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|  | <b>Peregrine Eye and Laser Institute<br/>Institutional Review Board</b> |
| PELI-IRB-OP-30-06-2026                                                            | <b>SOP 30<br/>Data Privacy and Confidentiality</b>                      |
| Version No. 6                                                                     |                                                                         |
| Approval Date: March 9, 2026                                                      |                                                                         |
| Effective Date: March 9, 2026                                                     |                                                                         |
| Supersedes: SOP 31 V. 5 July 16, 2022                                             |                                                                         |

## SOP 30 Data Privacy and Confidentiality

### I. Policy

The PELI-IRB shall protect confidentiality and privacy of research records and participant data in all activities, consistent with applicable national data privacy laws and ethical norms.

### II. Purpose

To describe procedures related to maintaining the confidentiality of the study files and other IRB documents.

### III. Scope

This SOP covers the different steps in maintaining the confidentiality of all study files and other IRB documents. It starts from the receipt of the study files and IRB documents or request to access the study files and related documents and ends upon the return of the documents to the protocol folder.

### IV. Responsibility

It is the responsibility of the IRB to ensure that confidentiality is maintained in the management of all study files and records. This will protect the intellectual property rights of the researchers and the integrity of the IRB.

### V. Process Flow/ Steps

| STEP     | ACTIVITY                                                 | PERSON RESPONSIBLE  | TIMELINE                                    |
|----------|----------------------------------------------------------|---------------------|---------------------------------------------|
| <b>1</b> | Handle original and copies of IRB documents              | Staff Secretary     | Upon receipt of documents                   |
| <b>2</b> | Receive and log request to access the confidential files | IRB Staff Secretary | Upon receipt of request to access documents |

|   |                                                                   |                           |                                            |
|---|-------------------------------------------------------------------|---------------------------|--------------------------------------------|
| 3 | Approve request for access and retrieval of confidential document | Chair<br>Member-Secretary | 1-2 calendar days after receipt of request |
| 4 | Supervise the use of the retrieved document                       | Staff Secretary           | During the use of documents                |
| 5 | Return document to the files                                      | Staff Secretary           | After the use of documents                 |

**VI. Detailed instructions**

**Step 1** The Staff Secretary keeps confidential documents either in locked cabinets or in password-protected devices in the IRB office, ensuring that these files are protected under the Data Privacy Act of 2012.

Study files submitted to the IRB and related documents are considered confidential, such as:

- a. Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- b. IRB documents (minutes of meeting, advice, and decisions)
- c. Correspondence (expert, auditors, study participants, etc.)

**Step 2** Access to IRB confidential documents is subject to the following limitations:

- a. Non-IRB members can access specific documents by submitting a formal request. The Staff Secretary will provide a copy of the Confidentiality Agreement Form for Non-members Requesting for Copies of IRB documents to be accomplished by the person making the request. Upon receipt of the request to access confidential files, the Staff Secretary refers this to the Chair or Member-Secretary for approval.
- b. IRB members can access confidential documents outside of protocol review upon request and with a signed Confidentiality agreement
- c. Researchers can access only their protocol files upon request.
- d. Regulatory authorities have full access to IRB documents provided it is within their mandate and upon reasonable notice to make the files available and signed by the recognized official of the regulatory authority.

**Step 3** The Chair or Member-Secretary considers the reasons for the request and if found satisfactory, approves the request. The Staff Secretary asks the user to sign a confidentiality agreement.

**Step 4** The IRB Staff Secretary asks the requesting individual to sign a logbook, restricts him/her to comply with room -use only. Only concerned researchers can photocopy their protocol documents.

**Step 5:** The Staff Secretary records the retrieval of the IRB document and returns the retrieved document to the Protocol files. The Staff Secretary makes a record every time a document of the IRB is accessed as described above.

A log filed in the protocol folder is dedicated for purposes of recording access as described above which contains the following:

- e. Study file code
- f. Date borrowed
- g. Name of borrower
- h. Signature of borrower
- i. Signature of Staff Secretary upon return of document to the file folder
- j. Document copied
- k. Number of copies made
- l. Number of copies received

All requests for access are recorded by the Staff Secretary in the log before copies of any documents are released. The Staff Secretary makes only the exact number of copies requested and the recipient signs for the copies requested upon receipt of the copies.

