PEREGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute Institutional Review Board**
PELI-IRB-SOP-18-06-2026	
Version No. 6	**SOP 18 Site Visits**
Approval Date: March 9, 2026	
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SOP 18 Site Visits

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall conduct site visits as part of its ongoing oversight responsibilities to verify compliance with approved research protocols, Good Clinical Practice (GCP), and applicable ethical and regulatory requirements.

1. Site visits may be conducted on a routine basis or for cause, including but not limited to concerns related to participant safety, protocol compliance, data integrity, or investigator performance.
2. The purpose of site visits is to:
    a. assess protection of the rights, safety, and welfare of research participants;
    b. verify adherence to the IRB-approved protocol, informed consent process, and study documents;
    c. evaluate compliance with GCP and applicable ethical guidelines; and
    d. identify areas requiring corrective or preventive action.
3. Site visits shall be conducted by designated IRB members or qualified representatives acting on behalf of the PELI-IRB, with appropriate expertise and without conflicts of interest.
4. Findings from site visits shall be documented, reviewed by the full board, and used to inform IRB decisions, including but not limited to:
    a. requests for corrective or preventive actions;
    b. increased monitoring or follow-up visits;
    c. requirement for protocol or consent amendments; or
    d. suspension or termination of IRB approval, when warranted.

5. Investigators shall be formally informed of site visit findings and required actions, and compliance with IRB directives shall be monitored and documented.
6. All site visit activities, findings, and resulting IRB decisions shall be maintained as part of the official IRB records and included in the protocol oversight file.

II. Purpose

To describe the IRB procedures related to the conduct of site visits.

III. Scope

This SOP applies to any site visit made in any study site, on behalf of the PELI IRB, to check compliance with GCP and PELI-IRB approved protocol and related documents.

IV. Responsibility

It is the responsibility of the PELI IRB to perform or designate some members or qualified representatives to perform on its behalf onsite visit of the research projects it has approved. The PELI-IRB members or Secretary in consultation with the Chair may initiate onsite evaluation of a study site for cause or for a routine audit.

V. Process Flow /Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Select study site	Members	Upon decision by the board
2	Notify PI of the planned visit	Staff Secretary	15 calendar days prior to visit
3	Review pertinent IRB files	Members	before the site visit
4	On-site visit proper	Members	
5	Write the report and make a recommendation	Members	7 calendar days
6	Present to Full Board and Decide on action	Members	Not applicable
7	Communicate IRB findings and recommendations to the PI	Staff Secretary	1-3 calendar days
8	File copies of documents and update database	Staff Secretary	On the day of receipt

VI. Detailed Instructions

Step 1 The IRB will review periodically the database files of the submitted/approved study protocols and select study sites needed to be monitored based on the following criteria:

a. New study sites or new PIs
b. Reports of remarkable SAE
c. High risk studies
d. Big number of studies carried out at the study site
e. Frequent protocol submission for PELI-IRB review
f. Noncompliance or suspicious conduct
g. Frequently fail to submit final reports
h. Frequent protocol violations

Step 2 The Staff Secretary informs the Principal Investigator (PI) of the planned site visit through a formal notification letter signed by the Chair.

The letter shall be sent within 1–3 calendar days after the IRB decision and at least 15 calendar days prior to the scheduled visit.

The Staff Secretary coordinates the schedule with the PI and arranges logistics for the visiting team, when applicable.

Step 3 Review of pertinent IRB files

a. Members shall review the PELI-IRB files for the study and site. They shall make appropriate notes or copy some parts of the files for comparison with the study files. Staff Secretary shall assist members in such tasks.
b. Member-Secretary shall ensure that original study files cannot be taken out of the IRB office premises.

Step 4. For the on-site visit proper, members shall use the Form 18 Site Visit checklist and do the following:

a. Review the informed consent document to make sure that the site is using the most recent version,
b. Review randomly the subject files to ensure that participants are signing the correct informed consent,
c. Check for adverse events and protocol violation
d. Check if case record forms are up to date
e. Check if the files are orderly and confidentiality is maintained,
f. check if the facilities are appropriate

g. Debrief the PI about the site visit findings and comments

h. Get immediate feedback

Step 5 After the site visit, the members will:

a. **w**rite a report/comment within **7 calendar days** describing the findings

b. **f**orward a copy of the site visit to the Staff Secretary for inclusion in the next board meeting.

c. **s**end a copy of the report to the site for their files, and

d. **p**lace the report in the correct site files.

Step 6 The Primary Reviewer presents the findings of the on-site visit to the Full Board. The other members present during the visit are allowed to expound on their findings. Issues of concern, if any are discussed, and the board deliberates on the implications of the findings on the rights, safety, and welfare of the study participants; and makes an overall determination of protocol compliance in the study site.

Step 7. Staff Secretary communicates the board decision to the PI for appropriate action with a letter signed by the **Chair.**

Step 8 The Staff Secretary files the Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly. (SOP 28 Management of Active Files)

VII. Forms

1. Form 18 Site Visit Form

VIII. References

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

IX. Revision Index

Version	Date	Reasons For Revision
01	August 8, 2013	Patterned SOP after the SOP drafted by the DOH SOP Team (based on the FERCAP template)
02	February 3, 2014	Revised section 3.7 (additional requirements from the PI for premature suspension or termination of a research study), added section 3.8 suspension or termination of IRB approval, added Form 3.11 (Reminder Letter), added section 3.9 continuing review, added Form 3.12 Application for Continuing Review
03	January 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 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.11, 3.12

04	June 15, 2017	The following major revisions of both SOP and forms 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.11, 3.12 made in compliance with PHREB recommendations of official finding report last June 8, 2017: ● State in the SOP 3 that the IRB reviews by full board reports of onsite SAE/SUSARs and indicate timelines for reporting (SOP 3.1.5.2 SAE reporting timelines should comply with the ICH-GCP guidelines) ● Ensure that Protocol violations and deviations are categorized accordingly ● Define major and minor violations Organize the sequence of discussion of the protocol (i.e. Scientific, then ethical issues, ICF; include the PDPVs and reasons for that) Ensure appropriate timelines for SAE reporting are incorporated in the SOP AND communicated to the PI ● Ensure timely review of the continuing reports ● Indicate reviewers of SAEs in the minutes ● Ensure that SAE reviewer is a medical doctor ● Categorize protocol deviations into major or minor and how deviations will affect risk ● Reflect recommended actions required of PI on deviations/violations in the meeting minutes ● Consistently require Final reports for all studies Communicate to the PI the results of review of final report. Ensure consistency of the flow chart with the detailed instructions (e.g. person responsible for a particular process).
5	July 16, 2022	Reformat numbering to conform to 2020 PHREB SOP workbook Refer to SOP 3.6 of version 4 of PELI IRB Add references within the SOP Add “forms” to include forms used in the SOP. remove the steps between “communication of IRB decision to the PI” and “Filing of documents and updating of database” indicate under step 6 under full board presentation who among the Members will make the presentation during the REC meeting and how the IRB makes a determination of action Add : check facilities, occurrence of SAE and protocol violation/deviation , case record forms if updated, and use of most recent informed consents in Step 4 : On-site visit proper Add “high risk studies” in criteria for possible on-site visits
6	March 9, 2026	Revised and reclassified as SOP 17 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics Added a Policy section to define the governing principles and general guidelines of the SOP. Convert all timelines to calendar days 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