

	<b>Peregrine Eye and Laser Institute</b>  <b>Institutional Review Board</b>
PELI-IRB SOP 19/05-0-2022	<b>SOP 19</b> <b>Site Visits</b>
Version No. 5	
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Supersedes: Previous SOPs of the PELI-IRB	

## SOP 19 Site Visits

### 1. Purpose

To describe the IRB procedures related to the conduct of site visits.

### 2. Scope

This SOP applies to any site visit made in any study site, on behalf of the PELI IRB, to check compliance with GCP and PELI-IRB approved protocol and related documents.

### 3. Responsibility

It is the responsibility of the PELI IRB to perform or designate some members or qualified representatives to perform on its behalf onsite visit of the research projects it has approved. The PELI-IRB members or Secretary in consultation with the Chair may initiate onsite evaluation of a study site for cause or for a routine audit.

### 4. Process Flow /Steps

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Select study site	Members	Upon decision by the board
2	Notify PI of the planned visit	Staff Secretary	1-3 days upon being informed
3	Review pertinent IRB files	Members	before the site visit
4	On-site visit proper	Members	
5	Write the report and make a recommendation	Members	within 1 week from site visit
6	Present to Full Board and Decide on action	Members	Not applicable
7	Communicate IRB findings and recommendations to the PI	Staff Secretary	1-3 days upon being informed

8	File copies of documents and update database	Staff Secretary	On the day of receipt
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## 5. Detailed Instructions

**Step 1** The IRB will review periodically the database files of the submitted/approved study protocols and select study sites needed to be monitored based on the following criteria:

- New study sites or new PIs
- Reports of remarkable SAE
- High risk studies
- Big number of studies carried out at the study site
- Frequent protocol submission for PELI-IRB review
- Noncompliance or suspicious conduct
- Frequently fail to submit final reports
- Frequent protocol violations

**Step 2** Notification of PI of planned visit

The Staff secretary shall Inform PI of the planned visit with a letter signed by the Chair and member-secretary 1-3 day upon IRB decision and make the appropriate travel arrangements.

**Step 3** Review of pertinent IRB files

- Members shall review the PELI-IRB files for the study and site. They shall make appropriate notes or copy some parts of the files for comparison with the study files. Staff secretary shall assist members in such tasks.
- Member secretary shall ensure that original study files cannot be taken out of the IRB office premises.

**Step 4.** For the on-site visit proper, members shall use the **Form 3.7** Site Visit checklist and do the following:

- Review the informed consent document to make sure that the site is using the most recent version,
- Review randomly the subject files to ensure that subjects are signing the correct informed consent,
- Check for adverse events and protocol violation
- Check if case record forms are up to date
- Check if the files are orderly and confidentiality is maintained,
- check if the facilities are appropriate
- Debrief the PI about the site visit findings and comments
- Get immediate feedback

**Step 5** After the site visit, the members will:

- Write a report/comment within 1 week describing the findings of the audit.
- Forward a copy of the site visit to the Staff Secretary for inclusion in the next board meeting.

- Send a copy of the report to the site for their files, and
- Place the report in the correct site files.

**Step 6** The Primary Reviewer presents the findings of the on-site visit to the Full Board. The other members present during the visit are allowed to expound on their findings. Issues of concern, if any are discussed, and the board deliberates on the implications of the findings on the rights, safety, and welfare of the study participants; and makes an overall determination of protocol compliance in the study site

**Step 7.** Staff Secretary communicates the board decision to the PI for appropriate action with a letter signed by the Chair and member-secretary.

**Step 8** The Staff Secretary files the Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly. (SOP 29 Management of Active Files)