## **VII. Forms**

1. Form 30 Confidentiality Agreement form for Non-members requesting to access Peregrine Eye and Laser Institute-IRB Documents

## **VIII. References**

1. National Ethical Guidelines for Health and Health -related Research 2017
2. Philippine Health Research Ethics Board SOP 2020
3. PELI-IRB SOP 201

## **IX. Revision Index**

| Version | Date            | Reasons For Revision                                                                   |
|---------|-----------------|----------------------------------------------------------------------------------------|
| 01      | August 30, 2013 | Patterned SOP after the SOP drafted by the DOH SOP Team (based on the FERCAP template) |
| 02      | April 1, 2014   | Added Section 4.7 Conduct of Meeting                                                   |

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| 03 | Jan 26, 2016  | Changed logo of “Pacific Eye and Laser Institute” to “Peregrine Eye and Laser Institute” in the document header                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 04 | June 15, 2017 | <p>The following major revisions of both SOP and forms 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, 3.7, 3.8, 3.11, 3.12 made in compliance with PHREB recommendations of official finding report last June 8, 2017:</p> <p>Clarify the following and state specific procedures on the following:<br/> Invitation of “guest” (SOP 4.7.2), ensure confidentiality<br/> Attendance by video or teleconference SOP 6.5<br/> Decision via consensus or voting page 15 #1<br/> abstention of member page 15 #1 confidentiality clause SOP 4.6.9<br/> Follow the standard agenda and minutes format<br/> Call to order<br/> Declaration of quorum<br/> Declaration of COI<br/> Approval of previous minutes<br/> Business arising from the previous minutes<br/> Review of new protocols<br/> Review of resubmitted protocols<br/> Progress Reports<br/> Amendment/s<br/> PD/PV and Noncompliance<br/> SAE/SUSARS<br/> Early Study Termination, close out reports, Final Reports<br/> Site visits<br/> Reports of expedited reviews<br/> Other matters</p> <p>The above items should always be part of the agenda and minutes, whether a report on any of the items will be discussed in the meeting. If there are no reports for a specific item, then it should be indicated as NONE.<br/> invite PI only to the IRB meeting for clarificatory purposes<br/> Use PELI IRB Protocol No., full title of protocol and name of PI to identify protocols in the meeting agenda<br/> Ensure the agenda is complete following the template suggested in the SOP<br/> Ensure that the IRB deals with the PI directly and not with the sponsor<br/> Indicate type of review in the agenda and minutes of the meeting (expedited or full board)<br/> Document in the SOP current practices of the Staff Secretary on filing of documents<br/> Prepare an SOP on the disposal of archives<br/> Ensure that the archiving color coding scheme of the Staff Secretary be formalized in the SOP<br/> Ensure adequate space for archiving for future protocols<br/> Improve the database to track timelines of critical points in the review process and that can generate data useful for the IRB</p> |
| 5  | July 16, 2022 | Reformat numbering to conform to 2020 PHREB SOP Workbook<br>Refer to SOP 4.6 of version 4 of PELI-IRB<br>Add references used in the SOP<br>Revise “Scope” to indicate specific coverage<br>Revise “ Responsibility”<br>Revise “ Process Flow/Steps”                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

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|   |               | <p>Make “Detailed Instructions and “Process Flow/Steps consistent</p> <p>Add “ Forms” to include forms to be used in this SOP</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| 6 | March 9, 2026 | <p>Revised and reclassified as SOP 29 to align with the PHREB Accreditation Policy 2024 for Specialty Clinics</p> <p>Changed SOP Title from “<b>Maintenance of Confidentiality of Study Files and IRB Documents</b>”</p> <p>Added a Policy section to define the governing principles and general guidelines of the SOP.</p> <p>Convert all timelines to calendar days</p> <p>Forms were re-numbered to correspond with the SOP in which they are used to ensure consistency, traceability, and proper document control. All form numbers mentioned in the SOP were updated accordingly to align with the revised numbering system</p> |