


	CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD	
Version 1	SOP 6 – DOCUMENTATION OF IRB ACTIONS 6.1 Preparing the Meeting Minutes	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 meeting minutes shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

2. Objective of the Activity

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in an IRB meeting.

3. Scope

This SOP covers IRB actions related to the documentation of a full board meeting, the final output of which is the minutes of the meeting. This SOP begins with the entry of preliminary information on the minutes template and ends with the storage of the approved minutes.

4. Responsibility

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

5. Process Flow/Steps

ACTIVITY	RESPONSIBILITY
<i>Step 1: Entry of preliminary information on the minutes template</i>	<i>IRB Secretariat</i>
<i>Step 2: Preparation of the draft minutes</i>	<i>Member Secretary</i>
<i>Step 3: Approval of the minutes in the next IRB meeting</i>	<i>IRB Chair and Members</i>
<i>Step 4: Storage of the approved minutes (SOP on Managing Active Files SOP#7.2)</i>	<i>IRB Staff</i>



6. Description of Procedures

Step 1: Entry of preliminary information on the minutes template

- The IRB Secretariat shall fill up the minutes template (Form 6.1) based on the submitted documents/protocol-related information, and other matters ahead of time.

Step 2: Preparation of the draft minutes

- During the meeting, the Member Secretary shall record all board opinions and proceedings in accordance with the agenda. Recording shall be done by real time / note taking while the minute template is projected on screen.

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- Comments and recommendations on the scientific issues, ethical issues, and informed consent form issues shall likewise be recorded. The opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members.
- The Secretariat reviews the proceedings prepared during the meeting and verifies that it contains the following sections:
 - Date and venue of meeting
 - Member attendance (members present and absent) to determine quorum
 - Time when the meeting was called to order
 - Presiding officer
 - Conflict of interest declaration by IRB members
 - Discussion of items based on the Meeting Agenda
 - Decisions and recommendations arrived at during the meeting
 - Name and signature of person who prepared the Minutes
- An electronic copy of the draft minutes will be sent to the IRB Chair within 5 days after the meeting.

Step 3: Approval of the minutes in the next IRB meeting

- The draft minutes shall be presented in the next IRB meetings for comments and/or corrections.
- The approval of the minutes is done through a formal motion from any member of the committee and seconded accordingly.
- See SOP on conduct of meeting

Step 4: Storage of the approved minutes

- Both hard and electronic copies of the approved minutes will be saved
- See SOP on Managing Active Files (SOP #7)

7. Forms



Annex: Minutes Template Form 6.1

8. History of SOP



Version No.	Date	Authors	Main Change
01	March 3, 2017	IRB Members	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.



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- 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



