CHAPTER 7

SITE MONITORING VISITS

SOP NUMBER: SOP/021/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

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Table of Contents

1. PURPOSE

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

2. SCOPE

This SOP shall apply 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

The IRB shall be responsible to perform or designate some qualified agents to perform on its behalf 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. FLOW CHART

No.	Activity	Responsibility
1	Selection of study sites ↓	IRB members and Chairperson
2	Procedures before the visit ↓	IRB members and/or representative
3	Procedures during the visit ↓	IRB members and/or representative
4	Procedures after the visit ↓	IRB members and/or representative
5	Review and approve the site visit report during the IRB meeting ↓	IRB members and/or representative
6	Notify the study site ↓	IRB secretariat
7	Storage of the document	IRB secretariat

5. DETAILED INSTRUCTIONS

5.1. Selection of study sites

5.1.1. Review periodically the database files of the submitted/approved study protocols.

5.1.2. Select study sites needed to be monitored based on the following criteria:

5.1.2.1. Reports of remarkable serious adverse events

5.1.2.2. Non-compliance or suspicious conduct

5.1.2.3. Research involving clinical drug trials

5.1.2.4. Not submitting information/reports on time

5.2. Before the visit

The IRB representatives shall

5.2.1. Contact the site to notify them that they shall be visiting them. At that time, the monitor and the site shall coordinate a time for the site evaluation visit.
5.2.2. Make the appropriate travel arrangements.
5.2.3. Review the IRB files for the study and site,
5.2.4. Make appropriate notes, or
5.2.5. Copy and take some parts of the files for comparison with the site files.

5.3. During the visit

5.3.1. Bring the Site Monitoring Report (AF/01-021/01) form as a checklist for the site visit.
5.3.2. The IRB representatives shall
5.3.2.1. Review the informed consent document to make sure that the site is using the most recent approved version,
5.3.2.2. Review randomly the subject files to ensure that subjects are signing the correct informed consent,
5.3.2.3. Observe the informed consent process, if possible,
5.3.2.4. Observe laboratory and other facilities necessary for the study at the site.
5.3.2.5. Review the IRB files for the study to ensure that documentation is filed appropriately.
5.3.2.6. Collect views of the study participants.
5.3.2.7. Debrief the visit report/comments.
5.3.2.8. Get immediate feedback.

5.4. After the visit

The IRB representative shall:
5.4.1. Write a report/comment (use the ANNEX - AF/01-021/01) within 2 weeks describing the findings during the audit
5.4.2. Send the site visit report to the IRB Secretariat for Full Board review.

5.5. Review and approve the site visit report during the IRB meeting

5.5.1. The IRB Secretariat shall schedule the presentation in the meeting agenda.
5.5.2. The IRB representative shall present the results of on-site inspections to the Full Board.
5.5.3. The full board review & discuss the findings and comments of the report
5.5.4. The IRB Secretariat shall record the discussion and decision in the meeting minutes.

5.6. Notify the study site

5.6.1. The IRB Secretariat shall prepare a letter to inform the site of the Committee's decision and recommendation.
5.6.2. The Chairperson shall sign and date the letter.
5.6.3. The IRB Secretariat shall send the letter to the study site within 5 working days of the meeting.

5.7. Storage of the documents

5.7.1. Keep the site visit report with the related review meeting minutes in the site files.
5.7.2. Keep the copy of the letter in the Correspondence File.

6. GLOSSARY

IRB representative/s	Many IRB members rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees of local institution to perform the tasks on their behalf and later report their findings to IRB.
Monitoring visit	An action that IRB or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit shall be arranged in advance with the principal investigators.

7. REFERENCES

7.1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
7.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.

8. ANNEX

ANNEX 1 AF/01-021/01: Site Monitoring Visit Report

ANNEX 1
AF/01-021/01

Site Monitoring Visit Report

Protocol Number:	Date of the Visit:	
Study Title:		
Principal Investigators:		Phone:
Institute:	Address:	
Sponsor:	Address:	
Total number of expected subjects:	Total subjects enrolled:	
Are site facilities appropriate? ☐ Yes ☐ No	Comment:	
Are Informed Consents of approved version? ☐ Yes ☐ No	Comment:	
Any adverse events found? ☐ Yes ☐ No	Comment:	
Any protocol non-compliance /violation? ☐ Yes ☐ No	Comment:	
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:	
Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:	
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:	
Any outstanding tasks or results of visit? ☐ Yes ☐ No	Give details:	
Duration of visit: …….hours	Starting from:	Finish:
Name of IRB member/ representatives and accompanier:		
Completed by:		Date: