

	<b>Peregrine Eye and Laser Institute Institutional Review Board</b>
PELI-IRB-SOP-33-02-2026	<b>SOP 33 SJREB JOINT REVIEW</b>
Version No. 2	
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## SOP 33 SJREB Joint Review

### **I. Policy**

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall participate in the Single Joint Research Ethics Board (SJREB) joint review process for applicable multi-site studies, in accordance with Department of Health Administrative Order No. 2017-0021, to promote a harmonized, efficient, and ethically sound ethics review across multiple sites.

1. For studies requiring joint review under the SJREB, the PELI-IRB shall contribute to the review process through technical, scientific, ethical, and informed consent form (ICF) assessment, with particular attention to site-specific considerations relevant to the Peregrine Eye and Laser Institute.
2. The PELI-IRB recognizes the authority of the SJREB to conduct joint ethics review for eligible multi-site studies and shall, as a general rule, uphold SJREB decisions on protocol submissions.
3. Notwithstanding participation in the SJREB process, the PELI-IRB retains its ethical responsibility to protect research participants at its site, including the authority to review and deliberate on local context, site-specific risks, investigator qualifications, and implementation considerations.
4. Decisions of the SJREB shall be upheld by the PELI-IRB unless a major ethical issue specific to the PELI site is identified, and a majority of the PELI-IRB members determine that such issue warrants non-acceptance of the SJREB decision.
5. In cases where the PELI-IRB does not uphold an SJREB decision, the justification for opting out shall be clearly documented, deliberated during a convened PELI-IRB meeting, and communicated in accordance with established procedures.
6. Review of SJREB-submitted protocols by the PELI-IRB shall utilize the standardized study assessment forms and documentation requirements applied in full board review, to ensure structured, consistent, and well-documented evaluation of ethical and scientific considerations.

7. All actions, communications, deliberations, and decisions related to SJREB joint review shall be documented and maintained as part of the official IRB records, and made available for audit, accreditation, or regulatory review.

## **II. Purpose**

To describe the IRB procedures in the management of protocol submissions that are for joint review under the SJREB.

## **III. Scope**

This SOP begins with the receipt and screening of protocol submission for SJREB joint review and ends with the documentation and communication of the PELI-IRB decision to uphold or opt out of the SJREB decision.

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## **IV. Responsibility**

It is the responsibility of the PELI-IRB to participate in the SJREB review process through the assessment of the technical and scientific aspects and the review of the ethics and ICF soundness of the protocol.

Decisions of SJREB on protocol submissions will be upheld by the PELI-IRB in all instances except when a major ethical issue is raised by any member of the IRB, and the majority disagrees with the SJREB decision. In which case the PELI-IRB may opt out of the decision to the uphold the approval of the protocol.

## V. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive, check completeness, stamp application form, log protocol submission, notify Chair of submission	Staff Secretary	On day of receipt
2	Assign code and enter into database	Staff Secretary	1-2 calendar days upon receipt
3	Forward copy of protocol package to Chair	Staff Secretary	1-3 calendar days upon receipt
4	Assign reviewers and instruct Staff Secretary	Chair	1-2 calendar days upon instruction by Chair
5	Distribute received files and assessment form for technical review, scientific/ethical review, and ICF review	Staff Secretary	1-3 calendar days upon receipt
6	Review protocol and ICF and accomplish assessment forms	Technical Reviewer, primary reviewers	1-2 weeks upon receipt
7	Receive and forward reviewers' assessment forms to Chair, PI, SJREB	Staff Secretary	1 day upon receipt
8	Obtain agenda and meeting details of the SJREB Meeting	Staff Secretary	1 calendar day
9	Attend the SJREB Meeting	Reviewer or representative	1 calendar day
10	Obtain minutes of the meeting and decision letter from SJREB	Staff Secretary	7 calendar days
11	Include SJREB decision in the agenda of the next PELI-IRB full board meeting	Staff Secretary	1 calendar day
12	During presentation of SJREB decision to Full Board Meeting, vote with finality on the approval of the decision.	IRB Full Board Members	1 calendar day
13	If with resubmission, receive resubmission of the site PI containing response to preliminary decision (with parallel resubmission to SJREB)	Staff Secretary	1-2 calendar days
14	Notify primary reviewers to conduct review of the resubmission	Staff Secretary	1-2 calendar days
15	Accomplish corresponding review resubmission form and send to Staff Secretary	IRB primary reviewers	5 calendar days
16	Send IRB decision to the site PI and the required SJREB form to the SJREB staff	Staff Secretary	1-2 calendar days
17	Obtain SJREB decision on the post-approval resubmission.	Staff Secretary	1-7 calendar days
18	Include SJREB decision in the agenda of the next PELI-IRB full board meeting	Staff Secretary	1-2 calendar days

