



Philippine Children's Medical Center
Institutional Research – Ethics Committee (IR-EC)
SOP 30.0 Archiving of Inactive Files

Effective Date:
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PCMC IR-EC SOP 30.0: Archiving of Inactive Files

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30.0 ARCHIVING OF INACTIVE FILES

30.1 Policy Statement

Inactive Files include completed study protocols, terminated protocols, and those that are declared inactive due to lack of communication from the researcher.

The IR-EC shall keep inactive files physically separate from the active files for at least 3 years.

30.2 Purpose of the Activity

To provide reference materials for administrative and research purposes that which information may not be found in the database.

30.3 Scope

This SOP includes the procedures for archiving inactive files that begins from the identification of inactive protocol files and ends with the updating protocol database.

30.4 Process Flow/Steps for Archiving of Inactive Files

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Identification inactive protocol files	IR-EC Secretariat
2	Affixing appropriate label to files for archiving & recording in Database of Archived Documents	IR-EC Secretariat
3	Transferring files to the archiving room	IR-EC Secretariat
4	Updating protocol database	IR-EC Secretariat

30.5 Detailed Instructions

30.5.1 Identification inactive protocol files

- 30.5.1.1** Studies shall be considered completed and inactive when the closure/ final report of the study has been reviewed and approved by the IR-EC.
- 30.5.1.2** Studies shall also classified as inactive when no further communication has been received by the IR-EC after two years.
- 30.5.1.3** Studies that underwent early termination shall subsequently categorized as inactive upon receipt of relevant information about termination.



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30.5.1.4 The IR-EC Staff shall remove the protocol file folders from the storage file cabinet for active studies, shall check its contents and update the protocol file index.

30.5.1.5 IR-EC Staff shall shred extra copies that are not needed.

30.5.2. Affixing appropriate label to files for archiving & recording in Database of Archived Documents

30.5.2.1 The IR-EC Secretariat shall label protocol file as inactive by attaching red sticker and adding the year the study is declared inactive as a suffix to the original protocol code. For example if the Final Report of Protocol **PCMC IR-EC 2010-002** is approved in 2012, the archiving code shall be **PCMC IR-EC 2010-002/2012**.

30.5.2.2 The IR-EC Secretariat shall log the protocol number and other protocol identifiers in the Database of Archived Documents.

30.5.3 Transferring files to the archiving room

30.5.3.1 The IR-EC Staff shall transfer the protocol file to the designated secure archive room.

30.5.3.2 As in active study files, protocol files in the secure storage cabinet for inactive studies shall be arranged sequentially. The storage cabinet shall be properly labeled with the year in the original protocol code.

30.5.3.3 Protocols shall be archived for 3 years. Archived protocols can be accessed in accordance with the SOP on Maintaining Confidentiality of Study Files and IR-EC Documents.

30.5.3.4 After 3 years in the archive, the protocol files shall be transferred to the hospital archive or shredded.

30.5.4 Updating protocol database

30.5.4.1 The archiving data shall be entered accordingly in the protocol database.

30.5.4.2 IR-EC Secretariat shall review entries in the protocol database for the protocol for archiving, to check if all fields are completely filled.

30.6 Forms

30.7 Glossary