




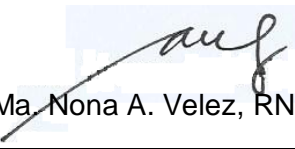
**CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**



Version 1

**SOP 1-IRB STRUCTURE AND COMPOSITION
SOP 1.1: Selection and Appointment of Members**

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



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



Version 1

SOP 1-IRB STRUCTURE AND COMPOSITION
SOP 1.1: Selection and Appointment of Members

Effective Date:
January 02,
2019

TABLE OF CONTENTS

CONTENT	PAGE NO.
Table of Contents	2
Policy Statement	3
Objective	3
Scope	3
Responsibilities	3
Workflow	3
Description of Procedures	4
Forms	6
History	6
References	7
Annex	8



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



Version 1

**SOP 1-IRB STRUCTURE AND COMPOSITION
SOP 1.1: Selection and Appointment of Members**

Effective Date:
January 02,
2019

1. Policy Statement

The selection of CIM-CVGH IRB members shall ensure the representation of different disciplines (scientists and non-scientists), gender, and age. There shall be a non-affiliated member (i.e. a member who is not affiliated with the institution).

2. Objective

This SOP aims to ensure that the selection of CIM-CVGH members complies with the international and national guidelines and that appropriate expertise is taken into consideration.

3. Scope:



This SOP applies specifically to the selection of members of the CIM-CVGH IRB. This SOP begins with the definition of the composition of the IRB, and ends with the filing of appointment documents and CVs of IRB members in the membership file.

4. Responsibilities

It is the responsibility of the IRB members, officers, and secretariat to understand and implement this SOP of the CIM-CVGH IRB.

5. Workflow

ACTIVITY	RESPONSIBILITY
Step 1: Define the composition of the membership of the IRB	Dean; Chair
Step 2: Call for nominations	Dean; Chair
Step 3: Submission of nominations	IRB Chair / Members, Hospital Management, Department Chairs, Section Heads
Step 4: Shortlisting of nominees	Chair
Step 5: Invitation to and confirmation of interest of the nominees	Chair
Step 6: Appointment of new members	Dean
Step 7: Ensure completion of membership documents; Signing of conflict of interest disclosure and confidentiality agreement	New IRB Members; Secretariat
Step 8: Filing of appointment documents and CVs in the membership file (SOP on Managing Active Files - SOP VII)	Secretariat

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	SOP 1-IRB STRUCTURE AND COMPOSITION SOP 1.1: Selection and Appointment of Members	Effective Date: January 02, 2019

6. Description of Procedures:

Step 1. *Define the composition of the membership of the IRB*

- The Dean, together with the Chair discusses the qualifications of additional/new members of the IRB.
- The IRB shall be composed of at least 9 members.
- The membership shall be multi-disciplinary. The IRB member should have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by its own affiliated and non-affiliated researchers.
 - The membership shall include persons whose primary concerns are in medical science and/or public health, with at least one member who is in a non-medical/non-scientific area, and at least one member who is not affiliated with CIM-CVGH.
 - Relevant expertise may include medicine and research, social or behavioral science, law, philosophy, environmental science and public health. It is recommended that the IRB should include a person who will represent the interest and concerns of the community.
 - The IRB shall aim for adequate representation of men and women members in order to promote gender sensitivity and its review procedures.
 - The IRB shall have representatives from both the older and younger generations.
 - During review meetings, the IRB shall adhere to quorum requirements as defined in international and national guidelines for IRB that review health research. When reviewing clinical trials involving children or pediatric patients, a pediatrician or child development specialist shall be present during its board meeting. (Refer to SOP 5.3 on Conduct of the Meeting)

Step 2: *Call for nominations*



- The Dean, through the Chair announces the open nomination process for the IRB to hospital management, department chairs, and section heads.

Step 3: *Submission of nominations*

- Any hospital staff may submit the name of their nominees to the Chair, with their corresponding Curriculum Vitae for deliberation.
- During the IRB meeting the Chair presents the credentials of the person being nominated. IRB Members discuss and decide by consensus on the final list of nominees to be submitted to the Director. Conflict of interest issues of nominees shall also be discussed.

Step 4: *Shortlisting of nominees*

- Members are selected based on their good moral character and personal capacities, their scientific expertise and knowledge of ethical principles, as well as their willingness to volunteer their time and effort to perform their functions in the IRB.

