CHAPTER 10

AUDITING AND INSPECTION OF THE IRB

SOP NUMBER: SOP/028/01

INSTITUTIONAL REVIEW BOARD
(IRB)

Khesar Gyalpo University of Medical Sciences of Bhutan

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1. PURPOSE

The purpose of this procedure shall be to guide how to prepare for an audit or inspection of the IRB processes.

2. SCOPE

This SOP shall apply to every unit of the IRB

3. RESPONSIBILITY

The Secretariat, the Members, and the Chairperson of the IRB shall be responsible to perform all tasks according to the SOPs and shall be accountable during evaluation, audit or inspection visits of authorities and guests.

4. FLOW CHART

No.	Activity	Responsibility
1	Call for an Audit / Inspection ↓	IRB Chairperson / Head of Organization
2	Prepare for the visit ↓	IRB Secretariat / Members and Chairperson
3	Receive Auditor / Inspector ↓	IRB Secretariat / Members and Chairperson
4	Correct the mistakes ↓	IRB Secretariat / Members and Chairperson
5	Record the Event	IRB Secretariat

5. DETAILED INSTRUCTIONS

5.1. Call for an Audit / Inspection

5.1.1. Receive a notice of inspection visit
5.1.2. The Chairperson informs the Secretariat /Head of Organization.
5.1.3. The Chairperson alerts every unit to get ready.

5.2. Prepare for the visit

5.2.1. Get a checklist form, ANNEX – AF/01-028/01.
5.2.2. Go through all steps on the list.
5.2.3. Note and comment on each part.
5.2.4. Emphasize on the studies with problems.
5.2.5. Check if all documents are labeled and kept in the right order for easy and quick search.
5.2.6. Check for any missing or disorganized records.
5.2.6.1. Background and training records of IRB members

5.2.6.2. Application Submission Records
5.2.6.3. Protocol Assessment Records
5.2.6.4. Communication Records
5.2.6.5. Amendment Approval
5.2.6.6. Meeting Agenda, Minutes, Action letters
5.2.6.7. Active files
5.2.6.8. Continuing and Final reports

5.2.7. Reserve a meeting room and all necessary facilities.
5.2.8. Review the IRB SOPs.
5.2.9. Make sure that no omission or deviation exists.
5.2.10. Make sure to have good reasons for any omission or deviation.
5.2.11. Inform IRB members about the inspection date if they are able to attend the audit/inspection meeting.

5.3. Receive Auditor / Inspector

5.3.1. The Chairperson or the Secretariat shall receive and accompany the auditors/inspectors to the reserved meeting room.
5.3.2. Members and some key staff shall also be present in the meeting room.
5.3.3. The conversation starts with the auditor/inspector stating the purpose of the visit and what kind of information and data are needed.
5.3.4. Answer questions of the auditors/inspectors clearly, politely and truthfully with confidence and straight to the point.
5.3.5. Find and get all information and files requested by the auditors/inspectors.
5.3.6. Take note of the comments, recommendation of the auditors/inspectors.

5.4. Correct the mistakes

5.4.1. Review comments and recommendations of the auditors/inspectors.
5.4.2. Write a report and have it approved by the Chairperson.
5.4.3. The Chairperson calls for the correction.
5.4.4. Allow appropriate time for correction and improvement process.
5.4.5. Carry an internal follow-up audit.
5.4.6. Evaluate the outcome.
5.4.7. Report the outcome to the IRB.

5.5. Record the Audit/Inspection Event

5.5.1. Keep record of the report on the audit/inspection meeting in the audit/inspection file.
5.5.2. Record also the findings from the internal follow-up audit in the internal audit file.

6. GLOSSARY

Audit	A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements
Inspection	The act by a regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organization (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities

7. REFERENCES

7.1.1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.

7.1.2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 2016.

7.1.3. World Health Organization, Surveying and Evaluating Ethical Review Practices, Feb. 2002.

7.2. World Health Organization, Standards and operational guidance for ethics review of health-related research with human participants, 2011.

7.3. Associated SOPs: SOP/001/01, SOP/028/01

8. ANNEX

ANNEX 1 AF/01-028/01 Audit and Inspection Checklist

ANNEX 1
AF/01-027/01

Audit and Inspection Checklist

Internal Audit External Audit Inspection		Date:
The date(s) which the audit/inspection has been agreed for:		
Will an interpreter be required? If yes, what arrangement has been made?		☐ Yes…… ☐ No
Review the SOPs and note details of any omissions or deviations, with reasons		
Check the files for the presence of all signed documents. Note any that are missing and actions taken. ☐ Background and training records of IRB members ☐ Application Submission Records ☐ Protocol Assessment Records ☐ Communication Records ☐ Amendment Approval ☐ Meeting Agenda, Minutes, Action letters ☐ Active files ☐ Continuing and Final reports		
Are any documents known to be missing from the study master file?		
Which personnel and members will be available? Give details of times and dates.		
What arrangements are there in the event the auditor/inspector needs to make copies of documents?		
Completed by:		Date: