and define scientific, non-scientific members in the SOP o 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

06	March 9, 2026	• Revised and reclassified as SOP 2 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics • 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.