	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD CHH IRB	
Version No: 09 Date of Approval: 08/21/24 Date of Effectivity: 08/21/24	**SOP 2.3 EXEMPT FROM REVIEW**	

1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) procedures for the review of protocols that qualify for exemption from review.

2. Scope

This SOP applies to the review of a study protocol submitted to the CHH IRB that qualifies for exemption from review. The criteria for study protocols which are exempted from review are found in SOP 2.1 Management of Initial Protocol Submissions. Section 5.4.

3. Responsibility

The Chair or an IRB Member designated by the Chair is responsible for the assessment whether the submitted protocol qualifies for exemption from review.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Review a study protocol applying for exemption from review	Chair/Designated Member	To be done within 7 working days
Step 2: Issue Certificate of Exemption or recommend expedited or full-board review	Chair	
Step 3: Prepare a report of protocols that are exempt from review to full-board	Secretariat	
Step 4: Communicate the IRB decision to the PI	CHH IB Staff	
Step 5: File copy of the documents in the protocol binder and update protocol database for exemption from review	CHH IRB Staff	

5. Procedures

Step 1- Review a study protocol applying for exemption from review: The CHH IRB Chair or a designated IRB member who does not have any conflict of interest should review the study protocol applying for review exemption. The CHH IRB Chair or a designated IRB member shall then evaluate the study protocol using the Exemption Criteria.

Step 2- Issue Certificate of Exemption or recommend expedited or full-board review: If the protocol qualifies for exemption from review, the reviewer submits the results of the assessment to the Secretariat for the IRB staff to prepare a Certificate of Exemption from Review FORM 2023-HRP-IRB-035-CERTIFICATE OF EXEMPTION FROM REVIEW. If the protocol does not meet the Exemption Criteria, the Chair reclassifies the protocol for expedited or full-board review.

Step 3- Prepare a report of protocols that are exempt from review to full-board: The CHH IRB Staff prepares a report to the next full board meeting to include details of all protocols exempted from review.

Step 4- Communicate the IRB decision to the PI: The CHH IRB Staff prepares the Certificate of Exemption from Review and forwards it to the IRB Chair for signature. The CHH IRB Staff issues the Certificate of Exemption to the Principal Investigator.

Step 5- File a copy of the documents in the protocol binder and update protocol database for exemption from review: Prepare a binder to contain all protocols exempt from review. File the properly-labeled binder in the appropriate shelf of the storage cabinet. Update protocol database for exemption from review

6. History of SOP

Version No.	Date	Authors	Main Change
1	-	-	-
2	-	-	-
3	-	-	-
4	-	-	-
5	-	-	-
6	02 October 2017	Rev. Fr. Benedicto P. Tao	First draft
7	04 January 2021	Rev. Fr. Roderich L. Teriote	No change
8	04 January 2024	Atty. Dean G. Decal	Revisions made in compliance with action plans submitted for PHREB/FERCAP re-accreditation
9	21 August 2024	Atty. Dean G. Decal	No Change

7. References

- 2017 Department of Health – SOP Version No. 2
- 2020 PHREB SOP Workbook