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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, EC documents, and correspondence with experts, auditors and the general public.

3. Responsibility

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

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Access to MRIN EC documents ↓	MRIN EC members and Secretariat
2	Classify confidential documents ↓	MRIN EC members and Secretariat
3	Copy confidential documents ↓	MRIN EC Secretariat
4	File Log of Copies	MRIN EC Secretariat

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5. Detailed instructions

5.1 Access to MRIN EC Documents

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

5.1.1 Members of the MRIN EC

- Sign a confidentiality agreement (AF/01-004/2020/01.4) with MRIN institute before the start of any activity for the MRIN EC.
- Shall have access to all MRIN EC documents.
- Are free to request and to use original documents or copies of original documents.

5.1.2 Secretariat of the MRIN EC

- The secretariat staff of the MRIN EC is a staff member of the MRIN
- Sign a confidentiality agreement with MRIN
- Have access to any document issued by or to the MRIN EC, according to SOP/026/2017/01.2 (Maintaining Confidentiality of MRIN EC's Documents).


5.2 Classify confidential documents.

Types of documents

The types of documents reviewed by MRIN EC members include:

- Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- MRIN EC documents (SOPs, meeting minutes, advice and decisions)
- Correspondence (experts, auditors, study participants, etc.)

Note: 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.

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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 MRIN EC are allowed to ask for copies.
- Only staff members of the Secretariat of the MRIN EC are allowed to make such copies.
- The Secretary of the MRIN EC is responsible for maintaining confidentiality of all documents.

5.3.2. Log of Copies

- A Log of Copies (see ANNEX 1 Form AF/01-026/2017/01.2) must be kept by the Secretariat.
- The log should include: the name and signature of the individual receiving the copy; the initial of the MRIN EC 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 MRIN EC

- Copies of the MRIN EC's documents requested by non-members of the MRIN EC (including Secretary) can only be given after the permission from the Chairperson of the MRIN EC and the person requesting for the documents signs a confidentiality agreement form (SOP/004/2020/01.4)
- Copies made for non-members of the MRIN EC must be recorded in both the Log of Request for Copies of MRIN EC's documents (SOP/026/2017/01.2)

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,

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scientific documents, reports, records, expert opinions or reviews)

- MRIN EC 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.

7. Annex


Annex 1	AF/01-026/2017/01.2	Log of Requests for Copies of MRIN EC's Documents
Annex 2	AF/02-026/2017/01.2	Log of Copies of Original Documents
Annex 3	AF/03-026/2017/01.2	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.

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- 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/004/2020/01.4

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Annex 3
Form AF/03-026/2017.01.2

Document History

Author	Version	Date	Description
EC Members	01.0	2 January 2013	Final version
Ivet, Lia, Mona	01.1	11 October 2014	<ol style="list-style-type: none"> 1. Synchronize the topic number and SOP number 2. Format Document History : Author, Version, Date and Description of the main change
Suryani As'ad, Ivet Suriapranata	01.2	1 April 2017	<ol style="list-style-type: none"> 1. Delete Komite Etik Penelitian Kesehatan (KEPK) on the header