



Standard Operating Procedures (SOP -19/01)

For
Procedures to Archive and Retrieve Documents



Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for storing *inactive* study files and administrative documents in a secure manner while maintaining access for review by auditors and inspectors.

2. Scope

This SOP applies to archiving the study files and administrative documents that are retained for at least five years (or more for some particular cases) after completion of the research so that the records are accessible for auditors and inspectors. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3. Responsibility

It is the responsibility of Independent Ethics Committee (IEC) Secretariat for maintaining inactive study files and administrative documents.

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	After receiving the final report	IEC members, secretariat
2	Retrieving Documents	IEC secretariat

5. Detailed instructions

5.1 After receiving the final report

- IEC Secretariat and Members review the Final Report of the study.
- A member of the Secretariat should
 - Remove the contents of the entire file from the active study filing area.
 - Verify that all documents are present in an organized manner.
 - Shift it to a cupboard where in all files to be archived are placed.
- The Secretariat will hold the files of multi-center studies, until all the study sites are closed.



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- The Administrative Officer will place the files in the cupboard at a given area together.
- A staff of the IEC Secretariat should
 - Perform inventories of miscellaneous administrative documents
 - Send it to the appropriate storage facility so that it may be easily retrieved.
- The IEC Secretariat maintains past board membership information as well as the active administrative documents as permanent records.

5.2 Retrieving Documents

- The Secretariat will keep in mind the SOP 20/01 (Maintaining Confidentiality of Ethical Review Committee Documents)
- Retrieval of documents can only be done with a request form (*AF/01/01-SOP19/01*) signed and dated by the IEC Chairperson or the Secretariat.
- The requestor must also sign and date the log of request (*AF/02/01-SOP19/01*)
- The Secretariat retrieves archived documents and returns the file back to its place.
- The Secretariat will also record, sign and date when the document has been returned and kept.

6. Glossary

Administrative Documents	Documents include official minutes of Board meetings and the Standard Operating Procedures, both historical files and Master Files as.
Inactive Study Files	Approved and supporting and documents (protocols, protocol amendments, informed consents, advertisements, investigator and site information), records containing communications and correspondence with the investigator, and reports (including but not limited to Continuing Review Reports, IND Safety Reports, reports of injuries to subjects, scientific evaluations) that correspond to each study approved by the <i>IEC</i> Board for which a final report has been reviewed and accepted.



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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-SOP19/01	Document Request Form
ANNEX 2	AF/02/01-SOP19/01	Log of Requested IEC Documents



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Annex 1
AF/01/01-SOP19/01

Document Request Form

Name of Document requested:	Code:	
Requested by:	Date:	
<input type="checkbox"/> Chairperson	<input type="checkbox"/> Secretariat	<input type="checkbox"/> IEC Member
<input type="checkbox"/> Secretariat staff	<input type="checkbox"/> Authority	<input type="checkbox"/> Others.....
Purpose of the request:		

Sign & date of Requester

Sign & date of IEC Chairperson



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Annex 2
AF/02/01-SOP19/01

Log of Requested IEC Documents

#	Document	Requester	Date Requested	Retrieved by	Returned Date	Archived by