PEREGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 22/05-0-2022	
Version No. 5	**SOP 22** **Application for Continuing Review**
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 22 Application for Continuing Review

1. Purpose

To describe the policies and procedures for continuing review application.

2. Scope

Continuing review and approval must be obtained prior to the end of the day on which approval expires. Continuing review is required through all follow-up and data analysis activity (data is being maintained, and/or analyzed, and the identity of participants has not been separated from the research data), even if the study is closed to enrollment and research related interventions are complete. Continuing review is also required for studies that have been suspended, in whole or in part. Requests for continuation are submitted using the PELI IRB form Continuing Review Application (**Form 3.12**) a request for continuation requiring full board review that is submitted early will be placed on the agenda of the next regularly scheduled IRB meeting. The approval period by which subsequent continuing review must occur will be adjusted accordingly. The IRB staff secretary will forward requests for expedited continuation to the Chair or Primary Reviewers for review and approval as they are received.

3. 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 days; except when the approval period includes part of a leap year, resulting in a maximum approval period of 366 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:

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

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Remind PI to apply for continuing review (Form 3.11)	Staff Secretary	One month before the due date of expiration of approval
2	Submit properly accomplished **Form 3.12** and necessary documents to IRB	PI	On or before date of expiration of approval
3	Receive and check completeness of application for continuing review documents and correspond with PI until submission is complete	Staff Secretary	One day upon receipt
4	Determine type of review designate the reviewers and inform Staff Secretary	Chair	1 week upon receipt
5	Distribute documents to designated reviewers	Staff Secretary	Upon instruction by Chair
6A	Do expedited review and submit the decision to the Chair	Primary Reviewers	1 - 2 weeks upon receipt
6B	If for full board review, include in the next meeting agenda	Staff Secretary	One day upon instruction by the chair

6C	Discuss during full board meeting	Members	Not applicable
7	Communicate the IRB decision to the PI	Staff secretary	1-3 days after final IRB decision made
8	File copies of documents and update database	Staff Secretary	1-3 days after final IRB decision made

5. Detailed Instructions

Step 1 The Staff Secretary will send one reminder notice thru a letter **(Form 3.11)** signed by the chair and member-secretary to the PI to request for continuing review one (1) month before the study approval expires.

Step 2 The PI accomplishes **Form 3.12** along with any relevant materials and submits to Staff Secretary on or before the deadline. Study documents that may be required for a continuing review are as follows:

- Study protocol
- Informed consent form
- Investigator's brochure
- SUSAR
- FDA registration, or any permit/clearance from any regulatory agency
- Study protocol amendment submissions
- Study protocol deviation/violation/non-compliance submission
- CV of new personnel
- Statement of disclosure of conflict of interest

Step 3 The Staff Secretary screens **Form 3.12** and other documents submitted for completeness and corresponds with the PI by e-mail and/or phone until the submission is complete.

Step 4 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:

- The study was initially eligible and continues to be eligible for expedited review procedures; or

- 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
- 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
- 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 Chair assigns two (2) members with appropriate qualifications (clinician/scientist with appropriate expertise related to the protocol and a non-medical person to review the consent form) as Primary Reviewers. The Chair may opt to appoint the same Primary Reviewers who performed the initial review to do the continuing review.

Step 5 The Staff Secretary upon instruction by the Chair, shall distribute to the designated Primary Reviewers all necessary documents for continuing review.

Step 6A For expedited review, see SOP 9 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 1-2 weeks 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 6B If the continuing review is for full board review, the Staff Secretary includes the application in the meeting agenda of the next board meeting.

Step 6C For full board review, see SOP 10 Full Board Review.

Step 7 The IRB communicates the decision to the PI see SOP 28 Communicating IRB Decisions .The Staff Secretary prepares the decision letter **Form 2.8** Approval Letter for

Continuing Review Application and the Chair finalizes and signs the decision letter. Possible decisions include the following:

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

Step 8 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.