Title: Maintaining Confidentiality of IEC Documents

SOP Code : SOP/23/V1.1

Effective date: 24/09/2014

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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: - Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) - IEC 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 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 1 **AF/EC/01/23/V1.1**

Log of Requests for Copies of IEC's Documents

No.	Documents requested	No. of Copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

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*