PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 11/08-0-2022	
Version No. 8	**SOP 11** **Review of a Medical Device Study**
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 11 Review of a Medical Device Study

1. Purpose

To describe the procedures in the review of medical device protocols submitted to the IRB.

2. Scope

This SOP provides instructions for review and approval of medical device protocols intended for human participants submitted to the PELI-IRB.

Medical device protocols are reviewed through the same expedited or full review board procedures depending on the level of risks involved in the study. An investigational new device is given a Significant Risk (SR) or Non- Significant Risk (NSR) classification by the regulators in the sponsor country. This information should be provided by the sponsor to the IRB. The IRB should make provisions to minimize the risks to human participants during review of the protocol and related documents.

3. Responsibility

It is the responsibility of the IRB members to review medical device protocols in accordance with international and national guidelines and regulations.

4. Process Flow /Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receive, check completeness, stamp application form, log protocol submission	Staff Secretary	on day of receipt
2	Assign code and enter into database	Staff Secretary	on day of receipt
3	Notify Chair of submission and forward protocol package to Chair	Staff Secretary	1-2 days upon receipt
4	Check risk assessment of device by FDA of the sponsor country , determine type of review, assign primary reviewers and instruct Staff Secretary	Chair	1 week upon receipt
5	Distribute received files and assessment form for technical review to Technical Reviewer	Staff Secretary	1-3 days upon receipt
6	Review protocol and accomplish assessment form	Technical Reviewer	1-2 weeks upon receipt
7	Receive and forward technical approval of protocol to Chair and PI	Staff Secretary	1-3 days upon receipt
8	Distribute protocol package and assessment forms to assigned Primary Reviewers	Staff Secretary	1-3 days upon
9	For expedited review (see SOP 9) or For full board include in agenda and discuss at Full Board (see SOP 24; SOP 10)		
10	Communicate IRB Decision	Chair and Staff Secretary	1-3 days upon final decision
11	File original package in a properly coded Protocol File Folder and update database with names of Primary Reviewers	Staff Secretary	1 day upon receipt

5. Detailed Instructions

Step 1 The Staff Secretary receives the documents for initial protocol review, checks the completeness of the documents according to the checklist in **Form 2.1** Application Form for Protocol Review and puts a receiving stamp with the date received and name on each copy of the application on the same day. Incomplete or incorrect submissions will not be accepted and will be returned to the Principal Investigator. The Staff Secretary keeps the original copy of the **Form 2.1** for the IRB files, gives the duplicate (receiving copy) to the PI on the same day and enters the submission in the database and logbook.

Step 2 The Staff Secretary assigns an IRB protocol code indicating the year and the order in which the protocol was received. The IRB Code is assigned as follows:

<YYYY-NN>

YYYY Represents the year submitted (i.e. 2020)

NN Represents sequential number as issued by the staff secretary (i.e. 01)

This code is the ID number of the protocol and cannot be assigned to any other protocol. The code will be communicated to the PI in subsequent communications regarding the protocol on the same day. The Staff Secretary logs and encodes the submission using the database and logbook.

Step 3 The Staff Secretary forwards a copy of the protocol package to the Chair within 1-2 days of receipt of submission

Step 4 The Chair checks the information/communication from the PI related to SR or NSR determination by regulators (FDA) from the sponsor country. Chair then determines the type of review - expedited or full board assigns Primary Reviewers and instructs the Staff Secretary accordingly within one (1) week upon receipt of the protocol package.

Step 5 The Staff Secretary distributes the protocol package and **Form 2.2.1** Study Protocol Assessment Form for Technical Reviewer to the technical reviewer 1-3 days from receipt of protocol.

Step 6 The technical reviewer reviews the protocol and accomplishes **Form 2.2.1** within 1- 2 weeks upon receipt. See SOP 8 Use of Study Assessment Forms. The Staff Secretary assists the technical reviewer in corresponding with the PI for any clarifications on the protocol and recommended modifications or revisions in research design, sampling design, sample size, statistical analysis plan and data analysis plan. The final approval on the assessment form is given only once any and all suggested revisions by the technical reviewer are done by the PI. The technical reviewer then forwards the approval in **Form 2.5** Notification of IRB Decision to the Staff Secretary for communicating to the Chair and the PI.

Step 7 The Staff Secretary forwards the accomplished **Form 2.2.1** and a copy of **Form 2.5** with technical approval to the Chair and the **Form 2.5** to the PI.

Step 8 The Staff Secretary distributes the following to the Primary Reviewers and Independent Consultants (if needed):

- Protocol package as hard copies and soft copies with access to the electronic files
- **Form 2.2.2** Study Protocol Assessment Form for Ethical Review to the medical member Primary Reviewer
- **Form 2.3** Informed Consent Evaluation Form to the lay member Primary Reviewer.

Step 9 For expedited review, the Primary Reviewers and Independent Consultants (if needed) then proceed to do an expedited review (see SOP 9). For full board review, the Chair and Staff Secretary include the review in the next meeting agenda and the IRB discusses and decides at Full Board (see SOP 24; SOP 10).

When reviewing a medical device protocol, the reviewers should consider the following:

- Proposed investigational plan
- Informed consent form
- Description of the device/Product information
- Description of study participant selection criteria
- Safety monitoring procedures
- Reports of prior investigations conducted with the device
- PI's curriculum vitae
- Risk assessment determination for new investigational device (SR or NSR)
- Statistical plan and analysis
- Copies of all labeling for investigational use
- Risk assessment determination for new investigational device (SR or NSR)
- Statistical plan and analysis
- Copies of all labelling for investigational use

Step 10 The Chair dictates his/her decision to the staff for preparation of the draft approval letter **Form 2.6** Document Decision Form or **Form 2.5** Notification of IRB Decision and sends it to the PI. See SOP 28 Communicating IRB Decisions.

Step 11 The Staff Secretary files the original package in a properly coded Protocol File Folder and updates the database with the names of the assigned Primary Reviewers and type of Review. The Member Secretary shall check and oversee compliance done or will be made by the staff secretary and members to the SOP and timelines set in the process flow chart.