Table of Contents

1. Purpose

The purpose of this procedure is to guide how to prepare for an audit or inspection of the MRIN EC processes.

2. Scope

This SOP applies to every unit of the MRIN EC Office.

3. Responsibility

It is the responsibility of the Secretariat, the Members, and the Chairperson of the MRIN EC 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	MRIN EC Chairperson / Director of the Institution
	↓	
2	Prepare for the visit	MRIN EC Secretariat / Members and Chairperson
	↓	
3	Welcome Auditor / Inspector	MRIN EC Secretariat / Members and Chairperson
	↓	
4	Correct the mistakes	MRIN EC Secretariat / Members and Chairperson
	↓	
5	Record the Event	MRIN EC Secretariat

5. Detailed instructions

5.1 Call for an Audit / Inspection

- ☐ Receive a notice of inspection visit

- ☐ The Chairperson informs the Secretariat and Director or Head of Institution.
- ☐ The Chairperson alerts every party to get ready.

5.2 Prepare for the visit

- ☐ Get a checklist AF/01-027/2017/01.2 (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 MRIN EC 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 MRIN EC SOPs.
- ☐ Make sure that no omission or deviation exists.
- ☐ Make sure to have good reasons for any omission or deviation.
- ☐ Inform MRIN EC members about the inspection date.
- ☐ Make sure the key staff and members will be present

5.3 Welcome Auditor / Inspector

- ☐ The Auditors/Inspectors sign confidentiality/conflict of interest agreement (AF/01-004/2020/01.4)
- ☐ 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 one months for correction and improvement process.
- ☐ Carry out an internal follow-up audit.
- ☐ Evaluate the outcome.
- ☐ Report the outcome to the Chairperson.

5.5 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 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 Helzinki and applicable regulatory requirements. Audit includes Internal and External Audit
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's (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities

7. Annex

Annex 1	AF/01-027/2017/01.2	Audit and Inspection Checklist
Annex 2	AF/02-027/2017/01.2	Document History

8. References

- Operational Guidelines for Ethics Committees that Review Biomedical Research, World Health Organization, 2000, Geneva.
- Surveying and Evaluating Ethical Review Practices, World Health Organization, 2002, Geneva.
- International Conference on Harmonisation (ICH) Harmonised Tripartite : Guideline for Good Clinical Practice E6(R1), Current Step 4 version dated 10 June 1996, November 2005.
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, 2011, World Health Organization, www.who.int.
- Pedoman Nasional Etik Penelitian Kesehatan, Komisi Nasional Etik Penelitian Kesehatan, 2011.
- SIDCER Self-Assessment Tool, http://www.fercap-sidcer.org/selftool.php, accessed January 2013.
- FERCAP Standard Operating Procedures (SOPs) for Ethics Committees (ECs)/Institutional Review Boards (IRBs), http://www.fercap-sidcer.org/selftool.php, accessed January 2013.
- Associated SOPs: SOP/001/2020/01.3- SOP/027/2017/01.2.

Annex 1
Form AF 01-027/2017/01.2

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 MRIN EC 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:……..

Annex 2
Form AF/02-027/2017/01.2

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	**Final version**
Ivet, Lia, Mona	01.1	11 October 2014	1. Synchronize the topic number and SOP number 2. Format Document History : Author, Version, Date and Description of the main change
Suryani As'ad	01.2	1 April 2017	1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header 2. Item 5.3: Add the sentence "The Auditors/Inpectors sign confidentiality/conflict of interest agreement (AF/01-004/2017/01.2)"