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

SOP 8 Use of the Study Assessment Forms

1. Purpose

To describe the procedures related to the use of study assessment forms in ethics review.

2. Scope

This SOP applies to the use of the Study Assessment Forms in the review and assessment of protocols and related documents submitted to the PELI- IRB for initial review and approval. The IRB uses two (2) study assessment forms for initial review. The two (2) assessment forms are accomplished both by the Principal Investigator (upon submission) and individual reviewers. Any comments, evaluation, recommendations and the initial decision of each reviewer regarding a protocol are all noted in these two (2) forms. The Study Assessment Forms are designed to standardize the review process and to facilitate reporting of the recommendation and comments given to each individual protocol and related documents.
There are three (3) PELI-IRB Assessment Forms for protocol review:

a. **Form 2.2.1** Study Protocol Assessment Form for Technical Reviewer
b. **Form 2.2.2** Study Protocol Assessment Form for Ethical Reviewer
c. **Form 2.3**Informed Consent Evaluation Form

3. Responsibility

It is the responsibility of Principal Investigator to fill up the necessary information on the space provided and the PELI-IRB reviewers to individually fill up the assessment forms after reviewing each study protocol. The Staff Secretary, under supervision of member-secretary, is responsible for recording and filing the PELI-IRB's action, relevant points, and deliberation about a particular protocol, including the comments for specific action. The IRB decision and assessment on each reviewed protocol will be reflected in the Minutes of the meeting.

4. Process Flow/ Steps

STEPS	ACTIVITY	PERSON RESPONSIBLE	TIMELINE

1	Submit completely filled-out assessment forms	Principal Investigator	1 month before quarterly full-board meeting
2	Receive and distribute necessary documents and forms for technical review	Staff Secretary	1-2 days upon receipt
3	Accomplish the Study Assessment Form during technical review of the protocol and submit to the Staff secretary	Technical Reviewer	1-2 weeks upon receipt
4	Distribute documents for ethical review once technical review approval is given	Staff Secretary	1-3 days upon receipt of technical review approval
5	Accomplish the Study Assessment Forms during review of the protocol and submit to the Staff secretary	Primary Reviewers	1-2 weeks upon receipt
6	Check completeness of the study assessment forms and forward to the Chair	Staff Secretary	on day of receipt
7	Proceed to Expedited or Full Board review as determined by Chair	Chair	1-3 days upon receipt
8	Prepare a draft of Approval Letter	Staff Secretary Chair	1 day after decision
9	File copies of duly accomplished forms in the protocol file folder	Staff Secretary	

5. Detailed Instructions

Step 1 The PI submits **Form 2.1** Application Form for Protocol Review to the Staff Secretary at least 1 month before a quarterly board meeting.

Step 2 The Staff Secretary under the supervision of the Member-Secretary, receives and checks completeness of submitted documents including the form and the initial protocol package one to two days upon receipt. The Staff Secretary forwards to the Technical Reviewer the initial protocol package for technical review and the **Form 2.2.1** Study Protocol Assessment Form for Technical Review.

Step 3 The Technical Reviewer has one (1) to two (2) weeks to review the technical or scientific aspect of the study. Technical Review committee conducts clarificatory interviews as needed with site's Principal Investigator to enable faster and more efficient channel of communication. The Staff Secretary assists the Technical Reviewer in corresponding with the site regarding technical review (e.g. approval letter/ notification letter/ request for further information/recommendation).

The Study Protocol Evaluation Forms ensures assessment of the technical aspects of the protocol that may include:

- Objectives of the study
- Review of literature
- Sampling design
- Research design
- Statistical Analysis Plan
- Data analysis plan

The Staff secretary assists the Technical Reviewer with his/her response to the site regarding technical review and shall forward site's feedback to the Technical Reviewer for cases where, but not limited to:

- Request for clarification is needed.
- Recommendation (major or minor) is advised

Step 4 Once technical review approval is given, the Staff Secretary has 1 to 3 days to distribute all necessary documents including **Form 2.2.2** Protocol Evaluation Form for Ethical Review to delegated Primary Reviewers set by the chair.

Step 5 The Primary Reviewers check if the two (2) study assessment forms (Form 2.2.2 Study Protocol Evaluation Form for Ethical Review and Form 2.3 Informed Consent Assessment Evaluation Form) are attached with each protocol package received for review.

The Primary Reviewers proceed to review the study only once approval is given by the technical reviewer. They have 1-2 weeks to review and properly accomplish the assessment forms.

The Study Protocol Evaluation Forms ensure assessment of the scientific and ethical aspects of the protocol including:

- Rationale and significance of the study
- Objectives of the study
- Review of literature
- Inclusion/exclusion criteria
- Control arms (placebo, if any)
- Withdrawal or discontinuation criteria
- Vulnerability determination
- Risk/benefit assessment

The Informed Consent Evaluation Form checks if the following are complied with:

- Full disclosure of information, including risks
- Benefits that may be derived from the study
- Use of understandable language

- Voluntary participation
- Confidentiality
- Appropriate person to sign the consent form

In addition, special attention must be paid to the elements of the review enumerated in the WHO Guidelines Section 6.2.

After a thorough review and writing a detailed evaluation and of each aspect on the assessment forms, the Primary Reviewers sign the forms and submit the evaluation forms to the Staff Secretary.

Step 6 The Staff Secretary checks whether the assessment forms are complete and submits these to the Chair. The temporary online access granted to the Primary Reviewers is removed.

Step 7 Proceed to Expedited or Full Board review (as determined by the Chair in Step 4 of SOP 6A Management of Protocol Submissions / Step 3 of SOP 6B Management of Protocol Resubmissions). See SOP 9 Expedited Review and SOP 10 Full Board Review.

For expedited review, the Staff Secretary prepares the approval letter **Form 2.6** Document Decision Form for approved protocols of **Form 2.5** Notification of IRB Decision Form for protocols or protocol related documents with requested revisions letter within 1-3 days after decision. The forms are checked and signed by the Member Secretary and Chair and sent to the PI. If there are revisions required, they are communicated to the PI who has to resubmit the revised protocol and related documents before approval is given.

For full-board review, the Staff Secretary includes the protocol in the agenda of the next PELI IRB meeting for discussion and decision. See SOP 24 Preparing the Meeting Agenda

Step 8 The Staff Secretary prepares a draft of the Approval letter **Form 2.6** Document Decision Form for checking and signing by the Member-Secretary and the Chair one (1) day after the final decision was made.

If there, are revisions, notification letter **Form 2.5** is prepared by the Staff Secretary, signed by the Chair and sent to the PI who has to resubmit the revised protocol and related documents and undergo review by the board again before a final decision is made.

Step 9 Staff Secretary ensures that a copy of the signed letter is retained in the protocol file folder.