PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 21/05-0-2022	
Version No. 5	**SOP 21** **Suspension or Termination of IRB Approval**
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 21 Suspension or Termination of IRB Approval

1. Purpose

To describe the IRB procedures related to suspension or termination of IRB approval by the IRB.

2. Scope

The scope of this section includes the standard operating procedure for study suspension or termination, the responsible people and their duties or delegations, and the different reasons for imposing a suspension or termination. The SOP on lifting the suspension is also described here.

3. Responsibility

The Chair or convened IRB may suspend a study. The authority to suspend studies cannot be delegated to other individual members of the IRB, except the Vice Chair. Only the convened IRB may terminate a study.

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Review and Discuss possibility of suspension or termination of the study in full-board meeting	Members	Not applicable
2	Inform the PI in writing of the possible suspension or termination duly signed by the chair and member-secretary	Staff Secretary	1-3 days after final decision shall be made
3	Check and receive PI response letter	Staff Secretary	1 day upon receipt
3	Include the notice of possible suspension or termination and response of PI on the next meeting agenda	Staff Secretary	
5	Communicate board decision to PI through a response letter signed by the member-secretary and the chair	Staff Secretary	1-3 days upon final decision was made and should be sent

6	File copies of documents and keep an up to date database	Staff Secretary	within 5 working days of the effective date of suspension or termination

5. Detailed Instructions

Step1 Members shall review and discuss possibility of suspension or termination of the study in full-board meeting.
Reasons for imposing a suspension or termination include, but are not limited to, learning of (1) previously unanticipated risks to participants, (2) findings of serious or continuing noncompliance, or (3) findings from the continuing review or internal monitoring process. The IRB may also seek advice from other institutional areas (eg legal counsel) in determining whether to impose a suspension or termination of IRB approval. In addition, when imposing a suspension or termination the IRB will consider the impact of that suspension or termination may have on participant safety and/or welfare. Consideration will include, but is not limited to:

- Whether participation can be stopped safely;
- Whether participants should be transferred to another physician for clinical care, if applicable;
- Whether participants can be kept on study under the same PI;
- If kept on study under the same PI, whether additional monitoring is required;
- Whether participants can be kept on study under another PI.

Step 2 Staff Secretary shall inform the PI in writing of the possible suspension or termination duly signed by the Chair and Member Secretary within 1-3 days after final decision shall be made.

Step 3 Staff secretary check and receives PI response letter one day upon receipt. The investigator is to direct a written response to the person who imposed possible suspension/termination and copy the other individuals noted on the notification of possible suspension/termination letter. The letter shall include:

- A justification as to why continuation is in the best interest of the participant;
- A request for approval for continuation of the specific activity either until the suspension is lifted or until alternate arrangements can be made for the participant
- For terminations, confirmation that alternated arrangements are actively being sought and provide the anticipated time frame by which arrangements should be finalized;
- Confirmation that the PI will inform the participants that the study has been suspended or terminated but that permission for the activity has been obtained;
- The confirmation that the investigator will direct participants to continue to report adverse events or unanticipated problems;

- Confirmation that the PI will continue to report all activity in accordance with policy.

Step 4 Include the notice of possible suspension or termination and response of PI on the next meeting agenda. The IRB member-secretary is responsible for directing IRB Staff secretary to include any notice of suspension or termination on the next meeting agenda for presentation to and review by the convened board.
The IRB members in a convened meeting shall review, discuss and decide on protocol suspension or termination.

- In case of protocol termination, only a convened IRB may terminate a research.
- In case of protocol suspension, lifting of protocol suspension can be done using either the expedited review process or full board process. The IRB Chair may use the expedited review process to lift the suspension in the following cases:
  - Suspension imposed by the Chair
  - Suspension imposed by the convened board when the board specifically delegated to the Chair the authority to lift the suspension
  - Otherwise, the convened IRB will determine whether to lift a suspension.

Step 5 Staff Secretary shall communicate board decision whether to proceed with suspension/termination or withdraw such notification of possible suspension/termination to PI through a response letter signed by the member-secretary and the chair 1-3 days upon final decision was made and should be sent within 5 working days of the effective date of suspension or termination. The Staff secretary shall file copies of documents and keep an up to date database

- In the event of suspension or termination of approval, the IRB or person imposing the suspension or termination will inform the investigator in writing. If immediate action is required, the person imposing the suspension or termination may give the directive verbally to the PI and the letter will follow. Such letters should include:
  - The effective date of suspension or termination
  - If notification was initially done verbally the letter will reference the date of verbal notification;
  - The reason for the suspension or termination;
  - For suspension, identification of the research activity, in whole or in part, that must stop;
  - Any corrective action or clarification that must occur;
  - If the reason for suspension may bear on the participant's decision to continue participation, a directive that currently enrolled participants be informed of the suspension;
  - For terminations, a directive that all currently enrolled participants be informed of the termination;
  - If applicable a directive of how to deal with any currently enrolled participants; and
  - A direction to the PI regarding to whom to submit responses.

Step 6 The Staff Secretary files copies of the documents relating to the suspension or termination of the IRB approval and updates the database.