	<h1 style="margin: 0;">CIM-CVGH</h1>		<div style="border-left: 1px solid black; padding-left: 10px;"> <p style="margin: 0;">IRB MINUTES TEMPLATE</p> <p style="margin: 0; color: #0070C0;">FORM 6.1</p> </div>														
<p style="margin: 0;">INSTITUTIONAL REVIEW BOARD 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127</p>																	
DATE : _____		VENUE: _____															
	IRB MEMBERS	POSITION	ATTENDANCE														
1)	Dr. Manuel Emerson Donaldo	Chairman	() present () absent														
2)	Dr. Corazon Tan-Meneses	Co-Chairman	() present () absent														
3)	Dr. Consolacion Cutillar	Secretary	() present () absent														
4)	Dr. Rudy Amatong	Member	() present () absent														
5)	Mdm. Charito Calumpang	Member	() present () absent														
6)	Fr. Raphael Catane, SHF	Member	() present () absent														
7)	Dr. Ma. Lourdes Chan	Member	() present () absent														
8)	Atty. Terence Fernandez	Member	() present () absent														
9)	Dr. Saleshe Tracy Anne Fernandez	Member	() present () absent														
10)	Dr. Nerissa Sanchez	Member	() present () absent														
11)	Dr. Pamela Tarongoy	Member	() present () absent														
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Meeting No.: 2019-01</td> <td style="width: 50%;"></td> </tr> <tr> <td style="text-align: center;"> <input type="checkbox"/> Regular <input type="checkbox"/> Emergency Meeting </td> <td></td> </tr> <tr> <td>MEETING CHAIRED BY:</td> <td></td> </tr> <tr> <td>❖ Announcement of formal start of meeting</td> <td></td> </tr> <tr> <td>❖ Time started</td> <td></td> </tr> <tr> <td>❖ Determination of a duly constituted quorum by the Secretary to proceed with the meeting.</td> <td></td> </tr> <tr> <td>❖ COI Disclosures</td> <td></td> </tr> </table>				Meeting No.: 2019-01		<input type="checkbox"/> Regular <input type="checkbox"/> Emergency Meeting		MEETING CHAIRED BY:		❖ Announcement of formal start of meeting		❖ Time started		❖ Determination of a duly constituted quorum by the Secretary to proceed with the meeting.		❖ COI Disclosures	
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<p>I. Review of the previous minutes:</p> <p>II. Business or matters arising from the minutes:</p> <p>III. Conflict of Interest:</p> <p>IV. Agenda of the Meeting:</p>																									
<p>A. INITIAL REVIEW</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr style="background-color: #e1eef6;"> <td style="width: 40%;">(A.1) IRB Reference No.:</td> <td></td> </tr> <tr><td>Protocol No.</td><td></td></tr> <tr><td>Study Title</td><td></td></tr> <tr><td>Principal Investigator</td><td></td></tr> <tr><td>Sponsor</td><td></td></tr> <tr><td>Independent Consultant</td><td></td></tr> <tr><td>Technical Reviewer</td><td></td></tr> <tr><td>Primary Reviewer</td><td></td></tr> <tr><td>Submitted Documents</td><td></td></tr> <tr><td>Discussion</td><td></td></tr> <tr><td>Recommendations/Actions Taken</td><td></td></tr> </table>				(A.1) IRB Reference No.:		Protocol No.		Study Title		Principal Investigator		Sponsor		Independent Consultant		Technical Reviewer		Primary Reviewer		Submitted Documents		Discussion		Recommendations/Actions Taken	
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<p>B. RESUBMISSION</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr style="background-color: #e1eef6;"> <td style="width: 40%;">(B.1) IRB Reference No.</td> <td style="text-align: center;">NONE</td> </tr> <tr><td>Protocol No.</td><td></td></tr> <tr><td>Study Title</td><td></td></tr> <tr><td>Principal Investigator</td><td></td></tr> <tr><td>Sponsor</td><td></td></tr> <tr><td>Primary Reviewer</td><td></td></tr> <tr><td>Submitted Documents</td><td></td></tr> <tr><td>Discussion</td><td></td></tr> <tr><td>Recommendations/Actions Taken</td><td></td></tr> </table>				(B.1) IRB Reference No.	NONE	Protocol No.		Study Title		Principal Investigator		Sponsor		Primary Reviewer		Submitted Documents		Discussion		Recommendations/Actions Taken					
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<p>C. PROTOCOL AMENDMENTS</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr style="background-color: #e1eef6;"> <td style="width: 40%;">(C.1) IRB Reference No.</td> <td style="text-align: center;">NONE</td> </tr> <tr><td>Protocol No.</td><td></td></tr> <tr><td>Study Title</td><td></td></tr> <tr><td>Principal Investigator</td><td></td></tr> <tr><td>Sponsor</td><td></td></tr> </table>				(C.1) IRB Reference No.	NONE	Protocol No.		Study Title		Principal Investigator		Sponsor													
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<p>D. PROGRESS REPORTS / CONTINUING REVIEW REPORTS</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr style="background-color: #e1eef6;"><td style="width: 40%;">(D.1) IRB Reference No.:</td><td></td></tr> <tr><td>Protocol No.</td><td></td></tr> <tr><td>Study Title</td><td></td></tr> <tr><td>Principal Investigator</td><td></td></tr> <tr><td>Submitted Documents</td><td></td></tr> <tr><td>Discussion</td><td></td></tr> <tr><td>Recommendations/Actions Taken</td><td></td></tr> </table>			(D.1) IRB Reference No.:		Protocol No.		Study Title		Principal Investigator		Submitted Documents		Discussion		Recommendations/Actions Taken					
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<p>F. PROTOCOL DEVIATIONS</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr style="background-color: #e1eef6;"><td style="width: 40%;">(F.1) IRB Reference No.:</td><td></td></tr> <tr><td>Protocol No.</td><td></td></tr> <tr><td>Study Title</td><td></td></tr> <tr><td>Principal Investigator</td><td></td></tr> <tr><td>Sponsor</td><td></td></tr> <tr><td>Primary Reviewer</td><td></td></tr> <tr><td>Submitted Documents</td><td></td></tr> <tr><td>Discussion</td><td></td></tr> <tr><td>Recommendations/Actions Taken</td><td></td></tr> </table>			(F.1) IRB Reference No.:		Protocol No.		Study Title		Principal Investigator		Sponsor		Primary Reviewer		Submitted Documents		Discussion		Recommendations/Actions Taken	
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Tel. 253-7413 Fax. (63-32) 253-9127



IRB MINUTES TEMPLATE

FORM 6.1

G. COMMUNICATIONS/NOTIFICATIONS

(G.1) IRB Reference No.	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	

H. FINAL REPORTS



(H.1) IRB Reference No.	
Protocol No.	
Study Title	
Principal Investigator	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	

V. Protocols Exempted from Review

(V.1) IRB Reference No.:	
Study Title	
Principal Investigator	
Decision	

VI. Protocol Reviewed by Expedited Process

(VI.1) IRB Reference No.:	
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Principal Investigator	
Primary Reviewer	
Decision	

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VII. Other Matters:		
VIII. Adjournment: 2:00 PM		
Prepared by:	NOTED BY:	APPROVED BY:
Staff -Secretary	SECRETARY- Institutional Review Board	CHAIR-Institutional Review Board