10.1 Auditing and Inspection of the IRB

Table of Contents

1. Purpose

The purpose of this SOP is to guide how to prepare for an audit or inspection of the IRB processes.

2. Scope

This SOP applies to every unit of the EPHI-IRB.

3. Responsibility

It is the responsibility of the Secretariat/SERO, the Members, and the Chairperson of the IRB to perform all tasks according to the SOPs and to be well-prepared and available to answer questions during evaluation, audit or inspection visits of authorities and guests.

4. Flow chart

No.	Activity	Responsibility
1	Call for an Audit / Inspection	IRB Chairperson / General Director of the Institution
	↓	
2	Prepare for the visit	IRB Secretariat / Members and Chairperson
	↓	
3	Welcome 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

- Receive a notice of inspection visit
- The Chairperson informs the Secretariat / Director or Head of Institution
- The Chairperson alerts every unit to get ready

5.2. Prepare for the visit

- Get a checklist EPHI-IRB AF 01-028/02.0 (see Annex 1)
- Go through all steps on the list
- Note and comment on each part
- Emphasize on the studies with problems
- Check if all documents are labeled and kept in the right order for easy and quick search
- Check for any missing or disorganized records
  - 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
- Reserve a meeting room and all necessary facilities
- Review the IRB SOPs
- Make sure that no omission or deviation exists
- Make sure to have good reasons for any omission or deviation
- Inform IRB members about the inspection date if they are able to attend the audit/inspection meeting

5.3. Welcome Auditor/Inspector

- The Chairperson or the Secretariat welcomes and accompanies the auditors/inspectors to the reserved meeting room
- Members and some key staff must also be present in the meeting room
- The conversation starts with the auditor/inspector stating the purpose of the visit and what kind of information and data are needed
- Answer questions of the auditors/inspectors clearly, politely and truthfully with confidence and straight to the point
- Find and get all information and files requested by the auditors/inspectors
- Take note of the comments, recommendation of the auditors/inspectors

5.4. Correct the mistakes

- Review comments and recommendations of the auditors/inspectors
- Write a report and have it approved by the Chairperson
- The Chairperson calls for the correction
- Allow appropriate time for correction and improvement process
- Carry an internal follow-up audit

- Evaluate the outcome
- Report the outcome to the Chairperson

5.6. Record the Audit/Inspection Event

- Keep record of the report on the audit/inspection meeting in the audit/inspection file
- 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 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, National Research Ethics guideline, 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 researches and that may be located at the research site, at the sponsor's and/or contract research organization's (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities

7. References

1. World Health Organization, Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participant, 2011.
2. International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guidance for Good Clinical Practice (ICH GCP) E6(R2), 2016.
3. World Health Organization, Surveying and Evaluating Ethical Review Practices, Feb. 2002
4. Associated SOPs: EPHI-IRB SOP/001- 029.

8. Annex

Annex 1: Audit and Inspection Checklist
(EPHI-IRB AF 01-028/02.0)

☐ 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 form 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:……..