Table of Contents

1. Purpose

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle original documents and copies of documents in order to protect confidentiality of documents.

2. Scope

This SOP applies to all kinds of handling, distribution and storage of submitted study protocols, IRB documents, and correspondence with experts, auditors and the general public.

3. Responsibility

Confidentiality of study protocols, IRB documents, and correspondence with experts and auditors is mandatory. IRB members and staff should have signed confidentiality agreements with the institute that enforces confidentiality.

If non-members of the IRB need copies of documents, the copies of IRB's documents need to be requested in written (format as per Annex 3) for the intended purpose to maintain confidentiality of documents.

4. Flow chart

No.	Activity	Responsibility
1	Access to IRB documents	IRB members and Secretariat
	↓	
2	Classify confidential documents	IRB members and Secretariat
	↓	
3	Copy confidential documents	IRB Secretariat
	↓	
4	File Log of Copies	IRB Secretariat

5. Detailed instructions

5.1. Access to IRB Documents

The IRB members and the staff of the Secretariat of the IRB, who must read, understand and agree to the following:

5.1.1 Members/alternate members of the IRB

- Sign a confidentiality agreement (EPHI-IRB AF 01-004/02.0) with EPHI before the start of any activity for the IRB
- Shall have access to all IRB documents
- Are free to request and to use original documents or copies of original documents

5.1.2 Secretariat of the IRB

- The secretary of the IRB is a staff member of the EPHI
- Sign a confidentiality agreement with EPHI
- Have access to any document issued by or to the IRB, according to EPHI-IRB AF 01-004/02.0 (if member and secretary of IRB) or EPHI-IRB AF 05-004/02.0 (if non-voting secretary of the IRB) (Maintaining Confidentiality of IRB's Documents)

5.2. Classify confidential documents.

- **Types of documents**

  The types of documents reviewed by IRB members include:
  - Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
  - IRB documents (SOPs, meeting minutes, advice and decisions)
  - Correspondence (experts, auditors, study participants, etc)

  <u>Note:</u> Copies of all versions of documents, including draft and sequential definitive versions, are to be kept private and confidential with the exception of those made according to the following sections.

5.3. Copy confidential documents

Copies of documents, including draft and sequential versions, are considered to be confidential and are not permitted to be brought out *except when a document is needed for day-to-day operations.*

5.3.1 Copy Authorization

- Only members of the IRB are allowed to ask for copies.
- Only staff members of the Secretariat of the IRB are allowed to make such copies
- The Secretary of the IRB may ask for help, but he is responsible for maintaining confidentiality of all documents

5.3.2 Log of Copies

- A Log of Copies (see Annex 1: EPHI-IRB AF 01-027/02.0) must be kept by the Secretariat
- The log should include: the name and signature of the individual receiving the copy; the initial of the IRB Secretary who made the copy; the number of copies made and the date that the copies were made

5.3.3 Copies requested by non-members of the IRB

- Copies of IRB's documents **requested** in written (request format as per Annex 3: EPHI-IRB AF 03-027/02.0) by non-members of the IRB can only be given after the permission from the Chairperson of the IRB and the person requesting for the document signs a confidentiality agreement form (EPHI-IRB AF 04-004/02.0)
- Copies made for non-members of the IRB must be recorded in both the Log of Requests for Copies of IRB's documents (EPHI-IRB AF 01-027/02.0) and the log of Copies of the Original Documents (EPHI-IRB AF 02-027/02.0)

5.4 File Log of Copies.

- The Log of Copies of Original Documents must be stored with the original documents.
- The Log of Copies of Original Documents is *not* a confidential document and can be reviewed upon request.
- A Log of Copies of Original Documents must be maintained.

6. Glossary

Document	Documents mean the followings: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IRB documents (SOPs, meeting minutes, advice and

decisions)
- Correspondence (experts, auditors, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.

Non-members of the IRB	Any relevant person/persons who presently is/are not a member of the IRB such as authorities, monitors, reviewers, auditors, subjects, etc.

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. Associated SOPs : EPHI-IRB SOP/004/02.0

8. Annex

Annex 1: Log of Requests for Copies of IRB's Documents
EPHI-IRB AF 01-027/02.0

#	Documents requested	# of Copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

Annex 2: Log of Copies of Original Documents
EPHI-IRB AF 02-027/02.0

Title of the Document: …….

……..

#	Name of Recipient	# of Copies	Reasons of the Request	Signature of Recipient	Secretariat Initials	Date

Note: *This log should be attached to the original documents.*

Annex 3: Form for requesting copies of original document
EPHI-IRB AF 03-027/02.0

Title of the document…….

……..

Protocol No. ……

Name of the person requesting the copies ……..……

I the undersigned person would like to request the copy(ies) of the above entitled document in ---------- copies for the purposes of ----------

:……..……..……

……..

:……..……..……

…….

I shall maintain the confidentiality of the documents as per the requirements of EPHI-IRB SOP/027/02.0.

Signature …… Date ……

Comments of the IRB chairperson

……..

:……..……..……

…….

Approved ---------- Disapproved ----------

Signature …… Date ……