






	<b>CEBU INSTITUTE OF MEDICINE – CEBU VELEZ GENERAL HOSPITAL INSTITUTIONAL REVIEW BOARD</b>	
Version 1	<b>SOP 5 MEETING PROCEDURES 5.2 Preparing the Meeting Agenda</b>	Effective Date: January 02, 2019

Supersedes:	Previous SOPs
Prepared by:	<del>SOP Team 2019</del>
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 agenda shall be based on the submissions received on or before the 2<sup>nd</sup> Wednesday of the month, or at least one week prior to the scheduled meeting. It shall follow the established template for meeting agenda.

**2. Objective of the Activity**

The preparation of the meeting agenda aims to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

**3. Scope**

This SOP describes how the IRB determines what items are included in the agenda of the regular and special meetings. This SOP begins with the preparation of the draft meeting agenda and ends with the filing of the final meeting agenda.

**4. Responsibility**

It is the responsibility of IRB Secretariat, under the supervision of the Secretary-Member, and Chair to draft and prepare the provisional meeting agenda.



**5. Process Flow/Steps**

<b>ACTIVITY</b>	<b>RESPONSIBILITY</b>
<b>Step 1:</b> Preparation of the draft meeting agenda ( <b>Form 5.1</b> )	IRB Secretariat
<b>Step 2:</b> Preparation of the provisional meeting agenda	Chair
<b>Step 3:</b> Distribution of the provisional meeting agenda (SOP on Preparing for a Meeting - SOP#5.1)	IRB Staff
<b>Step 4:</b> Approval of the provisional meeting agenda	Members
<b>Step 5:</b> Filing of the final meeting agenda (SOP on management of Active Files - SOP#7.2)	IRB Staff

**6. Detailed Instructions**

**Step 1: Preparation of the agenda (SOP on Preparing the Meeting Agenda - SOP#5.2)**

- The Secretariat shall encode the items to be discussed in the Meeting to include submissions for initial and continuing review using **Form 5.1 Meeting Agenda**. Only documents submitted on or before the 2<sup>nd</sup> Wednesday of the month (at least 7 days before the meeting) will be included in the agenda. The IRB Secretariat will email the Form 5.1 to the Chair and Member Secretary 6 days before the meeting. The Secretariat shall inform the Chair and the Member Secretary of the said email thru text.

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**Step 2: Preparation of the provisional meeting agenda**

- The Chair shall review Form 5.1, and make the necessary modifications and email the provisional meeting agenda to the IRB Secretariat 5 days before the meeting.

**Step 3: Distribution of the provisional meeting agenda**

- The Secretariat will forward the provisional agenda to all the IRB members at least 3 days before the scheduled meeting.

**Step 4: Approval of the provisional meeting agenda**

- The IRB members will approve the provisional agenda during the meeting

**Step 5: Filing of the final meeting agenda**

- The IRB Secretariat will file the meeting agenda after the meeting (SOP on management of Active Files - SOP#7.2)

**7. Forms**



*Meeting Agenda Template Form 5.1*

**8. History of SOP**



<b>Version No.</b>	<b>Date</b>	<b>Authors</b>	<b>Main Change</b>
01	April 7, 2016	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.
- 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;"> <h2 style="margin: 0;">IRB AGENDA TEMPLATE</h2> <p style="margin: 0; color: blue;">Form 5.1</p> </div>
<p><b>INSTITUTIONAL REVIEW BOARD</b> 79 F. RAMOS ST., CEBU CITY Tel. 253-7413 Fax. (63-32) 253-9127</p>			
DATE : _____		VENUE: _____	
MEETING NO: _____			
<input type="checkbox"/> Regular <input type="checkbox"/> Emergency Meeting			
<b>AGENDA</b>			
I. Approval of provisional agenda			
II. Review of the previous minutes:			
III. Business or matters arising from the minutes			
IV. Declaration of Conflict of Interest:			
V. Agenda of the Meeting:			
A. INITIAL REVIEW			
(A.1) IRB Reference No.:			
Protocol No.			
Study Title			
Principal Investigator			
Sponsor			
Independent Consultant			
Technical Reviewer			
Primary Reviewer			
Submitted Documents			
Discussion			
Recommendations/Actions Taken			
B. RESUBMISSION			
(B.1) IRB Reference No.			
Protocol No.			
Study Title			
Principal Investigator			
Sponsor			
Primary Reviewer			
Submitted Documents			
Discussion			
Recommendations/Actions Taken			

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# CIM-CVGH

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



## IRB AGENDA TEMPLATE

Form 5.1

**C. PROTOCOL AMENDMENTS**



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

**D. PROGRESS REPORTS / CONTINUING REVIEW REPORTS**



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

**E. SAE/SUSARS**

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

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F. PROTOCOL DEVIATIONS	
(F.1) IRB Reference No.:	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	
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	
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<b>V. Protocols Exempted from Review</b>		
(V.1) IRB Reference No.:	NONE	
Study Title		
Principal Investigator		
Decision		
<b>VI. Protocol Reviewed by Expedited Process</b>		
(VI.1) IRB Reference No.:		
Study Title		
Principal Investigator		
Primary Reviewer		
Decision		
<b>VII. Other Matters:</b>		
<b>VIII. Adjournment:</b>		
Prepared by:	NOTED BY:	APPROVED BY:
Staff -Secretary	SECRETARY- Institutional Review Board	CHAIR-Institutional Review Board