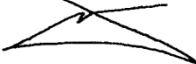
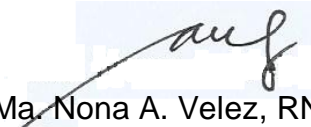




**CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL
INSTITUTIONAL REVIEW BOARD**



Version 1	SOP 1-IRB STRUCTURE AND COMPOSITION SOP 1.2: Designation of Officers	Effective Date: January 02, 2019
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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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SOP 1.2: Designation of Officers

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1. Policy Statement

The CIM-CVGH IRB shall have a chair, vice-chair, and member-secretary who shall be selected among the members by the appointing authority. The Chair is pre-selected by the Dean, and the Vice Chair and Member Secretary shall be nominated and voted upon by the members.

2. Objective

This SOP aims to ensure that the designation of IRB officers conforms to institutional practice.

3. Scope:

This SOP for the selection of officers is specific for the IRB of CIM-CVGH. This SOP begins with the call for a meeting and ends with the filing of appointment documents.

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
<i>Step 1: Call for meeting (SOP on Preparing for a Meeting (SOP #5.1))</i>	<i>Chair</i>
<i>Step 2: Nominations</i>	<i>IRB Members</i>
<i>Step 3: Election</i>	<i>IRB Members</i>
<i>Step 4: Appointment of new officers</i>	<i>Dean</i>
<i>Step 5: Filing of appointment documents (SOP on Managing Active Files (SOP # 7.2))</i>	<i>Secretariat</i>

6. Description of Procedures:

Step 1. *Call for meeting (Refer to SOP on Preparing for a Meeting SOP #5.1)*



- A committee meeting may be called by the current IRB Chair

Step 2: *Nominations*

- Nominations are open for officers other than the chair who is pre-selected by the Dean.
- The members shall nominate and vote by viva-voce. There shall be at least one nominee per position.
- The officers shall be selected based on their good moral character and personal capacities, and their willingness to perform their functions as officers of the IRB.

Step 3: *Election*

- The election shall be conducted by viva voce. One member is entitled to one vote. Conflict of interest issues of nominees shall also be discussed

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Step 4: Appointment of new officers

The Dean shall write an appointment letter to the new officers. The letter shall contain the following: 1) term of office which is three (3) years; designation, duties, and responsibilities of each:

- Chair
 - Ensures that all IRB members receive orientation and undergo basic Research Ethics Training immediately after their appointment, and continuing education there after
 - Obtains administrative and logistics support for the sustained operations of the IRB
 - Approves the agenda and presides over IRB review meetings (If Chair has COI relative to the protocol for deliberation s/he designates the Vice chair the Member Secretary or any Member to preside over the meeting.)
 - Selects suitable (somebody with related expertise) member/independent consultant to be the primary reviewer of a protocol whether by full board or expedited review, and ensures that aforementioned member does not have conflict of interest.
 - Manages complaints from study participants, authorities or the general public
 - Designates a member or group of members to investigate in cases of complaints or report of major non-compliance Ensures that the IRB is perceived as fair and impartial, and complies with institutional, national and international standards
 - Represents the IRB in various local, national and international meetings and conferences.
 - Ensure adherence to quality standards to maintain the accreditation status

- Vice-Chair
 - Performs other duties as designated by the Chair
 - Presides over meetings in the absence of the Chair

- Member Secretary
 - Supervises the IRB Staff related to good IRB office management
 - Prepares and finalizes the meeting agenda of full-board meeting after consultation with the Chair
 - Ensures that the members completely fill out necessary forms used for the review of protocol or protocol related submissions,
 - Supervises the IRB Staff in the preparation of the meeting agenda and minutes
 - Ensures good IRB documentation and archiving.
 - Ensures overall IRB compliance with good clinical practice.
 - Ensures good financial management of IRB resources

- CIM-CVGH IRB Secretariat composed of the Member-Secretary and administrative support staff who are employees of the CIM - CVGH and appointed by the Hospital Director. The Secretariat shall have the following functions:



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- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance and distribution of study files
- Organizing CIM-CVGH IRB meetings regularly
- Preparation and maintenance of meeting agenda and minutes
- Maintaining good CIM-CVGH IRB documentation and archiving procedures
- Communicating with the CIM-CVGH IRB members and Investigators
- Arrangement of training for personnel and CIM-CVGH IRB members
- Organizing the preparation, review, revision and distribution of SOPs and guidelines;
- Providing the necessary administrative support for CIM-CVGH IRB-related activities to the Chair of the CIM-CVGH IRB
- Member secretary/chair decides which protocols may be expedited (as stated in SOP2)
- Member secretary/chair assigns primary reviewers (as stated in SOP2)
- Ensures good CIM-CVGH IRB documentation
- Ensures overall CIM-CVGH IRB compliance with good clinical practice
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the CIM-CVGH IRB members
- Maintaining a library of relevant resource materials and references
- The Secretariat provides a copy of the agreement form (Form 1.3) to each member of the CIM-CVGH IRB together with the appointment letter (Form 1.1).

Step 5: Filing of appointment documents (SOP on Managing Active Files (SOP # 7.2)



- Secretariat staff shall file the appointment documents of the as provided for in SOP 7.2

7. Forms

- Annex 1: Form 1.1 Appointment Letter
- Annex 2: Form 1.2 Curriculum Vitae
- Annex 3: Form 1.3 Confidentiality Agreement

8. History:

Version No.	Date	Authors	Main Change
01	April 10, 2016	SOP Team	First Draft
02	December 14, 2018	SOP Team	<i>The function of the Chair to “prepare the Annual Work Financial Plan (WFP) and the Project Procurement Management Plan (PPMP) and approved by the hospital director” –was omitted Formatting; Addition of Annex</i>

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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		Letter of Appointment of IRB Member
INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127			Form 1.1

FORM 1.1: LETTER OF APPOINTMENT OF IRB MEMBER

Date _____

Dear _____,

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:

- 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

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.

Very truly yours,

Dean

Conforme:

Signature over printed name; Date



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ANNEX 2

 CIM-CVGH INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127		<p>Curriculum Vitae FORM 1.2</p>	
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			



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ANNEX 3

 CIM-CVGH INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel 253-7413 Fax. (63-32) 253-9127	 Confidentiality Agreement FORM 1.3
<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>	



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myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chair upon termination of my functions as an IRB member.

Whenever I have a conflict of interest, I shall immediately inform the Chair not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

(CIM - CVGH) IRB Chair Date