




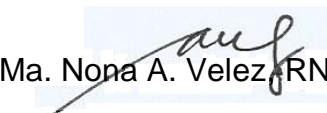
CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD





Version 1

**SOP 6 DOCUMENTATION OF IRB ACTIONS**  
**6.2 Communicating IRB Decisions**



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**

The IRB shall communicate its decisions to the researcher within 2 (two) weeks after the IRB meeting. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the IRB and signed by the chair.

**2. Objective of the Activity**

This SOP shall ensure proper completion, distribution and filing of all verbal and written communication as well as other study-related or process-related information done by investigators, sponsors, volunteer subjects, institution and/or relevant government agencies.

**3. Scope**

This SOP covers IRB actions related to the communicating IRB decisions (e.g. actions to applications submitted to the IRB). This SOP begins with the finalization of recommendations of the committee or the reviewers and ends with the filing of the decision document in the protocol file.

**4. Responsibility**

It is the responsibility of the Chair and the Board members as well as the secretariat to complete a written communication record for telephone or interpersonal discussions related to the past, present and/or future studies and/or processes involving the IRB.



**5. Process Flow/Steps**

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Finalization of recommendations of the committee	Chair
<b>Step 2:</b> Transfer of information from minutes or reports to REC decision forms or templates	IRB Secretariat
<b>Step 3:</b> Approval of the IRB decision document	Chair
<b>Step 4:</b> Dispatch of IRB decision document to researcher/ Primary Investigator	IRB Staff
<b>Step 5:</b> Storage of the decision document in the protocol file (SOP on Managing Active Files (SOP# 7.2)	IRB Staff

**6. Detailed Instructions**

**Step 1:** Finalization of recommendations of the committee

- Finalization of recommendations of reviewers (in case of full review see SOP on Full Review: SOP#4.2
- Finalization of recommendations of the committee (in case of expedited review see SOP on Expedited Review (SOP#4.1)

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**Step 2:** *Transfer of information from minutes or reports to IRB decision forms or templates*

- The record should contain, but is not limited to, the following information:
  - Date of communication
  - Study information, i.e., sponsor, protocol number, investigator, etc.
  - Name of person contacted
  - Contact address, telephone number, e-mail, fax, in person
  - Summary of the communications made
  - Notation of any follow-up if necessary
  - Signature of the individual responsible for the recording of the communication

**Step 3:** *Approval of the IRB decision document*

- The Chair shall review and approve the document within 1 week after the IRB Board meeting.

**Step 4:** *Dispatch of IRB decision document to researcher*

- An electronic copy of the IRB decision document will be sent to the investigators within 1 week after the IRB meeting. In the same email, they will be informed that a printed copy of the document can be obtained upon request from the IRB Secretariat.

**Step 5:** *Storage of the decision document in the protocol file (SOP on Managing Active Files (SOP# 7.2)*

**7. Forms**

Annex 1- Form 6.2 Communication Record

**8. History of SOP**

<b>Version No.</b>	<b>Date</b>	<b>Authors</b>	<b>Main Change</b>
01	March 17, 2017		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
- <http://chonghua.com.ph/irb/SOP.html>



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ANNEX 1



**CIM-CVGH**



**INSTITUTIONAL REVIEW BOARD**  
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**ANNEX 1  
COMMUNICATION  
RECORD FORM  
FORM 6.2**

<b>DATE:</b>	
<b>Means of Contact:</b>	<input type="checkbox"/> Telephone <input type="checkbox"/> Fax <input type="checkbox"/> E-mail <input type="checkbox"/> In-person
<b>Status of Contact:</b>	<input type="checkbox"/> In-coming <input type="checkbox"/> In-coming
<b>Person contacted:</b>	<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
<b>Name:</b>	
<b>Contact No:</b>	<b>Email:</b>
<b>Protocol No:</b>	
<b>Title:</b>	
<b>Communication Issues / Reasons for making contact:</b>	
<b>Follow up action:</b>	<input type="checkbox"/> Return call <input type="checkbox"/> send written communication <input type="checkbox"/> none
<b>Summary of Communication:</b>	
<b>Recorded by:</b>	