

	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB SOP 14/05-0-2022	SOP 14 Review of Amendments
Version No. 5	
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 14 Review of Amendments

1. Purpose

To describe the IRB review procedures for amendments of the protocol and related documents.

2. Scope

This SOP applies to approved study protocols and related documents that are being amended and submitted for approval by the PELI-IRB. As expressly stated in **Form 2.6** Document Decision Form, any amendment of the study related documents may not be implemented until reviewed and approved by the IRB. The SOP begins with the submission of an application for a protocol amendment receipt and ends with filing of the amendments and committee decision in the protocol file.

3. Responsibility

The IRB shall require the submission of proposed amendments for review and approval before their implementation to ensure that the conduct of the study complies with the approved protocol such that any change such as amendments does not impact safety and welfare of study participants. The IRB should properly inform the PI to submit an amendment application whenever there is any change regarding the composition of the study team, the study site and the protocol related documents for approvals previously granted by the IRB.

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive application for Protocol Amendment to IRB	Staff Secretary	as needed
2	Check completeness and enter application into logbook	Staff Secretary	1 day upon receipt

3	Retrieve pertinent protocol file	Staff Secretary	1 day upon receipt
4	Notify Chair	Staff	1 day upon receipt
5	Designate amendment reviewers	Chair	1-3 days upon receipt of inquiry
6	Distribute amendment packet	Staff Secretary	1 day upon receipt of instruction from the chair
7	Review Amendments	Technical and Primary Reviewers	1-2 weeks each group of reviewers
8	Forward recommendation to Chair	Staff Secretary	upon receipt
9	Review recommendations	Chair	1 week upon receipt
10	Communicate IRB Decision	Staff Secretary	1-3 days after final decision was made
11	File Amendment documents and committee decision and update the database	Staff Secretary	

5. Detailed Instructions

Step 1 The Staff Secretary receives the application of protocol amendment from the Principal Investigator by submitting a properly accomplished **Form 3.2** Protocol Amendment Review Form to the Staff Secretary.

Step 2 The Staff Secretary checks the completeness of the amendment packet submitted by the PI composed of the following:

- a. Cover Letter
- b. **Form 3.2** Protocol Amendment Form
- c. Clean protocol
- d. Tracked protocol

Staff Secretary then enters the amendment into the logbook of incoming documents one day upon receipt. See SOP 29 Management of Active Files.

Step 3 The Staff retrieves the corresponding protocol file for reference and guidance of the Chair and Reviewers 1 day upon receipt of amendment packet.

Step 4 IRB secretary notifies the Chair of the application for protocol amendment and sends the amendment packet to the Chair.

Step 5 The Chair designates the Primary Reviewers with or without the Technical Reviewer to review the amendments within 1-3 days upon receipt for documents and informs the Staff Secretary.

Step 6 Within one day after receipt of instruction from Chair, the Staff Secretary distributes the amendment packet to the designated reviewers.

Step 7 The designated amendment reviewers check the amended protocol (clean and tracked) and compare them with the previously IRB approved documents in the protocol files. If needed, the Technical Reviewer shall evaluate the amendment first before the Primary Reviewers. The Technical Reviewer determines if the amendment will not alter the scientific soundness of the study. The Primary Reviewers determine if the amendments will alter the risk/benefit ratio of the study.

Protocol amendments, which increase the risk to study participants, may include but are not limited to the following:

- A change in study design
- Additional treatments or deletion of treatments
- Any change in the exclusion/inclusion criteria
- Change in method of drug intake or route of drug intake
- Significant change in the number of subjects
- Significant decrease or increase in dosage amounts

The assigned amendment reviewers make appropriate recommendations using **Form 3.2** and sends this back to the Staff Secretary within 1-2 weeks upon receipt of the amendment packet.

Step 8 The Staff Secretary sends the Chair the recommendations of the amendment reviewers upon receipt of **Form 3.2** Protocol Amendment Form.

Step 9 The Chair shall review the recommendations of the assigned amendment reviewers in **Form 3.2** whether expedited or full board and the process proceeds accordingly. For expedited review, see SOP 9. For full board review, see SOP 10.

Amendments for expedited review are the following:

- Do not affect the substance of the original protocol and where no major new ethical issues are raised.
- Are protocol amendments for safety reasons, i.e., to protect the welfare of the participants.
- Request for extension of an approved project with no modification of protocol.
- Request for approval of recruitment and publicity materials for approved protocols.
- Indicate change of associate or co-investigators.
- Provides for a retrospective statement that the study have been conducted in an ethical manner to assist journal editors to assess articles presented for publications.
- Amendments for protocols that underwent expedited reviews in its initial approval.

For the full board review, if only minor changes that do not affect risk-benefit ratio are involved, the reviewers' recommendation becomes the basis for the final decision of the IRB and the IRB secretary prepares a letter granting approval, as instructed and signed by the chair and member-secretary.

Step 10 Staff Secretary prepares a communication letter to inform the investigators about the board decision. For amendments, the IRB action may be any of the following:

- Approved,
- Additional justification/information required,
- Re-consent required
- Disapproved

Secretary forwards the letter to the investigators for proper action with signature of both the Member Secretary and the Chair. Staff Secretary shall have 1-3 days from the time the final decision and completion of **Form 3.2** to release of decision in **Form 2.8** Approval Letter for Post-Approval Procedures and **Form 2.7** Request Information for Post-Approval Procedures. See SOP Communicating IRB Decisions

Step 11 The Staff Secretary files the Amendment and a copy of the committee decision in the appropriate protocol folder. S/he proceeds to update the pertinent protocol database. See SOP 29 Management of Active Files