PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute Institutional Review Board**
PELI-IRB-SOP-19-06-2026	
Version No. 6	**SOP 19 Early Protocol Termination**
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SOP 19 Early Protocol Termination

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) may require or approve early termination of a research protocol when continuation of the study is no longer ethically justified or when participant safety, rights, welfare, or scientific integrity may be compromised.

1. Early protocol termination may be initiated upon recommendation or notification from, but not limited to, the Principal Investigator, sponsor, Data Safety Monitoring Board (DSMB), Scientific Director, the PELI-IRB, or other authorized bodies.
2. The PELI-IRB shall require that all early terminations undergo full board review, regardless of the original level of review, to ensure comprehensive ethical assessment and institutional oversight.
3. Review of early termination shall focus on:
    - **a.** the reasons and justification for termination;
    - **b.** available safety data and adverse events;
    - **c.** the adequacy of plans for participant notification, continued care, and follow-up;
    - **d.** the status of data collection, management, and analysis; and
    - **e.** compliance with prior IRB approvals and reporting requirements.
4. Approval of early termination shall be contingent upon submission of a complete termination package, including a written summary of the study, justification for termination, and measures to protect participants affected by the termination.
5. The PELI-IRB may require additional actions or safeguards as a condition of accepting early termination, including submission of a final report, resolution of outstanding safety issues, or specific follow-up requirements.
6. Acceptance of early protocol termination does not relieve the investigator of responsibility for:

a. submission of required final reports;

b. resolution of unresolved adverse events, deviations, or violations; and

c. proper archiving of study records in accordance with institutional policies.

II. Purpose

To describe the IRB procedures related to the early termination of protocol implementation.

III. Scope

This SOP describes how the IRB proceeds and manages the premature or early termination of a protocol when subject enrollment is discontinued before the scheduled end of the study. Protocols are usually terminated at the recommendation of the Data Safety Monitoring Board (DSMB), the scientific director, sponsor, PI, by the IRB itself or other authorized bodies.

This SOP begins with the receipt and entry to logbook of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of the protocol database

IV. Responsibility

It is the responsibility of the PELI-IRB to act on an early protocol termination application. It is also the responsibility of the IRB to withdraw approval for any previously approved protocol when the safety or benefit of the study participants is doubtful or at risk. All applications are reviewed at full board for appropriate action. The Staff Secretary is responsible for the receipt and management of the termination documentation. The primary reviewers evaluate the reasons, and ensure the safety and welfare of patients if early termination shall proceed and make a recommendation to full board.

V. Process Flow /Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive, check completeness and enter into logbook the early termination report	Staff Secretary	1 calendar day
2	Retrieve pertinent protocol file and notify Chair and Primary Reviewers	Staff Secretary	1 calendar day
3	Review the termination package or termination issues and make recommendation	Primary Reviewers	7 calendar days
4	Discuss at full board	Members	During Meeting
5	Communication of committee action and update of the protocol database	Staff Secretary	1 calendar day after meeting

VI. Detailed Instructions

Step 1 Receive, check completion and enter into the logbook the application or recommendation for early termination.

The Staff Secretary shall receive the application or recommendation for early study termination.

a. Recommendation or application may vary from but not limited to comments from the Sponsor, DSMB, IRB members, Scientific Director, or other authorized bodies for study protocol termination.

b. The Staff Secretary receives and checks the completeness of the termination package submitted by the PI within 1 calendar day upon receipt, including Form 19 Study Termination.

c. The request for termination memorandum should contain **(a)** a brief written summary of the protocol, **(b)** its results and accrual data, **(c)** reason for termination with justification, **(d)** appropriate measures for participant care and follow-up; and **(e)** the procedures considered for notifying the participants.

d. A **Final Report** is required **as follows:**

(1) Multicenter studies: The local site may close if there are no further implications to local participants even though the study continues in other sites. For industry-sponsored studies, a Final Report Form (Form 14) should only be submitted to the IRB office after the sponsor has conducted the closeout visit. If the sponsor has no plans to conduct a close-out visit, the Form 14 must be submitted after all data clarifications have been completed and the sponsor has indicated to the PI that study files can be archived for long term storage.

(2) Local Single Center Studies: Form 14 must be submitted to the IRB office after the study when all study-related activities including long-term follow-up data are completed. For studies that do not involve participant participation for example, secondary use of data, a Final Report Form can be submitted when data acquisition is completed.

(3) For local registries or research database, a Final report Form must only be submitted after the database is destroyed or there is no intent to access the dataset for research purposes.

The Staff Secretary then enters the report into the logbook.

Step 2 Retrieve pertinent protocol file, notify Chair and distribute documents to Primary Reviewers. The Staff Secretary retrieves the protocol file and distributes the early termination packet to the Primary Reviewers for review and to the Chair for inclusion in the next board agenda. See SOP 22 Preparing the Meeting Agenda.

Step 3 The Primary Reviewers shall check the approval given by the IRB from the protocol files and collect relevant information. They shall review the termination package, termination issues and the safety data. They shall then make a recommendation. It is important for the termination package to contain a plan to follow-up the participants who are still active in the study.

Step 4 Primary reviewers shall report at full board and the IRB considers the following possible decisions in the review of an early termination report:

a. Acceptance of the decision with no further action;
b. Request for additional information; or
c. Requirement for further action.

Step 5 **The Staff Secretary communicates the IRB decision to the PI using appropriate forms (Form 4.8 or Form 4.9) signed by the Chair within 1–3 calendar days after final decision (see SOP 27).**

The Staff Secretary updates the protocol database accordingly..

VII. Forms

1. Form 4.8 Request for Information for Post Approval Procedures
2. Form 4.9 Approval Letter for Post-Approval Procedure
3. Form 19 Early Study Termination Form
4. Form 14 Final Report

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 3.7 of version 4 of PELI IRB Add references within the SOP Rewrite process flow and steps to make it consistent Add "forms" to include forms used in the SOP.
6	March 9, 2026	Revised and reclassified as SOP 11 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