

Title: Maintaining Confidentiality of IEC Documents

SOP Code: SOP 20/V1 dated 18th February 2017

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the handling of original documents, their copies and communications received from and sent to investigators, regulators, sponsors, etc. in order to protect confidentiality of documents.

2. Scope

This SOP applies to the handling, distribution and storage of submitted study protocols and other documents, the Institutional Ethics Committee (IEC) documents, and correspondence with experts, auditors and the general public.

3. Responsibility

Maintaining the confidentiality of study protocols and documents, IEC documents, and correspondence with experts and auditors is mandatory. IEC members and staff, Guest attendees or observers and independent consultants who have signed confidentiality agreement(s) have to ensure and enforce confidentiality.

If an IEC member/ staff requests for a copy of one of the documents listed above on behalf of a non-member, 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

Access to IEC Documents

Only IEC members and staff of the IEC Secretariat have access to the hard copy / soft copy of the study documents, IEC documents, IEC communications and letters and communications received from investigators, regulators, sponsors and other individuals/organizations concerned with study or research. They will have access only after they have read, understood, agreed upon and signed the Confidentiality Agreement.

5.1.1 Members of the IEC

- Each and every IEC member must sign a confidentiality agreement (AX 01/SOP 03/V1) before the start of a new tenure of IEC or IEC membership.
- Any member who is appointed during an ongoing term of the IEC is required to sign the Confidentiality Agreement before he/ she has access to any confidential material.

The IEC members shall have access to all IEC documents and are free to request and to use original documents or copies of original documents.

5.1.2 Secretariat of the IEC

- The Secretariat of the IEC is a staff member of the IEC.
- The member must sign a confidentiality agreement with IEC before he/ she has access to any of the IEC documents.
- The staff member will have access to any document issued by or to the IEC according to SOP 20/V1 (Maintaining Confidentiality of IEC Documents).

Classify confidential documents.

The types of documents reviewed by IEC members include:

- Study protocols and related documents (including case record forms, informed consent documents, diary forms, scientific documents, expert opinions, reviews, etc.)
- IEC documents (SOPs, meeting agenda and minutes, advice and decisions, periodic reports, audit reports, etc.)
- Correspondence (with experts, auditors, study participants, regulators, 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.

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 can request the Member Secretary IEC for copies of documents without having to take an express permission from the IEC Chairperson, provided the document is related to an active file/ project.
- Only staff members of the Secretariat of the IEC are allowed to make such copies.
- The overall responsibility of maintaining confidentiality of documents rests with the Secretary of the IEC. However, he/ she can be assisted by authorized staff members of the secretariat or IEC members in this regard.

5.3.2. Log of Copies

- A Log of Copies (AX 01/SOP 20/V1) 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.

5.4. Copies requested by non-members of the IEC

- A non-member can request the Chairperson/ Member Secretary of the IEC in writing for a copy of an IEC document citing specific reason(s).
- Copies of IEC documents requested by non-members of the IEC can only be given after the permission from the Chairperson/ Member Secretary of the IEC if the request is found to be reasonable and the person requesting for the document signs a confidentiality agreement form (AX 03/SOP 03/V1). If deemed necessary by the Chairperson/ Member Secretary, the letter of request may be discussed at the forthcoming full board meeting for final decision.
- Copies made for non-members of the IEC must be recorded in both the Log of Requests for Copies of IEC documents (AX 01/SOP 20/V1) and the log of Copies of the Original Documents (AX 02/SOP 20/V1).

File Log of Copies.

- The Log of Copies of Original Documents must be stored with the original documents. It is not necessary to maintain log of copies when IEC member has requested for them.
- 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 following: <ul style="list-style-type: none">- 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 person/persons/ organizations who/ that presently is/are not a member/members of the IEC such as administrative authorities, monitors, auditors, research participants, regulators, insurance agencies, etc.

7. References

- [1] World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000) - www.who.int/tdr/publications/publications/ (last accessed 31st August 2013)
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31st August 2013)

8. Annexure

Annexure 1 AX 01/SOP 20/V1 Log of Requests for Copies of IEC Documents

Annexure 2 AX 02/SOP 20/V1 Log of Copies of Original Documents

Annexure 1

AX 01/SOP 20/V1

Log of Requests for Copies of IEC Documents

No./ date of request	Documents requested (including file number if relevant)	No. of Copies	Name of the individual requesting for copy/ copies	Reason for request	Signature of the individual receiving the copy and date	Name and Signature of the IEC staff providing the copy and date

Annexure 2

AX 02/SOP 20/V1

Log of Copies of Original Documents

Title of the Document: _____

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

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