	CHONG HUA HOSPITAL INSTITUTIONAL REVIEW BOARD CHH IRB	
Version No: 09 Date of Approval: 08/21/24 Date of Effectivity: 08/21/24	**SOP 3.4 REVIEW OF REPORTABLE NEGATIVE EVENTS**	

1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH-IRB) requirement of the submission of Reportable Negative Events to ensure that the safety and welfare of human participants and the research team are safeguarded and that information on RNEs are properly documented and evaluated.

2. Scope

This SOP applies to the review of RNE reports. This SOP begins with the receipt and documentation of submission of RNE report in the logbook and ends with the filing of all related documents and update of the protocol database.

3. Responsibility

Reportable Negative Events (RNE) - are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.,

4. Workflow

ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
Step 1: Receive RNE report and document in the logbook.	CHH IRB Staff	Within 3 days from PI's knowledge
Step 2: Retrieval of pertinent protocol file	CHH IRB Staff	7 Days
Step 3: Notify the Chair	CHH IRB Staff	
Step 4: Call for a Special Meeting	CHH IRB Chair	
Step 5: Deliberate on the RNE at Full Board	CHH IRB members	
Step 6: Communicate CHH-IRB action to the PI (SOP 4.5 on Communication of IRB Decisions)	CHH IRB Chair CHH IRB Staff	
Step 7: File documents in protocol file folder (SOP 4.7 Management of Active Files) and Update database	CHH IRB Staff	

5. Description of Procedures

Step 1- Receive RNE report and document in the logbook: The Staff receives the accomplished RNE report form (Form ##) at the latest three (3) days after the event has come to the attention of the researcher and then enters the submission into the logbook. The Staff notes whether the submission is within the required timeline.

Step 2- Retrieval of pertinent protocol file: The Staff retrieves the approved protocol file and checks the identity of the primary reviewers.

Step 3- Notify the Chair: The Staff notifies and sends the report and the retrieved documents to the Chair who may decide to call for a special meeting.

Step 4- Call for a Special Meeting: The staff prepares for a special meeting (SOP 4.1). The researcher and other members of the study team may be invited for a clarificatory meeting.

Step 5- Deliberation of the Reported Negative Even in the Special Meeting: The CHH IRB Chair leads the discussion of the special meeting, summarizes the RNE report and informs the CHH IRB members regarding the presence of the research team for clarificatory meeting.

The following safety issues are evaluated:

- identification of risks to the participant's / research team
- nature and effectivity of preliminary interventions with or without the help of community
- impact on integrity of data and completion of the research

The Research team is excused and the CHH IRB members deliberate on possible options, as follows:

- recommend suspension of the study until risk is resolved.
- withdrawal of ethical clearance
- submission of a plan to mitigate risk/harm
- require an amendment to the protocol
- uphold original ethical clearance

Step 6- Communicate CHH IRB recommendation to the PI: See (SOP 4.4) on Communicating IRB decisions.

Step 7- File documents in protocol file folder: (SOP 4.6 Managing of Active Files) **and Update database**

6. History of SOP

Version No.	Date	Authors	Main Change
8	04 January 2024	Atty. Dean Decal	First draft
9	21 August 2024	Atty. Dean Decal	No change

7. References

- Philippine Health Research Ethics Board Standard Operating Procedures 2020