PEREGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 10/08-0-2022	
Version No. 8	**SOP 10** **Full Board Review**
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 10 Full Board Review

1. **Purpose**

   To describe the full board review for protocol and post approval submissions.

2. **Scope**

   This SOP applies to initial, resubmissions and post-approval submissions which are classified as entailing more than minimal risk to study participants or whose participants belong to vulnerable groups.

   The following types of protocols should undergo full board review after initial submission:

   - Clinical trials about investigational new drugs, biologics, or device in various phases (Phase 1, 2,3)
   - Phase 4 intervention research involving drugs, biologics, or device
   - Protocols including questionnaires and social interventions that are confidential in nature that may cause psychological, legal, economic and other social harm
   - Protocols involving vulnerable subjects that require additional protection from the IRB during review (refer to SOP 9.6 for definition of vulnerable subjects)
   - Protocols that involve collection of identifiable biologic specimens for research

   Criteria for Full Board Review of post approval submissions:

   - Major revisions of the protocol and informed consent after initial review
   - Amendments that involve major changes from previously approved protocol or consent form (major changes in the inclusion/exclusion criteria, safety issues, etc)
   - Major amendments that change the risk/benefit ratio

- Major protocol violations are those, which affect the safety of the patient or the integrity of data or study being conducted.
- Progress/Final reports that deviate from original approval given by the IRB
- Onsite SAE or SUSARs that may require protocol amendment or re-consent of participants

3. **Responsibility**

It is the responsibility of the IRB to conduct full board reviews of study protocols and post approval submissions to ensure compliance with technical and ethical standards in the conduct of research involving human participants and identifiable human data and materials.

Only protocols submitted for at least 4 weeks before a scheduled meeting shall be included in the agenda for full review. The IRB holds its regular full board meetings on the 3rd week of July, October, January and April. If the day is a holiday, the meeting shall be held on Thursday of the following week. Special meetings may be held upon the discretion of the board. The decision shall be communicated to the proponent within six (6) weeks after submission of required documents.

The Staff Secretary is responsible for receiving, verifying and managing the contents of both the hard copies and the electronic version of the submitted protocol package. In addition, the Staff Secretary should create a specific protocol file, make copies of the file and then distribute the copies to the PELI-IRB reviewers, together with a cover letter where the due date for returning the reviewed protocol is indicated. Member-secretary shall ensure compliance of Staff Secretary to the SOP.

It is the responsibility of the designated reviewers to thoroughly review the study protocols assigned to them, and reflect their findings, observations, comments and recommendations in the Study Assessment Forms before returning the reviewed protocol and assessment form to the Secretary on the due date.

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
Prior to full board review: See Steps 1-10 of SOP 6A for protocol submissions or see Steps 1-3 of SOP 6B for protocol resubmissions or see Steps 1-9 of SOP 11 for review of medical device or see first Steps of specific SOP for post approval submissions	Notable steps: determination of full board review, designation of reviewers , technical approval for protocol submissions , distribution of documents to designated reviewers	Chair Technical reviewer, Staff Secretary	see timeline of : first steps of SOP 6A, 6B for protocol approval or first steps of SOP 11 for review of medical device or first steps for specific post approval submission
1	Distribute documents to the rest of the IRB members	Staff Secretary	at least 1 week before full board
2	Review protocol/ post approval submission and submit decision/recommendation to the Staff Secretary	Primary Reviewers /Independent Consultants	1-2 weeks upon receipt
3	Send a copy of the assessment forms/evaluated reports to the Chair	Staff Secretary	upon receipt of documents
4	Include the protocol/post approval submission in the agenda of the next full board meeting	Chair Staff Secretary	at least 2 weeks before the next full board meeting
5	Presentation of review findings and recommendations	Primary Reviewers	during full board meeting
6	Discussion	IRB Members	during full board meeting
7	Summary of issues and resolutions	Chair	during the full board meeting

8	IRB action	Chair and IRB Members	during the full board meeting
9	Documentation of committee deliberation and action	Member Secretary and Staff Secretary	on day of decision
10	Communicate IRB decision to PI	Chair and Staff Secretary	1-3 days after final decision
11	File documents in protocol file folder and update database	Staff Secretary	

5. **Detailed Instructions**

Prior to Full Board Review

For initial approval of protocol submissions, see Steps 1-10 of SOP 6A (Management of Initial Submissions), or Steps 1-3 of SOP 6B for protocol resubmissions or Steps 1-9 of SOP 11 for review of medical device. Within these steps, the Chair determines that the protocol is for full board review and delegates two Primary Reviewers from among the IRB Members and an Independent Consultant, if needed, for ethical clearance of the protocol. Only protocols that have undergone technical approval can undergo ethical review.

