Title: Archiving and Retrieving Documents **SOP**

Code: SOP 19/V1 dated 18th February 2017

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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, inspectors and other authorized persons.

2. Scope

This SOP applies to archiving the study files and administrative documents that are retained for at least five years or for longer duration if specifically mandated after completion of the research/ termination of research so that the records are accessible to auditors, inspectors and other authorized persons. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3. Responsibility

It is the responsibility of the Institutional Ethics Committee (IEC) Secretariat to maintain inactive study files and administrative documents.

4. Flow chart

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

5. Detailed instructions:

After receiving the final report and/ or terminating the study:

- IEC Secretariat and Members will 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 files to be archived are placed.
- The Secretariat/ 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/ them to the appropriate storage facility so that it/ they may be retrieved.
- The IEC Secretariat maintains past board membership information as well as the active administrative documents as permanent records.

Retrieving Documents

- The Secretariat will keep in mind the SOP 20/V1 (Maintaining Confidentiality of IEC Documents)
- The request for retrieval can only be made by an IEC member, auditor or other authorized person in by filling up, signing and dating request form: *AX 01/SOP 19/V1*
- The requestor must also sign and date the log of request. (*AX 02/SOP 19/V1)*
- Retrieval of documents can only be done when a request is made in the request form (*AX 01/SOP 19/V1)* that is approved (signed and dated) by the IEC Chairperson/Member Secretary.
- For administrative purpose and while discussing / keeping the study completion report , IEC Secretary can retrieve archived file(s) without having to require IEC Chairperson's approval. For this purpose the IEC secretary can authorize a staff member of the IEC secretariat to physically retrieve a file. In such a situation, the register/ log will be signed by the secretariat member physically retrieving the file.
- A member of IEC Secretariat will retrieve archived document(s) and will return the remaining file back to its place.
- The Secretariat maintains a register with following information related to retrieval: File number, Name and designation of individual making a request for retrieval with his/her signature, Date of approval of request by IEC chairperson, Date and time of retrieval, Name and signature of IEC staff/ Secretariat retrieving the file, Date and time of returning the file.
- 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 research participants, scientific evaluations) that correspond to each study approved by the *IEC* Board for which a final report has been reviewed and accepted.

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 19/V1* Document Request Form

Annexure 2 *AX 02/SOP 19/V1* Log of Requested IEC Documents

Annexure 1

AX 01/SOP 19/V1

Document Request Form

Name of Document requested:		
Requested by: Name: ----------		
☐ Chairperson	☐ Secretariat	☐ IEC Member
☐ Secretariat staff	☐ Authority	☐ Others _____

Purpose of the request:

Signature of person requesting and date

Signature of Member Secretary/ Chairperson and date

Annexure 2

AX 02/SOP 19/V1

Log of requested IEC Documents

No	File Number and Document	Name and Designation of person requesting with his/her signature	Date Requested	Date of approval	Retrieved by (Name, Signature and Date)	Returned Date	Archived by (Name, Signature and Date)