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chh\_irb@chonghua.com.ph

## 6.1 Preparation of the Minutes of the IRB Meeting

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### **1. Purpose**

To describe procedures for the preparation and approval of the minutes of the IRB full board meeting

### **2. Scope**

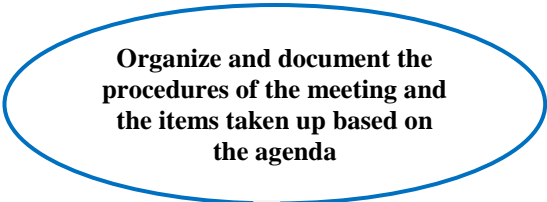


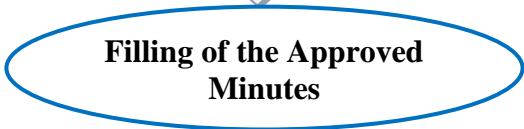
This SOP provides instructions related to the preparation of the minutes of the full board meeting of the IRB and its approval by the IRB members.

### **3. Responsibility**

It is the responsibility of the IRB Secretariat, under the supervision of the Member-Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the IRB meeting agenda.

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#### 4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I		Secretariat
II		Secretariat, Member-Secretary
III		Member Secretary, Chair
IV		Secretariat


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## 5. Detailed Instructions

- 5.1. The Secretariat uses **Form HRP-IRB-028\_ver05** as a template to organize the flow of the discussion of the meeting and to facilitate the writing of the minutes ahead of the meeting date.
- 5.2. The Secretariat documents the proceedings of the meeting as the meeting progresses by writing directly into the template.
- 5.3. The Secretariat reviews the proceedings prepared during the meeting and verifies the following documentation are completed:
  - Date and venue of meeting
  - Attendance of the members to determine the required quorum
  - Attendance of the guest and observers
  - Time when the meeting was called to order
  - Presiding officer
  - Declaration of any conflict of interest by the IRB members
  - Discussion of items specified in the agenda of the meeting
  - Decisions and recommendations arrived at during the meeting
  - Name and signature of the person who prepared the Minutes
  - Name and signature of the Chair of the IRB with the date of approval
- 5.4. Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.
- 5.5. The Secretariat submits a complete draft of the minutes to the Member-Secretary within **one week** after the meeting for corrections. The corrected draft will be forwarded to the Chair of the IRB for approval.
- 5.6. The Secretariat uses the information in the minutes to communicate full board IRB decisions to the respective Principal Investigators.
- 5.7. Once the minutes are finalized, they are sent to the members for comments or correction. This will be formally approved during the next full board meeting.
- 5.8. With the final approval by the board, the minutes will be filed in the meeting folder of the IRB.

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## 6. ANNEX

 <p><b>CHONG HUA HOSPITAL</b> Healing with Passion. Caring with Compassion.</p>	<p align="center"><b>IRB MINUTES OF THE MEETING</b></p> <p align="right">Form HRP-IRB-028_ver05</p>																																							
<p><b>DATE:</b></p> <p><b>VENUE:</b></p>	<p><b>Meeting Started:</b></p> <p><b>Meeting Adjourned:</b></p>																																							
<p><u><b>Attendees:</b></u></p> <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> <th></th> <th>IRB ALTERNATIVE MEMBERS</th> <th>AFFILIATION</th> </tr> <tr> <td>1)</td> <td></td> <td></td> </tr> <tr> <th></th> <th>INDEPENDENT CONSULTANT</th> <th></th> </tr> <tr> <td></td> <td></td> <td></td> </tr> </tbody> </table>			IRB MEMBERS	AFFILIATION	1)			2)			3)			4)			5)			6)			7)			8)				IRB ALTERNATIVE MEMBERS	AFFILIATION	1)				INDEPENDENT CONSULTANT				
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	INDEPENDENT CONSULTANT																																							
<p><b>I. Review of the previous minutes:</b></p> <p><b>II. Business or matters arising from the minutes:</b></p> <p><b>III. Conflict of Interest:</b></p> <p><b>IV. Agenda of the Meeting</b></p>																																								



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## CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD

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### Title: **6.1 Preparation of the Minutes of the IRB Meeting**

SOP/019/05

Effective date:  
**01 January 2017**

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### IRB MINUTES OF THE MEETING

Form HRP-IRB-028\_ver05

#### A. INITIAL REVIEW

<b>[A.1] IRB Reference No.:</b>	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Independent Consultant	
Primary Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	

#### B. RESUBMISSION

<b>[B.1] IRB Reference No.</b>	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	

#### C. PROTOCOL AMENDMENTS

<b>[C.1] IRB Reference No.</b>	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Primary Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	



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Title:

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### IRB MINUTES OF THE MEETING

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#### D. PROGRESS REPORTS / CONTINUING REVIEW REPORTS

[D.1] IRB Reference No.	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	

#### E. SAE/SUSARS

[E.1] IRB Reference No.	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	

#### F. PROTOCOL DEVIATIONS

[F.1] IRB Reference No.	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Reviewer	
Submitted Documents	
Discussion	
Recommendations/Actions Taken	



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#### G. COMMUNICATIONS/NOTIFICATIONS

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

#### H. FINAL REPORTS

[H.1] IRB Reference No.	
Protocol No.	
Study Title	
Principal Investigator	
Sponsor	
Reviewer	
Submitted Documents	
Discussion	
Recommendation/Actions Taken	

#### V. Protocols Reviewed by Expedited Process


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

#### VI. Other Matters:

#### VII. Adjournment:



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<p><b>PREPARED BY:</b></p> <p><b>DONAFLORE V. TUBES</b> IRB- SECRETARIAT</p> <p><b>NOTED BY:</b></p> <p><b>ELAINE L. GALLARDO, M.D.</b> SECRETARY – Institutional Review Board</p> <p><b>APPROVED BY:</b></p> <p><b>ATTY. DEAN G. DECAL</b> CHAIR – Institutional Review Board</p>	