## VI. Detailed Instructions

**Step 1** The Staff Secretary ensures correctness and completeness of submitted forms and documents according to the checklist in **Form 4.1** Application Form for Protocol Review and puts a receiving stamp with the date received and name on each copy of the application Form 4.1 on the same day. Incomplete or incorrect submissions will not be accepted and will be returned to the Principal Investigator. The Staff Secretary keeps the original copy of the Form 4.1 for the IRB files, gives the duplicate (receiving copy) to the PI on the same day and enters the submission in the database and logbook. The Chair is informed of the new protocol submission on the same day as receipt.

**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:

<YYYY-NN>

YYYY Represents the year submitted (i.e. 2020)

NN Represents sequential number as issued by the Staff Secretary (i.e. 01)

This code is the ID number of the protocol and cannot be assigned to any other protocol. The code will 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 a copy of the protocol package to the Chair within 1-2 calendar days of receipt of submission.

**Step 4** The Chair, or in the absence of the former, the Vice-Chair instructs the Staff Secretary to distribute the received files and assessment forms to the reviewers within 1-2 calendar days of receipt of the protocol package.

**Step 5** The Staff Secretary distributes the protocol package and Form 4.2 Study Protocol Assessment Form the Technical Reviewer as well as the primary reviewers for technical, primary and ICF review 1-3 calendar days upon receipt.

**Step 6** The technical, primary and ICF reviewers review the protocol and accomplishes Form 4.2 within 1- 2 weeks upon receipt. The Staff Secretary assists the reviewers in corresponding with the PI for any clarifications on the protocol and recommended modifications or revisions in research design, sampling design, sample size, statistical analysis plan and data analysis plan. The reviewers then forward the approval in Form

4.7 Notification of IRB Decision to the Staff Secretary for communicating to the Chair and the PI.

**Step 7** The Staff Secretary forwards the accomplished 4.2 and a copy of Form 4.7 with reviewers' approval to the Chair and the Form 4.7 to the PI and SJREB 1 day upon receipt of the forms.

**Step 8** The Staff Secretary communicates with the SJREB to obtain agenda and meeting details concerning the PELI-IRB SJREB reviewed protocol, and informs the reviewers of SJREB discussion meeting schedule.

**Step 9** A PELI-IRB reviewer or representative attends the SJREB meeting discussing the concerned PELI-IRB SJREB reviewed protocol.

**Step 10** The Staff Secretary contacts SJREB to obtain the minutes of the SJREB meeting and decision letter within 7 calendar days of the meeting.

**Step 11** The Staff Secretary includes the details of the SJREB decision in the agenda of the next PEL-IRB full board meeting.

**Step 12** During presentation of SJREB decision to Full Board Meeting, IRB members will make sure to address site specific issues raised by the SJREB, especially for the resubmissions. In addition, members are encouraged to vote with finality on the approval of the decision.

**Step 13** If SJREB protocol has a resubmission, Staff Secretary receives resubmission of the site PI containing response to preliminary decision (with parallel resubmission to SJREB) within 1-2 calendar days.

**Step 14** The Staff Secretary notifies primary reviewers to conduct review of the resubmission within 1-2 calendar days.

**Step 15** The PELI-IRB primary reviewers accomplish the Review Resubmission Form 9 and sends the completed form to the Staff Secretary within 5 calendar days.

**Step 16** The Staff Secretary sends PELI-IRB decision to the site PI and the required SJREB form to the SJREB staff within 1-2 calendar days upon receipt of completed forms.

**Step 17** The Staff Secretary obtains SJREB decision on the resubmission.

**Step 18** The Staff Secretary includes the SJREB decision in the agenda of the next PELI-IRB full board meeting.

## VII. Forms

1. Form 4.1 Application Form for Protocol Review
2. Form 4.2 Study Assessment for Technical Review
3. Form 4.7 Notification of IRB Decision
4. Form 9 Protocol Resubmission For

## VIII. References

1. SJREB SOP

## IX. Revision Index

Version	Date	Reasons for Revision
1	April 24, 2025	Initial Release
2	March 9, 2026	<ul style="list-style-type: none"><li>•Revised and reclassified as SOP 32 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>•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>