

 <p>Healing with Passion. Caring with Compassion.</p>	<p>CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD</p> <p>chh_irb@chonghua.com.ph</p>	<p>SOP/017/05</p> <p>Effective date: 01 January 2017</p> <p>Page 1 of 10</p>
	<p>Title:</p> <p>5.1 Preparation and Conduct of Meeting</p>	

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1. Purpose

To provide procedures for the preparation and distribution of the IRB meeting agenda

2. Scope

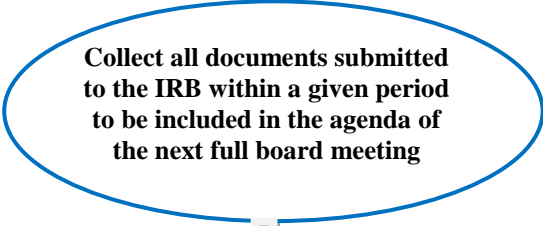



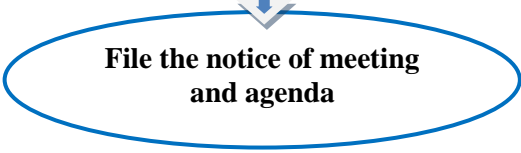
This SOP provides instructions related to the preparation of the IRB meeting agenda and its distribution to IRB members and other concerned individuals about the item/items for discussion during a full board meeting.

3. Responsibility

It is the responsibility of the IRB Secretariat, under the supervision of the Secretary-Member, to compile all documents/ information submitted to the IRB within a given period to include them in the agenda of the next full board meeting.

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4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I		Secretariat
II		Secretariat/ Chair
III		Secretariat
IV		Secretariat
V		Secretariat

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5. Detailed Instructions


- 5.1 Collect all documents submitted to the IRB within a given period and include them in the full board meeting agenda for discussion or information of the IRB members.
- 5.2 The standard notice of meeting or agenda contains the ff:
 - Date of preparation
 - Date, time and venue of meeting
 - Review of the previous minutes
 - Business or matters arising from the minutes
 - Conflict of interest
 - Agenda items
 - New protocols for initial review of full board
 - Resubmission
 - Amendments
 - Progress reports/ Continuing Review Reports
 - SAE/ SUSARS
 - Protocol Deviations
 - Communications/ Notifications
 - Final Reports
 - Protocols reviewed by Expedited Process
 - Other matters
 - Adjournment
- 5.3 For purposes of recommendation on protocols by the CHH IRB primary reviewers, principal investigators whose protocols require clarifications shall be notified of the scheduled meeting, informing them specifically of their time of appearance.
- 5.4 The Secretariat informs and consults the Chair about the agenda items.
- 5.5 The Secretariat arranges for the venue and other logistics of the meeting at least one week before the schedule.
- 5.6 The Secretariat shall send the notice of the meeting containing the approved agenda to the Chong Hua Hospital IRB members, at least one week before the meeting.

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- 5.7 The Secretariat confirms with the IRB members their attendance to ensure quorum.
- 5.8 The Secretariat files a copy of the agenda in the Agenda and Minutes folder.

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6. ANNEX

 <p>CHONG HUA HOSPITAL Healing with Passion. Caring with Compassion.</p>	<p align="center">IRB AGENDA</p> <p align="right">Form HRP-IRB-027_ver05</p>																																	
DATE:	VENUE:																																	
To:																																		
<table border="1"> <thead> <tr> <th></th> <th>IRB MEMBERS</th> <th>AFFILIATION</th> </tr> </thead> <tbody> <tr><td>1)</td><td></td><td></td></tr> <tr><td>2)</td><td></td><td></td></tr> <tr><td>3)</td><td></td><td></td></tr> <tr><td>4)</td><td></td><td></td></tr> <tr><td>5)</td><td></td><td></td></tr> <tr><td>6)</td><td></td><td></td></tr> <tr><td>7)</td><td></td><td></td></tr> <tr><td>8)</td><td></td><td></td></tr> <tr> <td>9)</td> <td>IRB ALTERNATE MEMBERS</td> <td>AFFILIATION</td> </tr> <tr> <td></td> <td>INDEPENDENT CONSULTANT</td> <td></td> </tr> </tbody> </table>		IRB MEMBERS	AFFILIATION	1)			2)			3)			4)			5)			6)			7)			8)			9)	IRB ALTERNATE MEMBERS	AFFILIATION		INDEPENDENT CONSULTANT		
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CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD

chh_irb@chonghua.com.ph

Title:

5.1 Preparation and Conduct of Meeting

SOP/017/05

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01 January 2017

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IRB AGENDA

Form HRP-IRB-027_ver05

- I. Review of the previous minutes:
- II. Business or matters arising from the minutes:
- III. Conflict of Interest:
- IV. Agenda of the Meeting:

A. INITIAL REVIEW

[A.1] IRB Reference No.:	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Independent Consultant	
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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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	
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Primary Reviewer	
Submitted Documents	
Discussion	
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IRB AGENDA

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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	
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Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Recommendation/Actions Taken	



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V. Protocols Reviewed by Expedited Process:

[V.1] IRB Reference No:	
Study Title	
Principal Investigator	
Primary Reviewer	
Decision	

VI. Other Matters:

VII. Adjournment:

PREPARED BY:

DONAFLORE V. TUBES
IRB SECRETARIAT

NOTED BY:

ELAINE L. GALLARDO, MD
SECRETARY – Institutional Review Board

APPROVED BY:

ATTY. DEAN G. DECAL
CHAIR – Institutional Review Board