PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 20/05-0-2022	
Version No. 5	**SOP 20** **Early Protocol Termination**
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 20 Early Protocol Termination

1. Purpose

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

2. 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

3. 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.

4. Process Flow /Steps

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

5. 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.

- 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.
- The PI prepares and submits a protocol termination package.
- Staff Secretary shall receive and check the study protocol termination package prepared and submitted by the PI one day upon receipt. Staff secretary shall check the completeness of the contents of the package to include the Study Termination **(Form 3.8).**
- The request for termination memorandum should contain a brief written summary of the protocol, its results and accrual data, reason for termination with justification, appropriate measures in place to assure appropriate therapy and follow-up for the participants; and the procedures considered for notifying the participants.
- A final study report is also required at the time the sponsor conducts the closeout visit as indicated below:
    - 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 3.4) 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 Final Report Form 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.
    - Local Single Center Studies: A Final Report Form 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.

- 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 24 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:

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

Step 5 The Staff Secretary shall communicate the IRB decision to the PI with Request for Information for Post Approval Procedures (Form 2.7) or Approval Letter for Post-Approval Procedure (Form 2.8) signed by the Chair and Member Secretary 1-3 days upon a final decision of the board . See SOP 28 Communicating IRB Decisions. Staff Secretary then updates the protocol database accordingly