SOP 20 Application for Continuing Review

I. Policy

The Peregrine Eye and Laser Institute Institutional Review Board (PELI-IRB) shall require continuing review and approval of all approved research involving human participants to ensure the ongoing protection of participant rights, safety, and welfare throughout the study lifecycle.

1. Continuing review shall be required prior to the expiration of IRB approval and shall remain applicable for as long as:
    a. participants are enrolled or undergoing research-related interventions;
    b. follow-up activities are ongoing; or
    c. identifiable research data are being maintained or analyzed.
2. Continuing review shall also be required for studies that are temporarily suspended, in whole or in part, until the study is formally closed and a final report is accepted by the PELI-IRB.
3. Applications for continuing review shall be submitted within the timeframe specified by the IRB. Failure to obtain continuing approval prior to expiration shall result in lapse of ethical clearance and suspension of research activities, except when continuation is necessary to eliminate immediate hazards to participants.
4. The PELI-IRB shall determine the appropriate level of review for continuing review applications—expedited or full board—based on:
    a. the level of risk;
    b. the nature of the study;
    c. the review category of the initial approval; and
    d. any new information affecting participant safety or study conduct.
5. The frequency of continuing review shall be risk-based and shall occur at least annually, and more frequently when required by:
    a. the degree of risk;
    b. the vulnerability of the study population; or

c. the absence of adequate external safety monitoring.

6. Review of continuing review applications shall include assessment of:
    a. compliance with the approved protocol and amendments;
    b. reported adverse events, SAEs, and SUSARs;
    c. protocol deviations or violations;
    d. participant enrollment status; and
    e. whether the risk–benefit ratio remains acceptable.
7. Approval of a continuing review application authorizes the continuation of the study for a defined approval period, as specified by the PELI-IRB. Disapproval or unresolved deficiencies may result in suspension or termination of IRB approval.

II. Purpose

To describe the procedures and requirements for the submission, review, and approval of continuing review applications to ensure ongoing ethical oversight of approved research protocols.

III. Scope

This SOP covers the procedures for the application for continuing review of approved research protocols, beginning from the submission and receipt of the continuing review application and ending with the communication of the IRB decision and filing and updating of protocol records.

It applies to all studies under IRB oversight that require continuing review, including those with ongoing participant follow-up, identifiable data collection or analysis, or those temporarily suspended, until final closure is approved by the PELI-IRB.

IV. Responsibility

The IRB shall require the submission of an Application for Continuing Review at least one (1) month before the expiration of the ethical clearance of a protocol. The PI retains the responsibility for submitting requests for continuation. The responsibility to review and approve applications for continuing review falls on the IRB (for full board reviews) or primary reviewer/Chair (in cases of expedited reviews).

Federal regulations require continuing review to occur not less than once per year (365 calendar days; except when the approval period includes part of a leap year, resulting in a maximum approval period of 366 calendar days). At each initial and continuing review, the IRB must specify the duration of the next approval period. This establishes the date by when the next continuing review must occur. Whenever possible, the PELI-IRB maintains a fixed anniversary date for the expiration of annual IRB approvals of a study. The PELI-IRB may require more frequent review, depending on the level of risk. Some examples of protocols that may be considered for review more frequently than annually include:

a. Studies involving planned emergency research (21 CFR 50.24);
b. Phase I studies of a new drug or biologic;
c. Studies involving a Category A significant risk device;
d. Studies in which a healthy volunteer may undergo anesthesia or a medical procedure involving sedation, but with no direct health benefits;
e. Studies in which individuals with impaired decision-making capacity will be enrolled;
f. Studies for which there is little external oversight or data safety monitoring;
g. Studies involving gene transfer or xeno-transplantation.

V. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Remind PI to apply for continuing review (Form 4.11	Staff Secretary	30 calendar days before the due date
2	Receive and check completeness of application for continuing review documents and correspond with PI until submission is complete	Staff Secretary	1 calendar day
3	Determine type of review designate the reviewers and inform Staff Secretary	Chair	7 calendar days
4	Distribute documents to designated reviewers	Staff Secretary	Upon instruction by Chair

5a	Do expedited review and submit the decision to the Chair	Primary Reviewers	7-14 calendar days
6a	If for full board review, include in the next meeting agenda	Staff Secretary	1 calendar day
7	Discuss during full board meeting	Members	During the meeting
8	Communicate the IRB decision to the PI	Staff Secretary	1-3 calendar days

9	File copies of documents and update database	Staff Secretary	1-3 calendar days

VI. Detailed Instructions

Step 1 The Staff Secretary shall initiate the continuing review process by notifying the Principal Investigator (PI) to submit an application for continuing review using Form 4.11 Reminder Letter. This ensures uninterrupted ethical oversight of the study.

