




chh_irb@chonghua.com.ph

7.1 SITE MONITORING VISITS

Page 1 of 8

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No.	Content	Page No.
	Table of Contents	1
1.	Purpose	2
2.	Scope	2
3.	Responsibility	2
4.	Flowchart	3
5.	Detailed Instructions.....	4
5.1	Selection of study sites	4
5.2	SOP before the visit	4
5.3	SOP during the visit	4
5.4	SOP after the visit	5
5.5	Present the inspection results to the Full Board	5
6.	ANNEX	
	Annex 1:	
	Checklist of a Monitoring Visit.....	6
7.	References	8

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	<p>Title:</p> <p>7.1 SITE MONITORING VISITS</p>	<p>Page 2 of 8</p>

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.

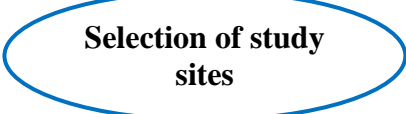



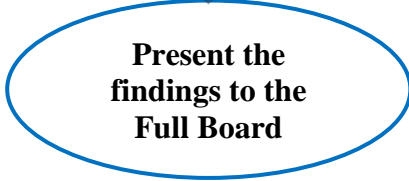
3. Responsibility


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.

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	<p>Title:</p> <p>7.1 SITE MONITORING VISITS</p>		<p>Effective date: 01 January 2017</p> <p>Page 3 of 8</p>

4. Flowchart

No.	ACTIVITY	RESPONSIBLE PERSONNEL
I		IRB members and Chairperson
II		IRB members and/or representative
III		IRB members and/or representative
IV		IRB members and/or representative
V		IRB members and/or representative

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	<p>Title:</p> <p align="center">7.1 SITE MONITORING VISITS</p>	<p align="center">Page 4 of 8</p>

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.

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	<p>Title:</p> <p align="center">7.1 SITE MONITORING VISITS</p>	

- 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.


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	<p>Title:</p> <p align="center">7.1 SITE MONITORING VISITS</p>	<p align="right">Page 6 of 8</p>

6. ANNEX

 <p>CHONG HUA HOSPITAL Healing with Passion. Caring with Compassion.</p>		<p><u>ANNEX 1</u></p> <p>CHECKLIST OF A MONITORING VISIT</p> <p>Form HRP-IRB-026</p>																																		
<table border="1"> <tr> <td>Protocol No.:</td> <td>Date of the Visit:</td> </tr> <tr> <td colspan="2">Study Title:</td> </tr> <tr> <td>Principal Investigator/s:</td> <td>Phone:</td> </tr> <tr> <td>Institute:</td> <td>Address:</td> </tr> <tr> <td>Sponsor:</td> <td>Address:</td> </tr> <tr> <td>CRO:</td> <td></td> </tr> <tr> <td>Total number of expected subjects:</td> <td>Total subjects enrolled:</td> </tr> <tr> <td>Are the site facilities appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> <tr> <td>Are the Informed Consent documents in use the most recent version approved by the CHH IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> <tr> <td>Any adverse events found? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> <tr> <td>Are there any SAE/SUSAR reports not previously reported to the CHH IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> <tr> <td>Any protocol non-compliance /violation not previously reported to the CHH IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> <tr> <td>Are investigation products and study documents secured adequately? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> <tr> <td>Are all other CHH IRB-approved documents (e.g. advertisements, cards, etc.) used in accordance with the approved study protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> <tr> <td>Are all Case Record Forms up to date? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> <tr> <td>How well are participants protected? <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Not good</td> <td>Comments:</td> </tr> <tr> <td>Is there anything that could affect the participant's/subject's rights, safety, or welfare? <input type="checkbox"/> Yes <input type="checkbox"/> No</td> <td>Comments:</td> </tr> </table>		Protocol No.:	Date of the Visit:	Study Title:		Principal Investigator/s:	Phone:	Institute:	Address:	Sponsor:	Address:	CRO:		Total number of expected subjects:	Total subjects enrolled:	Are the site facilities appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	Are the Informed Consent documents in use the most recent version approved by the CHH IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	Any adverse events found? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	Are there any SAE/SUSAR reports not previously reported to the CHH IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	Any protocol non-compliance /violation not previously reported to the CHH IRB? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	Are investigation products and study documents secured adequately? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	Are all other CHH IRB-approved documents (e.g. advertisements, cards, etc.) used in accordance with the approved study protocol? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	Are all Case Record Forms up to date? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	How well are participants protected? <input type="checkbox"/> Good <input type="checkbox"/> Fair <input type="checkbox"/> Not good	Comments:	Is there anything that could affect the participant's/subject's rights, safety, or welfare? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comments:	
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CHECKLIST OF A MONITORING VISIT	Page 1 of 2																																			

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	<p>Title:</p> <p align="center">7.1 SITE MONITORING VISITS</p>	<p align="right">Page 7 of 8</p>

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<p>Overall, does the site provide adequate protection for the rights, safety, and welfare of study participants/subjects?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Comments:</p>	
<p>Any further actions or queries resulting from this site visit?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Give details:</p>	
<p>Additional remarks:</p>		
<p>Duration of visit: _____ hours Starting from: _____ Finish: _____</p>		
<p align="center">COMPLETED BY THE FOLLOWING IRB MEMBERS/REPRESENTATIVES</p>		
NAME	SIGNATURE	DATE <dd/mm/yyyy>
<p>RECOMMENDED ACTION: (For CHH IRB use only)</p> <p><input type="checkbox"/> NO FURTHER ACTION RECOMMENDED</p> <p><input type="checkbox"/> REQUEST INFORMATION: (specify) _____</p> <p><input type="checkbox"/> RECOMMEND FURTHER ACTION: (specify) _____</p>		
<p>Primary Reviewer: (print name and sign) _____</p>		
<p>Date: _____</p>		
<p>CHH IRB Secretary: (print name and sign) _____</p>		
<p>Date: _____</p>		
<p>CHH IRB Chair: (print name and sign) _____</p>		
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<p>CHECKLIST OF A MONITORING VISIT</p>		<p>Page 2 of 2</p>

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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