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	SOP 1-IRB STRUCTURE AND COMPOSITION SOP 1.1: Selection and Appointment of Members	Effective Date: January 02, 2019



- Members preferably shall have prior training in research ethics, research methodology, and Good Clinical Practice or should be willing to undergo continuing training during their membership.
- During the IRB meeting the Chair presents the credentials of the person being nominated. IRB Members discuss and decide by consensus on the final list of nominees to be submitted to the Director. Conflict of interest issues of nominees shall also be discussed.
- The Dean reviews the list of nominees and decides on the appointment to be made.

Step 5: Invitation to and confirmation of interest of the nominees

- The Chair will issue the invitation through an official letter. The invitation letter will include the following:
 - Duties and responsibilities: The Members shall serve as Primary Reviewers for research protocol documents within their area of expertise, and as General Reviewers for all researches discussed at convened meetings of the IRB
 - Term of office: Members shall be appointed for a period of three (3) years and renewable for several consecutive terms depending on their performance.
 - The nominee shall confirm interest verbally and by signing the conforme in the letter of appointment

Step 6: Appointment of new members

- Appointment of new members shall be made by the Dean through a communication letter.
- The appointment letter shall include the following:
 - Term of Office: Members are appointed for a period of three (3) years and renewable for several consecutive terms depending on their performance.
 - Duties and Responsibilities:
 - Willingness to make public his/her full name, profession, and affiliation as an IRB member
 - Members shall disclose all financial accountability related to their work in the IRB that may record and publicly disclose its financial records upon request
 - Members shall sign the Confidentiality and Conflict of Interest Agreements. The agreement should cover all applications, meeting deliberations, information on research participants and related matters.
 - Participate in CIM-CVGH IRB meetings (SOP 5.3)
 - Review, discuss and consider research proposals submitted for evaluation (SOP 3.1, 3.2)
 - Review progress reports and monitor ongoing studies as appropriate (SOP 4.1)
 - Evaluate final reports. (SOP 4.1)
 - Assess serious adverse event reports and recommend appropriate action (SOP

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	SOP 1-IRB STRUCTURE AND COMPOSITION SOP 1.1: Selection and Appointment of Members	Effective Date: January 02, 2019

- 4.5)
- Maintain confidentiality of the documents and deliberations during IRB meetings
 - Participate in continuing education activities in health research and ethics
 - Declare any conflict of interest.
 - Update CV and training record every time appointment is renewed (Form 1.2)
 - Conform at all times with the legal and ethical principles accepted by the IRB
 - Attend basic and continuing education on Research Ethics at least once a year (Form 1.4)
 - Perform other tasks requested by the IRB Chair.

Step 7: *Ensure completion of membership documents; Signing of conflict of interest disclosure and confidentiality agreement*

- Once the member is appointed, he/she shall sign the Confidentiality and Conflict of Interest Agreements. The agreement should cover all applications, meeting deliberations, information on research participants and related matters. It should contain an attachment about the responsibilities of an IRB member, term of office, as included in the letter of invitation.

Step 8: *Filing of appointment documents and CVs in the membership file*



Secretarial files the documents and CVs of the members as provided for in SOP 7.4.

7. Forms:

- Annex 1: Form 1.1 Appointment Letter
- Annex 2: Form 1.2 Curriculum Vitae
- Annex 3: Form 1.3 Confidentiality Agreement
- Annex 4: Form 1.4 Training record of IRB Members

8. History:

Version No.	Date	Authors	Main Change
01	April 10, 2016	SOP team	First Draft
02	December 14, 2018	SOP team	Head of Research Division of the Institution WAS changed to The Dean Formatting; inclusion of forms

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	SOP 1-IRB STRUCTURE AND COMPOSITION SOP 1.1: Selection and Appointment of Members	Effective Date: January 02, 2019

