Standard Operating Procedures

(SOP -20/01)

For

Maintaining Confidentiality of IEC Documents

Independent Ethics Committee (Clinical Research) India

1. Purpose

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. The purpose of this Standard Operating Procedure (SOP) therefore is to describe 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, Independent Ethics Committee (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 that enforce confidentiality.

If non-members of the IEC need copies of documents, it is the responsibility of the IEC member/staff requesting a copy on behalf of the non-members 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 of the IEC

- The IEC members must sign a confidentiality agreement (*AF/01/01-SOP03/01*) before the start of the new tenure of IEC.
- Any one member who is appointed in between a given tenure signs the confidentiality agreement.
- The 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
- The member will have access to any document issued by or to the IEC according to SOP 20/01 (Maintaining Confidentiality of IEC Documents).

5.2 Classify confidential documents.

- **Types of documents**

The types of documents reviewed by IEC members include:

- Study protocols 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.

Independent Ethics Committee (Clinical Research) India

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 (*AF/01/01-SOP20/01*) 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 documents requested by non-members of the IEC can only be given after the permission from the Chairperson of the IEC and the person requesting for the document signs a confidentiality agreement form (*AF/03/01-SOP03/01*).
- Copies made for non-members of the IEC must be recorded in both the Log of Requests for Copies of IEC documents (*AF/01/01-SOP20/01*) and the log of Copies of the Original Documents (*AF/02/01-SOP20/01*).

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.

Independent Ethics Committee (Clinical Research) India

6. Glossary

Document	Documents mean the following: - 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

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)- *www.who.int/tdr/publications/publications/* (last accessed 24 March 2008)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *http://www.ich.org/LOB/media/MEDIA482.pdf* (last accessed 24 March 2008).

8.Annexure

ANNEX 1	AF/01/01-SOP20/01	Log of Requests for Copies of IEC Documents
ANNEX 2	AF/02/01-SOP20/01	Log of Copies of Original Documents

Independent Ethics Committee (Clinical Research) India

Annex 1
AF/01/01-SOP20/01

Log of Requests for Copies of IEC Documents

#	Documents requested	# of Copies	Name of Recipient	Signature of Recipient	Reason for request	Date

Independent Ethics Committee (Clinical Research) India

Annex 2
AF/02/01-SOP20/01

Log of Copies of Original Documents

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.*