For post approval submissions, refer to the first steps of the specific post approval procedure. The Chair may assign the same Primary Reviewers or designate another IRB Member/s for the review.

The Staff Secretary notifies the assigned reviewers and distributes the following necessary documents and forms for review and accomplishment:

For initial submission, resubmission or review of a medical device: the complete submission package in (hard copy and access to electronic files) and assessment forms. See SOP 8 Use of Study Assessment Form

- Form 2.2.2 Study Protocol Assessment Form for Ethical Review
- Form 2.3 Informed Consent Assessment Form

For post approval submissions: the pertinent information from the retrieved protocol and the report itself. See SOP 14 Review of Amendments, SOP 15 Review of Progress and Final Reports, SOP 16 Review of Protocol Violations and Deviations, SOP 20 Review of Early Protocol Termination, and SOP 22 Management of an Application for Continuing Review.

Full Board Review Proper

Step 1 The Staff Secretary distributes the protocol package to the rest of the IRB members by granting access to electronic files at least 1 week before the full board meeting.

Step 2 The assigned reviewers review the protocol or post approval report, properly accomplish the assessment forms and submit to the Staff Secretary once completed 1-2 weeks from receipt of the documents. See SOP 8 Use of Study Assessment forms.

The Primary Reviewers shall:

- Use the Protocol Evaluation Form for the protocol and the Informed Consent Evaluation Form to review the protocol and consent form and write relevant comments
- Check the CV or information of the investigators (including GCP training for clinical trials), the study sites and other protocol-related documents, including advertisements.
- Consider whether the study and training background of the PI are related to the study.
- Look for disclosure or declaration of potential conflicts of interest.
- Non-physician PI should be advised by a physician when necessary.
- Determine if the facilities and infrastructure at the study sites can accommodate the study.
- Check the "Assent Form" if the protocol involves children or other vulnerable subjects as study participants based on PHREB guidelines. The procedure for getting the assent of vulnerable participants should be clear (the objective of the study and the procedures to be done should be explained to the child or vulnerable participant separately).

The primary reviewers take note of the following Review Guidelines:

- The protocol manifests scientific validity and contains all the standard sections to ensure scientific soundness.
- In assessing the degree of risk against benefit, determine whether the risks are reasonable in relation to the anticipated benefits, and/or if the risks can be minimized.
- Study participants are selected equitably especially if randomization is not to be used. Study participant's information sheet should be clear, complete and written in understandable language.
- There is voluntary, non-coercive recruitment of study participants.
- The Informed Consent is adequate, easy to understand and properly documented.
- There should be a translation of the Informed Consent document into the local dialect which should be comprehensible by the general public.
- The procedure of getting the informed consent is clear and unbiased.

- The persons who are responsible for getting the informed consent are named and they introduce themselves to the study participants.
- The informed consent process entails use of adequate, complete and understandable written and oral information that are given to the research participant and, when appropriate, their legally acceptable representatives.
- If applicable, the informed consent process has clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangement for obtaining consent or authorization for the participation of such individuals.
- The research plan makes adequate provision for monitoring data collection to ensure the safety of study participants, where appropriate.
- There is provision for compensation to study participants. There should be reasonable provision for medical/psychosocial support; treatment for study related injuries, as well as compensation for participation to cover expenses like transport and loss of wages because of participation.
- The compensation for study participation should not unduly influence potential participants to participate in the research study.
- There are appropriate safeguards included to protect vulnerable study participants.
- Contact persons with address and phone numbers are included in the informed consent.
- There is clear justification for the use of biological materials and a separate consent form for future use of biological specimens.
- There are appropriate measures to ensure confidentiality and security of personal information concerning research participants.
- There is a description of the persons who will have access to personal data of the research participants, including medical records and biological samples.
- There are appropriate contracts or memoranda of understanding especially in collaborative studies.
- The medical care provided to research participants during and after the course of the research should be clearly stated.
- The steps to be taken if research participants voluntarily withdraw during the course of the research should be clearly stated.
- There should be provisions for compensation/treatment in the case of injury/disability/death of a research participant attributable to participation in the research.
- If applicable, there should be a description of the plan to make the study product available to research participants following the research.

