
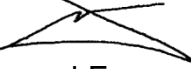
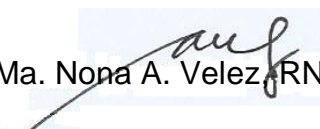
	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	SOP 7: MANAGEMENT AND ARCHIVING OF FILES 7.1 Managing REC Incoming and Outgoing Communications	Effective Date: January 02, 2019

Supersedes:	Previous SOPs
Prepared by:	SOP Team 2019
Reviewed by:	 Dr. Manuel Emerson Donaldo
Reviewed Date:	December 14, 2018
Approved by:	 Ma. Nona A. Velez, RN, MN
Date Approved	December 20, 2018
Date Effective:	January 2, 2019





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1. Policy Statement

Incoming and outgoing communications shall be recorded promptly and accurately in an electronic logbook or database.

2. Objective of the Activity

This SOP covers IRB actions related to organizing incoming and outgoing documents and ensuring an appropriate IRB response. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

3. Scope

This SOP covers IRB actions related to organizing incoming and outgoing documents and ensuring an appropriate IRB response. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

4. Responsibility

It is the responsibility of the IRB staff and IRB secretary to handle the processing of the communications, and the Chair to approve the outgoing documents.



5. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
<i>Step 1: Sorting of incoming/outgoing communications</i>	<i>IRB Staff</i>
<i>Step 2: Recording of incoming/outgoing communications</i>	<i>IRB Staff</i>
<i>Step 3: Acting on communications</i>	<i>Chair and Member Secretary</i>
<i>Step 4: Storing or filing of incoming/outgoing communications (SOP on Managing Active Files SOP#7.2)</i>	<i>IRB Staff</i>

6. Description of Procedures

Step 1: Sorting of incoming/outgoing communications

- IRB communications refer to documented communications to and from the IRB in the form of hard copy letters or emails.
- All IRB communications shall have a subject to facilitate sorting and documentation of all actions, instructions, and even responses to queries. Sorting shall be done by the IRB staff.

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Step 2: Recording of incoming/outgoing communications

- Both hard copies of the communications will be classified and saved. The IRB Staff shall record all communications in a “Communications Logbook” as they come, in chronological order.
- The following data shall be include:
 - Date received/sent
 - Subject
 - Person who sent the communication
 - Person who received the communication
 - Action taken

Step 3: Acting on communications

- Communications shall be acted upon by the Chair. The IRB secretary may also be tasked by the Chair to draft responses to the communications. All communications shall have the approval of the Chair.

Step 4: Storing or filing of incoming/outgoing communications (SOP on Managing Active Files SOP#7.2)

- Hard copies of the communications shall be filed by the IRB staff in their respective folders (Protocol-related communications; administrative communications, etc.)
- See SOP on Managing Active Files (SOP #7)

7. Forms

Annex 1 (Form 6.2)



Logbook for incoming and outgoing communications

8. History of SOP



Version No.	Date	Authors	Main Change
01	April 6, 2019		First Draft

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

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ANNEX 1

 CIM-CVGH INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127		ANNEX 1 COMMUNICATION RECORD FORM FORM 6.2
DATE:		
Means of Contact: <input type="checkbox"/> Telephone <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> In-person		
Status of Contact: <input type="checkbox"/> In-coming <input type="checkbox"/> In-coming		
Person contacted: <input type="checkbox"/> Reviewer <input type="checkbox"/> CIM-CVGH IRB Member <input type="checkbox"/> Chairperson <input type="checkbox"/> Secretariat <input type="checkbox"/> Sponsor <input type="checkbox"/> Investigator <input type="checkbox"/> Media <input type="checkbox"/> Subject		
Name:		
Contact No:		Email:
Protocol No:		
Title:		
Communication Issues / Reasons for making contact:		
Follow up action: <input type="checkbox"/> Return call <input type="checkbox"/> send written communication <input type="checkbox"/> none		
Summary of Communication:		
Recorded by:		