



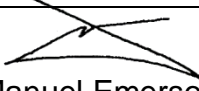
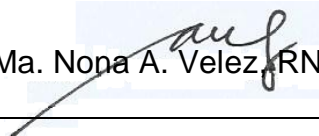
**CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL  
INSTITUTIONAL REVIEW BOARD**





Version 1

**9. Managing Queries and Complaints**



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
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Date Effective:	January 2, 2019

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**1. Policy Statement**

Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence.

**2. Objective of the Activity**

To describe the CIM-CVGH IRB procedures related to requests, queries, and complaints of research participants and other interested parties. Managing queries and complaints aims to promote public trust and confidence in the institution.

**3. Scope**

This SOP begins with the classification of the IRB documents which are confidential, and ends with the logging of access of the documents concerned.

**4. Responsibility**

A designated member of the CIM-CVGH Secretariat is responsible for receiving requests, queries, and complaints of research participants and other interested parties related to the participation in the research and research protocols and refers relevant issues to the CIM-CVGH IRB Chair for appropriate action. The Secretariat keeps records of all actions taken by the CIM-CVGH IRB.



**5. Process Flow/Steps**

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<i>Step 1: Receive the complaint or inquiry</i>	<i>IRB Staff</i>
<i>Step 2: Review the complaint/inquiry</i>	<i>IRB Chair and Member Secretary</i>
<i>Step 3: Discuss in convened meeting or report the decision/action taken to full board</i>	<i>IRB Chair and members</i>
<i>Step 4: Communicate IRB's response</i>	<i>IRB Secretariat and Chair</i>
<i>Step 5: File pertinent documents</i>	<i>IRB Staff</i>

**6. Detailed Instructions**

**Step 1: Receive the complaint or inquiry**

- The request, query, or complaint related to research participation or research protocols may come from research participants or other interested parties.
- The CIM-CVGH IRB Staff receives and studies the request, query, or complaint.
- The IRB Staff may assist to put the request, query, or complaint in writing especially if the complainant or inquiring party is a research participant.

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- The IRB Staff responds to the request, query, or complaint, if it is within his/her authority to do so, or refers this to the Chair/Member-Secretary for appropriate action.
- The IRB Staff records the submitted document in the Log of Incoming Communications

**Step 2: Review the complaint/inquiry**

- The CIM-CVGH IRB Chair or Member-Secretary reviews the request, query, or complaint.
- The PI maybe contacted to provide clarification or further information.

**Step 3: Discuss in convened meeting or report the decision/action taken to full board**

- The CIM-CVGHIRB Chair presents serious requests, queries, or complaints to full board for discussion.
- A request, query, or complaint is considered serious if it may have an adverse effect on the integrity and reputation of the CIM-CVGH IRB or any of its members.
- The IRB members discuss to take appropriate actions.

**Step 4: Communicate IRB's response**

- The CIM-CVGH IRB Staff Secretariat prepares the formal written response to the request, query, or complaint. The response must be communicated to the participant or requesting party within 7 days from the time of receipt of the request, query, or complaint.



**Step 5: File pertinent documents**

- The CIM-CVGH IRB Staff files the accomplished Form 3.6 in the protocol file folder together with the letter of request, inquiry, or complaint and the excerpts of the meeting minutes when this matter was deliberated or reported.
- The IRB Staff updates the protocol file index.

**7. Form** (See Annex Communication Record Form (Form 6.2))

**8. History of SOP**

<b>Version No.</b>	<b>Date</b>	<b>Authors</b>	<b>Main Change</b>
01	November 13, 2018	SOP TEAM	First Draft

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**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**

79 F. RAMOS ST., CEBU CITY  
Tel. 253-7413 Fax. (63-32) 253-9127

**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>	