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

SOP 16 Review of Protocol Violation/Deviation

1. **Purpose**

To describe the IRB review procedures for protocol violation/deviation.

2. **Scope**

The SOP provides instructions for taking action and maintaining records of various types of protocol deviation or violation. It includes investigators who fail to comply with the procedures in the approved protocol or to comply with national/international guidelines for the conduct of human research, including those who fail to respond to the PELI-IRB's requests.

It also covers actions taken by the IRB related to protocol violation/deviation reports submitted by the PI related to any event at the site that does not comply with the protocol documents previously approved by the IRB.

Types of Non-compliance

- Protocol Deviation is a non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety or welfare or the integrity of data.
  An example of a minor deviation is late case report form submission of site to sponsor. An example of a major deviation is a missed window visit because of an acceptable reason.

- Major Protocol Violation is a significant divergence from the protocol that materially (a) reduces the quality or completeness of the data, (b) makes the Informed Consent Form inaccurate, or (c) impacts a subject's safety, rights, or welfare such as but not limited to the following:

    - Inadequate or delinquent informed consent
    - Inclusion/exclusion criteria not me
    - Unreported serious adverse events

- Improper breaking of the blind
- Use of prohibited medication
- Incorrect or missing tests
- Mishandled samples
- Multiple visits missed (5% of total participant population) or outside permissible windows
- Materially inadequate record keeping
- Intentional deviation from protocol, Good Clinical Practice, or regulations by study personnel
- Subject repeated non-compliance with study requirements

- Minor Protocol Violation is repeated or frequent major protocol deviation that may still not be categorized

The SOP for review of protocol violations and deviations begins with the filing of protocol deviation /noncompliance report by the Private Investigator and ends with the filing of all related documents and update of the database.

3. Responsibility

It is the responsibility of the PI/Researchers to report protocol deviations and violations in the conduct of approved researches within a week from the detection of the occurrence.

It is the responsibility of the IRB Staff Secretary to receive protocol violation/deviation reports submitted to the IRB, assist in all procedures, and keep an up to date database. Member-secretary shall ensure compliance of the staff secretary to SOP. It is the responsibility of the board members or designated members to take actions related to protocol violation/deviation.

4. Process Flow/Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Submit Deviation/Noncompliance Report.	Principal Investigator	Violation report: 7 to 14 days of occurrence Deviation reports shall be included on the next submission of progress/continuing/final report
2	Receive and check completeness of submitted documents	Staff Secretary	1 day upon receipt
3	Notify Chair	Staff Secretary	1 day upon receipt
4	Instruct Staff Secretary as to delegated reviewers and type of review	Chair	1-3 days from notification
5	Distribute reports to assigned reviewers	Staff Secretary	1 day upon receipt of instruction from the chair
6	Review submission and recommend action	Technical and Primary Reviewers	1-2 weeks each group of reviewers

7	Review recommendations and determination of type of review	Chair	1 week upon receipt
8	Discuss at full board	Members	Not applicable
9	Communicate IRB decision to PI	Staff Secretary	1-3 days upon final decision was made
10	File all related documents and update of protocol database	Staff Secretary	

5. Detailed Instructions

Step1 Principal Investigator must submit completely filled out **Form 3.5** Noncompliance Report 7 to 14 days of Violation occurrence or attached the said form on the next progress/continuing review/ final report for deviations

Step 2 The Staff Secretary shall check and receive protocol violation/deviation reports from principal investigator related to any event in the site that is not in compliance with the previously IRB approved protocol and related documents.

Step 3 The Staff Secretary refers the submission to the Chair within 1 day upon receipt of the reports and awaits further instructions.

Step 4 The Chair shall instruct Staff secretary if both original technical and primary reviewers shall evaluate the submission.

Step 5 Staff secretary shall distribute all necessary documents to their respective reviewers one day upon being instructed by the chair.

Step 6 Review protocol deviation/violation report and recommend action The assigned reviewers shall review, give assessment and recommendations by filling out the specified space for reviewers on the report and give the form back to the Staff Secretary. Each group of reviewers shall have 1 to 2 weeks each to conduct such tasks. Technical reviewers shall evaluate before the Primary reviewers.

Whenever protocol deviation/noncompliance /violation has been observed:

- Member Secretary shall ensure that the issues as well as the details of noncompliance involving research investigators are included in the agenda of the IRB meeting.
- Staff Secretary shall maintain a file that identifies investigators who are found to be non-compliant with national/international regulations or who fail to follow protocol approval stipulations or fail to respond to the IRB's request for information or action. Member-secretary shall oversee staff secretary.
- The IRB may opt to require a clarificatory interview on identified research issues.

- The IRB may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.

Step 7 The Chair reviews the recommendations of the assigned reviewers and determines the need for an expedited or full board review. Possible decisions on protocol deviations and violations include one or several of the following: (1) submission of additional information, (2) submission of corrective action, (3) invitation to a clarificatory interview, (4) Requirement for an amendment (5) site visit, (6) suspension of recruitment, and (7) withdrawal of ethical clearance.

Step 8 See SOP 9 Expedited Review, See SOP 10 Full Board Review

Step 9 Staff Secretary shall inform Principal Investigator about IRB decision through **Form 2.7** or Form **2.8** signed by the Member Secretary and Chair within 1-3 days of final decision. See SOP 28 Communicating IRB Decisions

Step 10 Filing of all related documents and update of the protocol database
See SOP 29 on Management of Active Study Files

Staff secretary shall keep a copy of all report, attached documents in the protocol file, and ensure that database for deviation is always up to date.