PERIGRINE EYE AND LASER INSTITUTE	**Peregrine Eye and Laser Institute** **Institutional Review Board**
PELI-IRB SOP 09/08-0-2022	
Version No. 8	**SOP 09** **Expedited Review**
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Supersedes: Previous SOPs of the PELI-IRB	

SOP 9 Expedited Review

1. Purpose

To describe the procedures for the review of protocols that qualify for expedited review.

2. Scope

This SOP applies to the review and approval of study protocols and post approval submissions with minimal risk to study participants whose participants do not belong to vulnerable groups, and where vulnerability issues do not arise.

The following are types of protocols that can be subjected to expedited review:

- Research methodologies that involve no more than minimal risk to the participants.
- Protocols of a non-confidential nature, not likely to harm the status or interests of the study participants and not likely to offend the sensibilities nor cause psychological stress of the people involved.
- Protocols not involving vulnerable subjects (individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation of benefits associated with participation or of a retaliatory response in the case of refusal to retaliate, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors and those incapable of giving consent).
- Protocols that involve collection on anonymized biological specimens for research purposes by non-invasive means (eg collection of small amounts of blood, body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).
- Research involving data, documents or specimens that have already been collected or will collected for ongoing medical treatment or diagnosis

The following post approval submissions are qualified for expedited reviews:

- Proposed continuing reviews, protocol amendments and end of study reports that have minor modifications and no significant risk to the study participants.
- Minor amendments to a previously approved research where such amendment
    i. Do not affect the substance of the original protocol and where no major new ethical issues are raised.
    ii. Protocol amendments for safety reasons, that is, in order to protect the welfare of the participants
    iii. Request for extension for an approved project with no modification of protocol
    iv. Approval of recruitment and publicity material for approved projects
    v. Change of associate or co-investigators
    vi. Provision of a retrospective statement that the quality assurance study has been conducted in an ethical manner to assist journal editors to assess articles presented for publications.

3. Responsibility

In doing an Expedited Review the IRB must demonstrate due diligence in the protection of human participants. Expedited review is the responsibility of Primary Reviewers appointed to assess any protocol that qualifies for the expedited process. The same assessment forms used for full board review should be used to evaluate the scientific and ethical merits of the protocol. Expedited reviews shall be carried out within 4 weeks of submission of documents.

4. Process Flow/ Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
Prior to expedited review: See Steps 1-9 of SOP 6A for protocol submissions or see Steps 1-3 of SOP 6B for protocol resubmissions or see Steps 1-8 of SOP 11 for review of medical device or see first Steps of specific SOP for post approval submissions	Notable steps: determination of Expedited review, designation of reviewers , technical approval for protocol submissions , distribution of documents to 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	Review protocol/ post approval submission and submit findings/recommendation to the Staff Secretary	Primary Reviewers /Independent Consultants	1-2 weeks upon receipt
2	Finalization of review results	Chair	1-3 days upon receipt of results
3	Notify PI of review results	Chair and Staff Secretary	1 day upon finalized results
4	File documents in protocol file folder and update database	Staff Secretary	1 day upon finalized results
5	Include Expedited Review results in the next meeting agenda	Chair and Staff Secretary	at least 2 weeks before meeting

5. Detailed Instructions

Prior to Expedited Review

For initial approval of protocol submissions, see Steps 1-9 of SOP 6A (Management of Initial Submissions), or Steps 1-3 of SOP 6B for protocol resubmissions or Steps 1-8 of SOP 11 for review of medical device. Within these, the Chair determines that the protocol is for expedited review and delegates two (2) 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 (hard copies and access to electronic files) and assessment forms See SOP 8 Use of Study Assessment Forms.

For post approval submissions

- The pertinent information from the retrieved protocol and the report itself. See SOP 14 Review of Amendments, SOP 16 Review of Protocol Violations and SOP 22 Management of an Application for Continuing Review.

Expedited Review Proper

Step 1 The Primary Reviewers carry out the expedited review of the protocol and related documents within 1-2 weeks from receipt of documents. The medical Member /Primary Reviewer reviews the subject of the research protocol to evaluate the scientific soundness and ethics of the study. The lay Member/ Primary Reviewer assesses the intelligibility and thoroughness of the informed consent.

For expedited reviews of post approval submissions, the assigned reviewers make sure that there is no change in the risk/benefit ratio to study participants before approving the submission. Reviewers may request for clarification or revisions of the protocol by the PI before recommending approval.

The assigned reviewers complete the assessment forms in a comprehensive and informative manner. Correspondences among the Chair, Staff Secretary and the assigned reviewers for expedited reviews are done through e-mail. The Staff Secretary collates the correspondences, assessment forms, other post approval forms, notification letters and decision letters used in the review.

- Form 2.2.2 Study Protocol Assessment Form for Ethical Review
- Form 2.3 Informed Consent Assessment Form
- For the forms used in post -approval submissions (amendment, protocol deviations, application for continuing review), refer to the specific SOP.

Step 2 The Chair reviews the collated correspondences of the reviewers, consolidates it and finalizes the review results. If the 2 reviewers considerably differ in opinion about the study, the Chair may have the final say.

Step 3 The Staff Secretary prepares a notification or decision letter in **Form 2.5, Form 2.6, Form 2.7, Form 2.8** to be checked and signed by Chair and Member Secretary and sends this to the PI. SOP 28 Communicating IRB Decisions.

Step 4 The Staff Secretary files the documents related to the expedited review in the protocol file and updates the database. See SOP 29 Management of Active Files.

Step 5 The Chair and Staff Secretary include the Expedited Review and final results in the next meeting agenda. See SOP 24 Preparing the Meeting Agenda