

**Title: Maintaining Confidentiality of IEC Documents**

**SOP Code : SOP/23/V1.1**

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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 maintaining confidentiality while handling, distribution and storage of submitted study protocols, IEC documents, and correspondence with experts, auditors and the general public.

**3. Responsibility**

Confidentiality of study protocols, IEC documents, and correspondence with experts and auditors is mandatory. IEC members and staff have signed confidentiality agreements with the institute that enforces confidentiality. If non-members of the IEC need copies of documents, it is the responsibility of the IEC member/staff to maintain confidentiality of documents.

**4. Flow chart**

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

**5. Detailed instructions**

**5.1 Access to IEC Documents**

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

**5.1.1 Members and Member Secretary of the IEC**

- Sign a confidentiality agreement (see ANNEX 1 AF/EC/01/03/V1.0) with NIRRH Ethics Committee for Clinical Studies institute before the start of any activity for the IEC.
- Shall have access to all IEC documents.
- Are free to request and to use original documents or copies of original documents.

### **5.1.2 Secretariat of the IEC**

- The Secretarial Assistant of the IEC is a staff member of the NIRRH Ethics Committee for Clinical Studies
- Sign a confidentiality agreement with NIRRH Ethics Committee for Clinical Studies  
Have access to any document issued by or to the IEC.

## **5.2 Classify confidential documents**

### **- Types of documents**

#### **The types of documents reviewed by IEC members include:**

- Study proposals and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- IEC 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.*

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

#### **5.3.2. Log of Copies**

- A Log of Copies (see ANNEX 1 Form AF/EC/01/23/V1.1) must be kept by the Secretariat.
- The log should include: the name and signature of the individual receiving the copy; the initial of the IEC 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 IEC**

- Copies of IEC's documents requested by non-members of the IEC (including the Secretary) can only be given after the permission from the Director or Member Secretary and the person requesting for the document signs a confidentiality agreement form (AF/EC/03/03/V1.0).

- Copies made for non-members of the IEC must be recorded in both the Log of Requests for Copies of IEC's documents (AF/EC/01/16/V1.0) and the log of Copies of the Original Documents (AF/EC/02/23/V1.1).

#### **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: <ul style="list-style-type: none"><li>- Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews)</li><li>- IEC documents (SOPs, meeting minutes, advice and decisions)</li><li>- 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.</li></ul>
Non-members of the IEC	Any relevant person/persons who presently is/are not a member/members of the IEC such as authorities, monitors, auditors, subjects, etc.

#### **7. References**

- 7.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- 7.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996.
- 7.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

#### **8. ANNEX**

- ANNEX 1 AF/EC/01/23/V1.1 Log of Requests for Copies of IEC's Documents
- ANNEX 2 AF/EC/02/23/V1.1 Log of Copies of Original Documents



ANNEX 2

AF/EC/02/23/V1.1

**Log of Copies of Original Documents**

*Title of the Document* : .....

No.	Name of Recipient	No. of Copies	Reasons of the Request	Signature of Recipient	Secretariat Initials	Date

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