

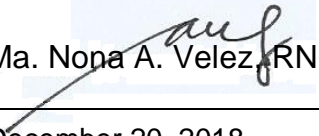
	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	SOP 7 MANAGEMENT AND ARCHIVING OF FILES 7.3 Archiving of Terminated, Inactive, and Completed Files	Effective Date: January 02, 2019

Supersedes:	Previous SOPs
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Date Approved	December 20, 2018
Date Effective:	January 2, 2019





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TABLE OF CONTENTS

CONTENT	PAGE NO.
Table of Contents	2
Policy Statement	3
Objective	3
Scope	3
Responsibilities	3
Workflow	3
Description of Procedures	3
Forms	4
History	4
References	4

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1. Policy Statement

Archiving terminated, inactive, or completed files ensures efficient and effective retrieval of information for reference and compliance with national and international guidelines..

2. Objective of the Activity

To describe IRB procedures related to archiving of completed, terminated and inactive studies.

3. Scope

This SOP includes IRB actions related to storage of protocols that are classified as inactive either by termination or completion. This SOP begins with the acceptance of final or early termination reports and ends with the reclassification of the file as inactive file.

4. Responsibility

It is the responsibility of IRB Secretariat, under the supervision of the Member- Secretary, to archive in an orderly manner all protocol files that have been completed, terminated, or are no longer active. They are kept together in a designated place in the institution where confidentiality and security of the documents can be maintained.



5. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
<i>Step 1: Selection of Files for archiving</i>	<i>IRB Secretariat</i>
<i>Step 2: Management for Archived Files</i>	<i>IRB Chair, Members and Secretariat</i>
<i>Step 3: Sorting of Archived Files</i>	<i>IRB Secretariat</i>
<i>Step 4: Storing the Protocol Documents</i>	<i>IRB Secretariat</i>
<i>Step 5: Management of file retrievals</i>	<i>IRB Secretariat</i>

6. Description of Procedures

Step 1: Selection of Files for archiving

- Archived Files (Completed/Terminated/Inactive, Closed) are:
 - Study protocols that have been completed with CIM-CVGH-IRB-Approved Final Reports
 - Study protocols declared “Inactive” by the CIM-CVGH IRB after a six (6) months period of no communication.
 - Study protocols that have been terminated or closed

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Step 2: Management for Archived Files

- Upon receipt of CIM-CVGH-IRB Final Report Form, IRB reviews it in accordance with SOP on Final Reports
- An archive number is assigned to the protocol by adding the (year of archiving) as a suffix to the original protocol code. For example, if the Final Report of Protocol CIM-CVGH IRB 2010-02 was approved in 2016, the archiving code is CIM-CVGHIRB 2010-02/2012.

Step 3: Sorting of Archived Files

- Sorting is done once at the end of the year after the documents have been Completed/ Terminated/Inactive for 6 months
- Sorting is done chronologically

Step 4: Storing the Protocol Documents

- Documents are stored in the cabinets for archived files after they have been sorted with the CIM-CVGH IRB document identifier duly logged in the protocol data base.
- After they have been kept in the active files cabinet for 6 months the files will be transferred to the archived files cabinet. Forms
- Logbook for incoming and outgoing communications

Step 5: Management of file retrievals

- See SOP on Managing Access to Confidential Files (SOP #7.4)

7. History of SOP

Version No.	Date	Authors	Main Change
01	April 6, 2019	CIM-CVGH IRB	First Draft

8. Forms: none

9. References:

- Philippine Health Research Ethics Board (PHREB) Workbook 2015
- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- National Ethical Guidelines for Health Research 2011 PNHRs
- <http://chonghua.com.ph/irb/SOP.html>