

	<b>Peregrine Eye and Laser Institute Institutional Review Board</b>
PELI-IRB-SOP-08-09-2026	<b>SOP 08 Review of a Medical Device Study</b>
Version No. 9	
Approval Date: March 9, 2026	
Effective Date: March 9, 2026	
Supersedes: SOP 11 V.8 July 16, 2022	

## SOP 08 Review of a Medical Device Study

### I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall review research involving medical devices using a risk-based regulatory framework to ensure the protection of research participants, particularly with respect to vision safety, surgical risk, and long-term outcomes.

1. Medical device studies submitted to the PELI-IRB shall be evaluated using recognized international and national regulatory standards, including but not limited to;
  - a. ISO 14155 (Clinical investigation of medical devices);
  - b. applicable ISO 11979 standards for ophthalmic implants and intraocular lenses;
  - c. risk-based medical device classification principles adopted by regulatory authorities such as the Philippine FDA and the US FDA.
2. Device risk classification shall take into account:
  - a. whether the device is implantable or non-implantable;
  - b. degree of invasiveness;
  - c. duration of contact with the human body;
  - d. whether the device is vision-critical or life-supporting
  - e. novelty of the device or its intended use; and
  - f. availability of prior clinical and post-market safety data.
  - g. For regulatory consistency, medical devices shall also be classified as Significant Risk (SR) or Non-Significant Risk (NSR) in accordance with ICH-GCP principles and internationally accepted regulatory guidance.

#### (1) Non-Significant Risk (NSR) Device

A device that does not present a potential for serious risk to the health, safety, or welfare of a subject.

Typical characteristics are:

- Non-implantable
- Non-invasive or minimally invasive
- Short duration of contact
- Not vision-critical or life-supporting
- Uses well-established technology
- Has sufficient prior clinical or post-market safety data

(2) Significant Risk (SR) Device

A device that presents a potential for serious risk to the health, safety, or welfare of a subject, including devices that are:

- Implantable
- Used to support or sustain human life
- Of substantial importance in diagnosing, curing, mitigating, or treating disease, where failure could cause serious harm (e.g., vision loss)
- Novel devices or devices used for a new indication
- Devices with limited or no prior human safety data

(3) In general, low-risk medical devices are considered Non-Significant Risk (NSR), while high-risk medical devices are considered Significant Risk (SR).

(4) Moderate-risk devices may be classified as either NSR or SR, depending on factors such as invasiveness, implantability, novelty, intended use, and the availability of prior safety data.

3. The level of IRB review for medical device studies shall be determined based on the assessed level of risk, as follows:

- a. Lower-risk medical device studies may be eligible for expedited review, provided all regulatory and ethical criteria for expedited review are met;
- b. Moderate-risk medical device studies may undergo expedited or full board review, depending on the nature of the device, study design, and participant population;
- c. High-risk medical device studies, including implantable ophthalmic devices such as intraocular lenses, shall require full board review.

4. Investigators shall submit documentation sufficient to support device risk assessment, including regulatory approvals, technical specifications, prior clinical data, and applicable international standards.
5. The PELI-IRB reserves the authority to require full board review of any medical device study if additional ethical or safety concerns are identified, regardless of initial risk classification.

## II. Purpose

To describe the procedures in the review of medical device protocols submitted to the IRB.

## III. Scope

This SOP begins with the receipt and screening of medical device protocol submission and ends with the communication of IRB decision, documentation, and updating of the IRB database.

## IV. Responsibility

It is the responsibility of the IRB members to review medical device protocols in accordance with international and national guidelines and regulations.

## V. Process Flow /Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive and screen submission	Staff Secretary	1 calendar day
2	Assign code and log in database	Staff Secretary	1 calendar day
3	Notify Chair and forward documents	Staff Secretary	1-2 calendar days
4	Determine risk classification and type of review	Chair	7 calendar days
5	Distribute to Technical Reviewer	Staff Secretary	1-3 calendar days
6	Conduct technical review	Technical Reviewer	7-14 calendar days
7	Forward technical approval	Staff Secretary	1-3 calendar days

8	Distribute protocol package and assessment forms to assigned Primary Reviewers	Staff Secretary	1-3 calendar days
9	For expedited review (see SOP 6) or For full board include in agenda and discuss at Full Board (see SOP 21; SOP 07)		
10	Communicate decision	Chair and Staff Secretary	1-3 calendar days
11	File and update database	Staff Secretary	2 calendar days

## VI. Detailed Instructions

**Step 1** The Staff Secretary receives the documents for initial protocol review, checks completeness using Form 4.1, and places a receiving stamp with date and name on each copy on the same day.

