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1. Purpose

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored as regards its performance or compliance to GCP.

2. Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the IRB-approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed.

3. Responsibility

It is the responsibility of the IRB to perform or designate some qualified agents to perform on its behalf an on-site inspection of the research projects it has approved.

The IRB members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit.

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I	Selection of study sites	IRB members and Chairperson
II	Procedures before the visit	IRB members and/or representative
III	Procedures during the visit	IRB members and/or representative
IV	Procedures after the visit	IRB members and/or representative
V	Present the findings to the Full Board	IRB members and/or representative

5. Detailed Instructions

5.1 Selection of study sites

- The IRB may monitor at random the database files of the submitted approved study protocols.

- Select study sites may need to be monitored based on the following:
  - 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
  - Reports of remarkable serious adverse events
  - Number of studies carried out at the study sites.
  - Frequency of protocol submission for IRB review
  - Non-compliance or suspicious conduct
  - Frequent failure to submit final reports

5.2 Before the visit

The IRB representatives will

- Contact the site to notify them that the IRB representative/s will be visiting them by a written communication a week prior to the schedule. At that time, the monitor and the site will coordinate a time for the site evaluation visit.
- Make the appropriate travel arrangements.
- Review the IRB files for the study and site,
- Make appropriate notes, or
- Copy some parts of the files for comparison with the site files.

5.3 During the visit

- Get a checklist (Form HRP-IRB-026, see ANNEX 1).
- 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.

5.4 After the visit

The IRB representative will:

- Write a report/comment (use the form HRP-IRB-026, see ANNEX 1) within 2 weeks describing the findings during the audit.
- Forward a copy of the site visit to the 'site monitoring' file for Full Board review.
- Send a copy of the report to the site for their files, and
- Place the report in the correct site files.

5.5 Present the inspection results to the Full Board

- Consult with the IRB secretariat.
- Schedule the presentation in the meeting agenda.
- Present the results of on-site inspections to the Full Board.

6. ANNEX

ANNEX 1

崇華醫院
Chong Hua Hospital
Fuente Osmeña, Cebu City
Tel# +63(32) 255-8000; Fax# +63(32) 253-5639

CHECKLIST OF A MONITORING VISIT

Form HRP-IRB-026

Protocol No.:	Date of the Visit:
Study Title:	
Principal Investigator/s:	Phone:
Institute:	Address:
Sponsor: CRO:	Address:
Total number of expected subjects:	Total subjects enrolled:
Are the site facilities appropriate? ☐ Yes ☐ No	Comments:
Are the Informed Consent documents in use the most recent version approved by the CHH IRB? ☐ Yes ☐ No	Comments:
Any adverse events found? ☐ Yes ☐ No	Comments:
Are there any SAE/SUSAR reports not previously reported to the CHH IRB? ☐ Yes ☐ No	Comments:
Any protocol non-compliance /violation not previously reported to the CHH IRB? ☐ Yes ☐ No	Comments:
Are investigation products and study documents secured adequately? ☐ Yes ☐ No	Comments:
Are all other CHH IRB-approved documents (e.g. advertisements, cards, etc.) used in accordance with the approved study protocol? ☐ Yes ☐ No	Comments:
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comments:
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comments:
Is there anything that could affect the participant's/subject's rights, safety, or welfare? ☐ Yes ☐ No	Comments:

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CHECKLIST OF A MONITORING VISIT

Form HRP-IRB-026

Overall, does the site provide adequate protection for the rights, safety, and welfare of study participants/subjects? ☐ Yes ☐ No	Comments:
Any further actions or queries resulting from this site visit? ☐ Yes ☐ No	Give details:
Additional remarks:	
Duration of visit: _____ hours	Starting from: _____ Finish: _____

COMPLETED BY THE FOLLOWING IRB MEMBERS/REPRESENTATIVES

NAME	SIGNATURE	DATE <dd/mm/yyyy>

RECOMMENDED ACTION: (For CHH IRB use only)

☐ NO FURTHER ACTION RECOMMENDED

☐ REQUEST INFORMATION: (specify)

☐ RECOMMEND FURTHER ACTION: (specify)

Primary Reviewer: (print name and sign) _____

Date:

CHH IRB Secretary: (print name and sign) _____

Date:

CHH IRB Chair: (print name and sign) _____

Date:

CHECKLIST OF A MONITORING VISIT Page 2 of 2

7. References

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996.
- National Ethical Guidelines for Health Research 2011 PNHRS