	Peregrine Eye and Laser Institute Institutional Review Board
PELI-IRB SOP 31/05-0-2022	
Version No. 5	**SOP 31** **Maintenance of Confidentiality of Study Files and IRB Documents**
Approval Date: July 16, 2022	
Effective Date: July 16, 2022	
Supersedes: Previous SOPs of the PELI-IRB	

SOP 31 Maintenance of Confidentiality of Study Files and IRB Documents

1. **Purpose**

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

2. **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.

3. **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

4. **Process Flow/ Steps**

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Handle original and copies of IRB documents	Staff Secretary	Upon receipt of documents
2	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 Member secretary	Within 1-2 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

5. 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:

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

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

- 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.
- IRB members can access confidential documents outside of protocol review upon request and with a signed Confidentiality agreement
- Researchers can access only their protocol files upon request.
- 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:
- Study file code

- Date borrowed
- Name of borrower
- Signature of borrower
- Signature of Staff Secretary upon return of document to the file folder
- Document copied
- Number of copies made
- 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.