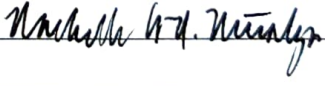






Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
SOP 31.0 Management of Access to Confidential Files

Effective Date:
JUN 25 2021

PCMC IR-EC SOP 31.0: Management of Access to Confidential Files

Supersedes:	PCMC IRB-EC SOP 01.0, V. 3.0
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31.0 MANAGEMENT OF ACCESS TO CONFIDENTIAL FILES

31.1 Policy Statement

The IR-EC shall protect the confidentiality of the following documents: study protocol and related documents, minutes of the meeting and shall limit access to confidential files to authorized persons (e.g. principal investigator, IR-EC Members, regulatory agency).

31.2 Purpose of the Activity

To protect intellectual property and the collegial integrity of the IR-EC

31.3 Scope

This SOP includes the procedures for management of confidential files that begins from the proper management of all active and inactive IR-EC files and ends with the returning document to the protocol file folder.

31.4 Process Flow/Steps for Management of Access to Confidential Files

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Proper management of all active and inactive IR-EC files	IR-EC Secretariat Chair
2	Receipt of request to access confidential files	IR-EC Secretariat
3	Approval and logging in requests for access and retrieval of documents	IR-EC Secretariat
4	Supervising the use of retrieved confidential document	IR-EC Secretariat
5	Returning document to the protocol file folder	IR-EC Secretariat

31.5 Detailed Instructions

31.5.1 Proper management of all active and inactive IR-EC files

31.5.1.1 Properly handle original documents and copies of these documents during the day-to-day operation of the IR-EC to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the IR-EC.



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- 31.5.1.2** Study files submitted to the IR-EC and related documents shall be 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. IR-EC documents (Meeting minutes, advice, and decisions)
 - c. Correspondence (with experts, auditors, study participants, etc.)

31.5.2. Receipt of request to access confidential files

31.5.2.1 Access to IR-EC confidential documents shall be subject to the following limitations:

- a. IR-EC members and staff with a signed *Confidentiality Agreement and Conflict of Interest Disclosure* shall be able to access confidential documents outside of regular protocol review access, upon request.
- b. Non-members can access specific documents by submitting a formal request. The Secretariat shall require a *Confidentiality Agreement Form for Non-Members* to be signed by the person making the request, and approved by the IR-EC Chair or Vice-Chair or designated IR-EC Member in the absence of the IR-EC Chair.
- c. Regulatory authorities can have full access to IRB-EC documents provided it shall be within their mandate (e.g. FDA), and shall be within a reasonable notice to make the files available.

31.5.2.2 The Secretariat shall record all transactions whenever any document of the IR-EC is accessed as described above.

31.5.3 Approval and logging in requests for access and retrieval of documents

31.5.3.1 A separate log shall be kept in the protocol folder to record access as described above. It shall contain the following information:

- a. Study file code
- b. Date borrowed
- c. Name of borrower
- d. Signature of borrower upon retrieval
- e. Signature of IR-EC Secretariat upon return of document to the file folder
- f. Document copied
- g. Number of copies made
- h. Number of copies received

31.5.3.2 All requests for access shall be recorded by the Secretariat in the log before copies of any documents are released.



31.5.4 Supervising the use of retrieved confidential document

- 31.5.4.1** Access to IR-EC documents shall generally be for room use only, but requests to make copies shall be accommodated on a case to case basis.
- 31.5.4.2** The Secretariat shall make only the exact number of copies requested.
- 31.5.4.3** The recipient shall sign the IR-EC log upon receipt of the copies.

31.5.5 Returning document to the protocol file folder

- 31.5.5.1** The IR-EC Staff shall be responsible for returning the documents in the protocol file folder in the storage cabinet after making sure that all documents are complete as per Protocol File Index.

31.6 Forms

Form 31.1 V.2.0 Confidentiality Agreement Form (for Non IR-EC Members)

31.7 Glossary

Confidentiality - prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity