1. Purpose

To describe the Chong Hua Hospital Institutional Review Board (CHH IRB) procedures related to the conduct of site visits.

2. Scope

This SOP applies to any visit made in any study site, on behalf of the CHH IRB, to check compliance with IRB approved protocol and related documents, and national and international standards. This includes virtual Site Visit during the pandemic.

3. Responsibility

It is the responsibility of the CHH IRB to conduct study site monitoring for cause or routine.

CHH IRB Members may recommend that a particular study site be visited.

The CHH IRB Chair/Member-Secretary selects members of the study site visit team.

4. Flowchart

ACTIVITY	PERSON/S RESPONSIB	TIMELINE
Step 1: Select study site to visit	CHH IRB Members	During the full board meeting
Step 2: Create Study site visit	CHH IRB Chair/ Member-secretary	
Step 3: Prepare Study Site Visit Plan	Study site visit team	
Step 4: Notify PI of date of site visit	CHH IRB Chair/ Member-Secretary	7 days
Step 5: Conduct site visit and debrief study team	Study Site Visit Team	
Step 6: Present findings during full committee meeting	CHH IRB Members	
Step 7: Communicate results of site visit and recommended actions, if any to PI	CHH IRB Staff	
Step 8: File pertinent documents	CHH IRB Staff	

5. Procedures

Step 1- Select study site to visit: The CHH IRB Members may recommend to visit study sites for any of the following reasons:

- When the CHH IRB has never approved the principal investigator for a research project, a study visit should be planned for at the appropriate time after the study starts.
- New study sites
- Frequent occurrence of SAE
- Protocol violations

Step 2- Create Study Site Visit Team

- The CHH IRB Chair/Member Secretary selects members of Study Site Visit Team and designates the Team Leader. Members should include the Primary Reviewers.
- The Site Visit Team members are formally informed of their assignment.
- The CHH IRB Staff prepares the Study Site Visit package consisting of the latest version of the approved protocol and informed consent documents, and other relevant documents, (like protocol deviation reports, on-site SAEs/SUSARs - initial and follow-up reports) and a copy of the Study Site Visit Report Form.

Step 3- Prepare Study Site Visit Plan: The Study Site Visit Team prepares the Study Site Visit Plan that includes the following:

  - Date and time of the planned visit
  - Members of the Study Site Visit Team
  - Objectives of the Visit
  - Documents to be reviewed
  - Persons to be interviewed
- The Study Site Visit Team, in consultation with the CHH IRB Chair, is given access documents in the protocol file folder of a study for monitoring. The Team may also photocopy some parts of the files (like advertisement materials, the informed consent form (ICF), case report form) for comparison with the documents used in the study site.

  The IRB representatives will:

  - Review the informed consent document to make sure that the site is using the most recent version.
  - Review randomly the subject files to ensure that subjects are signing the correct informed consent document.
  - Observe the informed consent process, if possible.
  - Observe laboratory and other facilities necessary for the study at the site.
  - Review the filing to ensure that documentation is filed appropriately.
  - Collect views of the study participants.
  - Debrief the visit report/comments.

- Get immediate feedback.

Step 4- Notify PI of date of site visit: The CHH IRB Staff prepares the letter informing the PI of the planned study site visit for signature by the CHH IRB Chair. Attached to the letter is the Study Site Visit Plan and the Study Site Visit Report form.

Step 5- Conduct site visit and debrief study team

- The Study Site Visit Team conducts the site visit as per the Study Site Visit Plan. Additional guide in the conduct of the visit is the Study Site Visit Report Form.
- At the end of the visit, the Study Site Visit Team presents the findings to the Study Team and solicits feedback.
- The Study Site Visit Team completes the Study Site Visit Report Form**.**
- Conflicting findings should be resolved by consensus.
- The report is submitted to the CHH IRB Staff within 7 calendar days from the date of the visit.
- CHH IRB Staff logs the submission in the Log of Incoming Documents.
- The CHH IRB Secretariat includes the presentation of the study site visit report in the meeting agenda.

Step 6-Present findings during full committee meeting: The Study Site Visit Team presents the report during the full committee meeting. The CHH IRB makes a determination whether the rights, safety and welfare of research participants are compromised and appropriate recommendations to the PI, if any.

Step 7- Communicate results of site visit and recommended actions, if any to PI: Based on the minutes of the meeting, the CHH IRB Staff prepares the Notification Letter – Study Site Visit for signature of the CHH IRB Chair. The PI may be requested to provide additional information or documents or implement corrective actions.

Step 8- File pertinent documents: The CHH IRB Staff files the Study Site Visit Report, excerpt of the minutes of the meeting when report was discussed and the Notification Letter (including the response from the PI, if any) in the protocol file folder and update the protocol file index.

6. History of SOP

Version No.	Date	Authors	Main Change
1	10 September 2010	Atty. Dean G. Decal	First Draft
2	01 January 2014	Rev. Fr. Benedict P. Tao	Change in the logo from CHH to CHH IRB logo Revised SOP and form numbering
3	01 September 2014	Rev. Fr. Benedicto P. Tao	Change of IRB SOP in accordance to PHREB SOP Format
4	01 October 2014	Rev. Fr. Benedicto P. Tao	Revised IRB SOP 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 Study Site report form
7	04 January 2021	Dr. Manuel Emerson S. Donaldo	No change
8	31 August 2023	Dr. Manuel Emerson S. Donaldo	No change
9	21 August 2024	Dr. Manuel Emerson S. Donaldo	No change

7.References

- 2017 Department of Health – SOP Version No. 2