Incomplete or incorrect submissions shall not be accepted and shall be returned to the PI. The Staff Secretary retains the original Form 4.1, provides the receiving copy to the PI, and records the submission in the database and logbook.

**Step 2** The Staff Secretary assigns an IRB protocol code indicating the year and the order in which the protocol was received. The IRB Code is assigned as follows:

- a. <YYYY-NN>
- b. YYYY Represents the year submitted (i.e. 2020)
- c. NN Represents sequential number as issued by the Staff Secretary (i.e. 01)

This code is the unique identifier and shall not be reassigned. The code shall be communicated to the PI in subsequent communications regarding the protocol on the same day. The Staff Secretary logs and encodes the submission using the database and logbook.

**Step 3** The Staff Secretary forwards the protocol package to the Chair within 1–2 calendar days from receipt.

**Step 4** The Chair checks the information/communication from the PI related to SR or NSR determination by regulators (FDA) from the sponsor country. Chair then determines

the type of review - expedited or full board assigns Primary Reviewers and instructs the Staff Secretary accordingly within 7 calendar days upon receipt of the protocol package.

**Step 5** The Staff Secretary distributes the protocol package and Form 4.2 Study Protocol Assessment Form for Technical Reviewer to the Technical Reviewer 1-3 calendar days from receipt of protocol.

**Step 6** The Technical Reviewer reviews the protocol to ensure scientific validity prior to ethical review and accomplishes Form 4.2 within 7- 14 calendar days upon receipt. The Staff Secretary assists in correspondence with the PI for clarifications and revisions. The final approval on the assessment form is given only once any and all suggested revisions by the Technical Reviewer are done by the PI. The Technical Reviewer then forwards the approval in Form 4.6 Notification of IRB Decision to the Staff Secretary for communicating to the Chair and the PI.

**Step 7** The Staff Secretary forwards the accomplished Form 4.2 and a copy of Form 4.7 with technical approval to the Chair and the Form 4.7 to the PI.

**Step 8** The Staff Secretary distributes the following to the Primary Reviewers and Independent Consultants (if needed):

- a. Protocol package as hard copies and soft copies with access to the electronic files
- b. Form 4.3 Study Protocol Assessment Form for Ethical Review to the medical member Primary Reviewer
- c. Form 4.4 Informed Consent Evaluation Form to the lay member Primary Reviewer.

**Step 9** For expedited review, the Primary Reviewers and Independent Consultants (if needed) then proceed to do an expedited review (see SOP 06). For full board review, the Chair and Staff Secretary include the review in the next meeting agenda and the IRB discusses and decides at Full Board (see SOP 22; SOP 07).

When reviewing a medical device protocol, the reviewers should consider the following:

- a. Proposed investigational plan
- b. Informed consent form
- c. Description of the device/Product information
- d. Description of study participant selection criteria

- e. Safety monitoring procedures
- f. Reports of prior investigations conducted with the device
- g. PI's curriculum vitae
- h. Risk assessment determination for new investigational device (SR or NSR)
- i. Statistical plan and analysis
- j. Copies of all labeling for investigational use
- k. Risk assessment determination for new investigational device (SR or NSR)
- l. Statistical plan and analysis
- m. Copies of all labelling for investigational use

**Step 10** The Chair dictates his/her decision to the staff for preparation of the draft approval letter Form 4.7 Document Decision Form or Form 4.6 Notification of IRB Decision and sends it to the PI. See SOP 27 Communicating IRB Decisions.

**Step 11** The Staff Secretary files the original package in a properly coded Protocol File Folder and updates the database with the names of the assigned Primary Reviewers and type of Review. The Vice-Chair shall check and oversee compliance done or will be made by the Staff Secretary and members to the SOP and timelines set in the process flow chart.

## VII. Forms

1. Form 4.1 Application Form for Protocol Review
2. Form 4.2 Study Assessment Form for Technical Reviewer
3. Form 4.3 Study Protocol Assessment Form for Ethical Review
4. Form 4.5 Informed Consent Evaluation Form
5. Form 4.7 Notification of IRB decision
6. Form 4.8 Document Decision Form

## VIII. References

1. FDA <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf>
2. PELI-IRB SOP 2017

## IX. Annex A

Device Risk Classification and IRB Review Level		
Device Type	Risk Level	IRB Review
Diagnostic imaging devices	Low	Expedited
Dry eye devices (IPL, thermal)	Low–Moderate	Expedited
Phacoemulsification systems	Moderate	Expedited / Full

<b>Vitreotomy machines &amp; probes</b>	Moderate	Expedited / Full
<b>Lasers (cataract/retina)</b>	Moderate	Expedited/Full
<b>Intraocular lenses (IOLs)</b>	High	Full
<b>Novel ophthalmic implants</b>	High	Full