Step 2 Upon receipt of the continuing review application, the Staff Secretary shall:

- Check completeness of submitted documents, including:
  - Accomplished Form 20 (Continuing Review Form)
  - Latest approved protocol version
  - Progress report (if applicable)
  - Summary of adverse events, protocol deviations, and amendments
  - Updated informed consent forms (if applicable)
- Verify that documents are properly signed, dated, and version-controlled
- Coordinate with the PI for any deficiencies or missing documents

Note: The application shall not proceed to review until all required documents are complete.

Step 3 The Chair determines if the continuing review is eligible for an expedited review or a full board review one week upon receipt. The policy is protocols that underwent Full review in its initial submission shall undergo Full review in its application for continuing review. Similarly, protocols underwent Expedited review shall undergo Expedited review in its application for Continuing review. The following circumstances may also be considered for expedited review procedures for a continuing review:

a. The study was initially eligible and continues to be eligible for expedited review procedures; or
b. The research is permanently closed to the enrollment of new participants; all participants have completed all research-related interventions; and the research remains active only for long-term follow-up of participants; or
c. Where no participants have been enrolled and no additional risks have been identified at the local study site or at any site if the research involves a multi-site study; or
d. The research involves the study of drugs and/or medical devices and either does not require an Investigational New Drug (IND) (21 CFR Part 312) and/or an Investigational Drug Exemption (IDE) (21 CFR Part 812) and/or the device is approved for marketing and being used in accordance with the approved labeling. The IRB must also have determined and documented at a convened meeting that the research is no greater than minimal risk and no additional risks have been identified.

If a request for continuation is received early, the study will be included on the agenda of the next full board meeting. The Staff Secretary prepares a full protocol file for each IRB member.

The Primary Reviewers who conducted the initial review of the protocol shall also be assigned to review the continuing review to ensure continuity of ethical and scientific assessment .

Step 4 The Staff Secretary upon instruction by the Chair, shall distribute to the designated Primary Reviewers all necessary documents for continuing review.

Step 5a For expedited review, see SOP 6 Expedited Reviews. A continuing review proceeds in the same manner as a new expedited protocol submission and the Primary Reviewers submit their decision to the Chair 7-14 calendar days upon receipt of the documents

The outcomes of continuing review are the same as the options as initial review: approval, minor revision, major revision for resubmission or disapproval. The Chair determines whether to uphold the decision of the primary reviewers or to refer for a full board review.

Disapproved continuing reviews must be forwarded to the full board for review and final decision.

Step 5b If the continuing review is for full board review, the Staff Secretary includes the application in the meeting agenda of the next board meeting.

For full board review, see SOP 7 Full Board Review.

Step 6 The IRB communicates the decision to the PI see SOP 27 Communicating IRB Decisions. The Staff Secretary prepares the decision letter Form 4.9 Approval Letter for Post-Approval Application and the Chair finalize and signs the decision letter. Possible decisions include the following:

a. Approval;
b. Additional information required; Submission of an explanation for failure to submit required reports;
c. Revision required or disapproval.

Step 7 The Staff Secretary files the application for Continuing review, the recommendations of the reviewers and decision letter in the appropriate protocol folder and updates the protocol database.

VII. Forms

1. Form 4.8 Request for Information for Post Approval Procedures
2. Form 4.9 Approval Letter for Post-Approval Procedures
3. Form 4.11 Reminder Letter
4. Form 20 Continuing Review Application

VIII. References

1. 2020 PHREB SOP Workbook

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 3.9 of version 4 of PELI IRB Add references within the SOP Change "approximately 4 weeks" to "1 month" from date of expiry of ethical clearance for the reminder deadline for application add "forms" to include forms used in the SOP . in determination of type of review , add: The policy is: protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review. Similarly, protocols underwent Expedited review shall undergo Expedited review in its application for Continuing review remove steps on revisions by the PI and checking revisions of PI
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