1.Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) procedures related to research participants' requests and/or queries.

2. Scope

This SOP applies to all queries and requests related to the rights and well-being of the research participants in studies approved by the CHH IRB.

3. Responsibility

A designated member of the secretariat is responsible for receiving participant queries and requests related to their participation, and refers relevant issues to the CHH IRB Chair to take appropriate action. The Secretariat keeps records of all actions taken by the CHH IRB.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Receive the complaint or injury	CHH IRB Staff	7 days
Step 2: Review the complaint/injury	CHH IRB Chair/Member Secretary	
Step 3: Discuss in convened meeting or report the decision/ action taken to full board	CHH IRB Members, Chair/Secretary	
Step 4: Communicate IRB's response	CHH IRB Staff/Chair	
Step 5: File pertinent documents		

5. Procedures

Step 1- Receive the complaint or injury

- Study protocol-related complaints and inquiries may come from research participants, or other parties.
- The CHH IRB Staff receives the complaint.
- The CHH IRB Staff may assist to put the complaint in writing especially if the complainant or inquiring party is a research participant.
- The CHH IRB Staff responds to inquiry, if it is within its authority to do so or refers the complaint or inquiry to the Chair/Member-Secretary for appropriate action.
- CHH IRB Staff records the submitted document in the Log of Incoming Documents.

Step 2- Review the complaint/inquiry: The CHH IRB Chair or Member-Secretary reviews the complaint. The PI may be contacted to provide clarification or further information.

Step 3- Discuss in a convened meeting or report the decision/action taken to full board: The Chair presents a serious complaint to the full board for discussion. The CHH IRB members discuss taking appropriate actions.

Step 4- Communicate IRB's response: CHH IRB Staff prepares response to inquiry complaints within 7 days from the time of review.

Step 5- File pertinent documents: The CHH IRB Staff files the accomplished Form HRP-IRB-022 (see Chapter on Forms) together with the letter of inquiry/complaint and excerpts of the meeting minutes when this was deliberated or reported in the protocol file folder. The CHH IRB Staff updates the protocol file folder and updates the protocol file index.

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Mr. Romel V. Cabazor	First Draft
2	01 January 2014	Rev. Fr. Benedicto P. Tao	Change in the logo from CHH to CHH IRB logo Revised SOP, Form numbering and Request Record Form
3	01 September 2014	Rev. Fr. Benedicto P. Tao	Change of irb SOP in accordance to PRHEB SOP Format
4	01 October 2014	Rev. Fr. Benedicto P. Tao	Revised IRB in accordance to PHREB SOP Format
5	01 January 2017	Atty. Dean G. Decal	Revised CHH IRB SOP from version 04 to version 05
6	02 October 2017	Dr. Manuel Emerson S. Donaldo	Revised CHH IRB SOP in accordance to 2017 DOH-REC SOP ver02 Template Revised CHH IRB Query/Complaint Record Form
7	04 January 2021	Dr. Manuel Emerson S. Donaldo	No change
8	04 January 2024	Dr. Manuel Emerson S. Donaldo	No change
9	21 August 2024	Dr. Manuel Emerson S. Donaldo	No change

7. References

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