## X. Revision Index

<b>Version</b>	<b>Date</b>	<b>Reasons For Revision</b>
2	August 8, 2013	Pattern SOP after the SOP drafted by the DOH SOP Team (based on the FERCAP template)
3	February 3, 2014	Added concise but detailed flowcharts as guides for PI/Research coordinators/PELI-IRB members/secretariat, changes made to IRB protocol submission checklist, changes to Form 2.1, added Form 2.9( Review of Protocol Modifications) (Statement of Agreement to Comply with Ethical Principles), changes to Form 2.3; considerations to decision-making during full-board review are added (based on WHO guidelines Section 7); added more elements to Review Guidelines following WHO Guidelines Section 6.2; revised Form 2.6, responsibilities of the PI, revised Form 2.1 (Application for Protocol Review); added section 2.6 SOP on Informed Consent Process; added Section 2.7 SOP on Assent of Children or Decisionally-Impaired Individuals, added Section 2.8 General Recruitment Practices and Advertisements
4	Sept 9, 2015	Added “Terms of Reference / Clinical Trial Agreement” to documents to be submitted under new protocol review
5	Jan 26, 2016	Changed logo of “Pacific Eye and Laser Institute” to “Peregrine Eye and Laser Institute” in the document header and in the header of forms 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9
6	June 15, 2017	<p>The following major revisions of both SOP and forms 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 made in compliance with PHREB recommendations of official finding report last June 8, 2017:</p> <p>Ensure SOP 2.7 on classification of assent for children and decision impaired individuals is consistent with the NEGHR</p> <p>Ensure consistency of the flow chart with the detailed instructions (e.g. person responsible for a particular process)</p> <p>Clarify the role of the Technical Review Committee; Ensure consistency in the implementation of SOP 2.4.5.10</p> <ul style="list-style-type: none"> <li>● Ensure that sponsors submit SR/NSR assessment for medical devices</li> <li>● Ensure that the IRB implements SOP 2.5 on risk assessment, i.e. Significant Risk [SR] vs No Significant Risk [NSR]) on type of review for medical devices</li> <li>● Ask the PI to submit the required number of copies of protocol package and other documents for initial review (SOP 2.1.5.5)</li> <li>● Include timelines for critical control points in the protocol review process to ensure efficiency of review submission and approval</li> <li>● Revise the contents and format of the Protocol and ICF assessment forms to reflect the essential elements of a protocol and informed consent</li> </ul>

		<ul style="list-style-type: none"> <li>● Require inclusion of Protocol and ICF Assessment form in the distribution of Protocol to IRB members prior to the IRB meeting</li> <li>● Explain in detail the methodology in the protocol or describe the process of getting the Informed Consent (Who, When, How)</li> <li>● Primary reviewer should present the summary or abstract of the protocol and the issues identified in the review of the protocol; invite Independent Consultant for risk assessment as needed. IRB should assess the R/B of the protocol not the PI</li> <li>● Lay member/s should comment on the language used in the ICF</li> <li>● Consider translating ICF in Chinese language, as needed</li> <li>● Describe clearly how the IC will be taken considering that the patient-participants may have visual problems</li> </ul> <p>Follow the SOP that the Chair should summarize protocol points of discussion</p>
7	Oct. 17, 2017	<p>The following major revisions made in compliance with PHREB recommendations stated in the provisional letter dated last July 31, 2017:</p> <ul style="list-style-type: none"> <li>● Clearly state the role of the Technical Reviewer and primary reviewer and provide specific timelines regarding technical review and ethics review.</li> <li>● - Assent for Children to follow 2017 NEGHR</li> <li>● - Change in Initial Submission Copies</li> </ul>
8	July 16, 2022	<ul style="list-style-type: none"> <li>● Reformat numbering to conform to 2020 PHREB SOP workbook</li> <li>● Refer to SOP 2.5 of Chapter 2 Initial Review Procedures of version 7 of PELI IRB SOP</li> <li>● Add references within the SOP</li> <li>● Make Process Flow and Detailed instructions consistent</li> <li>● Add “forms” to include forms used in the SOP .</li> </ul>
9	March 9, 2026	<ul style="list-style-type: none"> <li>● Revised and reclassified as SOP 8 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics</li> <li>● Added a Policy section to define the governing principles and general guidelines of the SOP.</li> <li>● Added Annex A: Device Risk Classification and Corresponding IRB Review Level.</li> <li>● Convert all timelines to calendar days</li> <li>● Forms were re-numbered to correspond with the SOP in which they are used to ensure consistency, traceability, and proper document control. All form numbers mentioned in the SOP were updated accordingly to align with the revised numbering system</li> </ul>