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



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



Version 1

**SOP 1-IRB STRUCTURE AND COMPOSITION
SOP 1.1: Selection and Appointment of Members**

Effective Date:
January 02,
2019

ANNEX 1

<h2 style="text-align: center; margin: 0;">CIM-CVGH</h2> <p style="text-align: center; margin: 0;">INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127</p>	<p align="center">Letter of Appointment of IRB Member</p> <p align="center" style="color: blue;">Form 1.1</p>
FORM 1.1: LETTER OF APPOINTMENT OF IRB MEMBER	
<p>Date _____</p> <p>_____</p> <p>_____</p> <p>Dear _____,</p> <p>I have the honor to appoint you as a _____ of the (CIM - CVGH) IRB for a period of _____ years, effective _____ until _____. As a member, you will have the following roles and responsibilities:</p> <ul style="list-style-type: none"> • Participate in the IRB meetings • Review, discuss and consider research proposals submitted for evaluation • Assess serious adverse event reports and recommend appropriate action(s) • Review the progress reports and monitor ongoing studies as appropriate • Check progress and final reports • Maintain confidentiality of the documents and deliberations of IRB meetings • Declare any conflict of interest; • Participate in continuing education activities in research methodology and research ethics <p>If you agree with the terms of this appointment, please sign on the space provided below, date your signature, and return one copy of this letter to the (CIM – CVGH) IRB Secretariat. Sign, date and submit your latest curriculum vitae and a copy of the Confidentiality and Conflict of Interest Agreement.</p> <p>Very truly yours,</p> <p>_____</p> <p>Dean</p> <p>Conforme:</p> <p>_____</p> <p>Signature over printed name; Date</p>	



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



Version 1

**SOP 1-IRB STRUCTURE AND COMPOSITION
SOP 1.1: Selection and Appointment of Members**

Effective Date:
January 02,
2019

ANNEX 2





CIM-CVGH





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

**Curriculum Vitae
FORM 1.2**

CURRICULUM VITAE			
Last Name		First Name	
Position in the IRB		Address	
Date of 1st Appointment		Contact No.	
Educational Background:			
Research and Ethics Training/s:			
WORK EXPERIENCE			
• Previous work Experience			
• Present work Experience			
• Research-related Experience			

	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	SOP 1-IRB STRUCTURE AND COMPOSITION SOP 1.1: Selection and Appointment of Members	Effective Date: January 02, 2019

ANNEX 3

<div style="display: flex; justify-content: space-between; align-items: center;">  <div style="text-align: center;"> <h1 style="margin: 0;">CIM-CVGH</h1> <p style="margin: 0;">INSTITUTIONAL REVIEW BOARD</p> <p style="margin: 0; font-size: small;">79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127</p> </div>  </div>	<h2 style="margin: 0;">Confidentiality Agreement</h2> <p style="margin: 10px 0 0 0; color: blue;">FORM 1.3</p>
<p>CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT</p> <p>Know all Men by these Presents:</p> <p>In view of the appointment as a member of the (CIM - CVGH) IRB, and hereinafter referred to as the <i>Undersigned</i>, and Whereas: the <i>Undersigned</i> has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines; the appointment of the <i>Undersigned</i> as a member of the (CIM - CVGH)IRB is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as the delegate of any organization or private interest; the fundamental duty of an IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and the (CIM - CVGH) IRB must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects; The following terms and conditions covering Confidentiality and Conflict of Interest arising in the discharge of said appointed IRB member's functions, are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the IRB to carry out its mandate.</p> <p>Confidentiality</p> <p>This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the <i>Undersigned</i> in conjunction with and/or in the course of the performance of his/her duties as a member/Independent Consultant of the (CIM - CVGH) IRB.</p> <p>Any written information provided to the <i>Undersigned</i> that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IRB.</p> <p>As such, the <i>Undersigned</i> agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information").Moreover, the <i>Undersigned</i> agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.</p> <p>The <i>Undersigned</i> further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the <i>Undersigned</i> confirms that her performance of this agreement is consistent with (CIM - CVGH)'s policies and any contractual obligations owed to third parties.</p>	



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



Version 1

**SOP 1-IRB STRUCTURE AND COMPOSITION
SOP 1.1: Selection and Appointment of Members**

Effective Date:
January 02,
2019

ANNEX 4



CIM-CVGH



INSTITUTIONAL REVIEW BOARD

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

Training Record of an

IRB Member

FORM 1.4

TRAINING RECORD OF AN IRB MEMBER

Last name		First name	
------------------	--	-------------------	--

BASIC COURSES	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2. Research Ethics				
3. IRB Standard Operating				

CONTINUING ETHICS EDUCATION : Research Ethics Workshops, Conferences, Meetings, Lectures	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2.				
3.				
4.				