Examine community involvement and impact/benefit of the study to the community and/or the institution. If relevant, the reviewer looks for the following in the protocol:

- Community consultation

- Impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn
- The influence of the community on the consent of individuals
- Involvement of local researches and institutions in the protocol design, analysis and publication of the results
- Contribution to development of local capacity for research and treatment in benefit to local communities
- Sharing study results with the participants/community
- A description of the availability and affordability of any successful study product to the concerned communities following the research

After reviewing the protocol and the documents, the reviewer recommends a decision:

- Record the decision by marking the appropriate block in the assessment form: Approved, Minor revision, Major revision for resubmission or Disapproved Include comments and reasons for disapproval.
- Check the completeness and correctness of marked items in the assessment forms. Indicate the date and affix the reviewer's signature in the decision form.

Once completed, the reviewers submit the assessment forms completed forms to the Staff Secretary together with the protocol documents.

Step 3 The Staff Secretary sends the hard and soft copies of the assessment forms to the Chair upon receipt from the reviewers.

Step 4 The protocol or post approval submission review is included in the next meeting agenda at least two (2) weeks before the next full board meeting. See SOP 24 Preparing the Meeting Agenda

Step 5 The assigned reviewers present their findings and recommendations during the full board meeting.

- **Form 2.2.2** and **Form 2.3** for initial approval
- **Forms 3.2**, **3.3**, **3.4**, **3.5**, **3.8**, **3.12** for the corresponding post approval submission

If a Primary Reviewer for a protocol or an assigned reviewer for a post approval submission cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.

Step 6 The chair leads the discussion of the ethical issues using **Form 2.2.2** Study Protocol Assessment Form for Ethical Review and the **Form 2.3** Informed Consent Assessment Form and the assessment of the primary reviewers as guides for an orderly exchange of ideas.

During the discussion, the following considerations should be observed:

- A member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of

interest should be indicated to the Chairperson prior to the review of the application and recorded in the minutes;

- A decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (eg investigators, representatives of sponsor, independent consultants) from the meeting, with the exception of EC staff;
- The decisions should only be made at meetings where a quorum is present;
- The documents required for a full review of the application should be complete and relevant elements should be considered before a decision is made;
- Decisions should be arrived at through consensus when possible; when a consensus is unlikely, the PELI- IRB members votes by raising of hands.
- Advice that is non-binding may be appended to the decision;
- In cases of conditional decisions, clear suggestions for revision and procedure for having the application re-reviewed should be specified;
- A negative decision should be supported by clearly stated reasons.

Step 7 The Chair summarizes the technical and ethical issues that were identified, the issues that were resolved /not resolved, including the recommendations for the issues that were not resolved.

Step 8 The Members in attendance arrive at a decision on the protocol or post approval submission. If the study is approved, the PELI-IRB determines the frequency of continuing review.

The following are the possible decisions/ actions for full board reviews:

For protocol submissions /resubmissions:

- Approval
- Minor revisions required
- Major revisions required
- Disapproval
- Pending, Clarification needed before decision can be made

For SAEs/SUSARs:

- Notation with no further action required
- Further information or action required
- Pending, Clarification needed before decision can be made

For Protocol amendments:

- Approval
- Request Information
- Recommend further action,
- Pending, if major clarifications are required before a decision can be made
- Disapproval

For Progress/Final reports:

- Take note and no further action required
- Request further information
- Recommend further action
- Pending, if major clarifications are required before a decision can be made

For Protocol Déviations /Violations :

- Take note and no further action required
- Request an amendment to the protocol
- Request an amendment to the informed consent form
- Suspend or Terminate the Study
- Pending, if major clarifications are required before a decision can be made

For Early termination report:

- Approve with no further action
- Request information
- Recommend further action

For continuing review:

- Uphold original approval with no further action
- Request for further information
- Recommend further action
- Pending, if major clarifications are required before a decision can be made
- Disapproval

If the study is approved, the IRB determines the duration of validity of approval and frequency of continuing review.

Step 9 The Staff Secretary documents the committee deliberation and action during the meeting and the Member Secretary ensures that the important points during the discussion are reflected in the minutes of the meeting. See SOP 26 Preparation of the Minutes of the Meeting

Step 10 The Staff Secretary communicates the decision of the IRB to the PI 1-3 days after full board decision. See SOP 28 Communicating IRB Decisions.

For protocol reviews: **Form 2.5** Notification of IRB Decision and/or **Form 2.6** Approval Letter are prepared by the Staff Secretary , checked and signed by the Chair and Member Secretary and sent to the PI. The letter contains identification of the document approved with version numbers and dates, the frequency of continuing review and the responsibilities of the PI throughout the course of the study.

For post-approval submissions, **Form 2.7** Request Information for Post Approval Procedures or **Form 2.8** Approval Letter for Post Approval Procedures is prepared by the Staff Secretary, checked and signed by the member-secretary and Chair and sent to the PI.

Step 11 The Staff Secretary files copies of the assessment forms in the Protocol File Folder and updates the database.