

	Institutional Ethics Committee (IEC) Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai – 400 012. Web: www.kem.edu	SOP 16/V5 Effective from 1st Aug 2017, Valid up to 30th July 2019
	Archiving and Retrieving Documents	


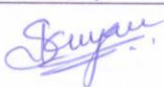
Title: Archiving and Retrieving Documents

SOP Code: SOP 16/V5 dated 26th July 2017

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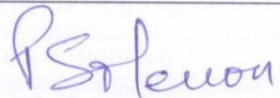
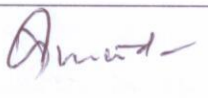

 Dr. Padmavathy Menon, Chairperson, IEC - I (Signature with Date)	 Dr. Alan Almeida, Chairperson, IEC - II (Signature with Date)
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Table of Contents:

No.	Contents	Page No.
1	Purpose	2
2	Scope	2
3	Responsibility	2
4	Flow Chart	2
5	Detailed Instructions	2
6	Glossary	4
7	References	4
8	Annexure	4

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for storage/archival / disposal of closed files and retrieval of 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 closed study files and administrative documents.


4. Flow chart

No.	Activity	Responsibility
1	After receiving the notification of termination, completion / final report	IEC members, secretariat
2	Retrieving Documents	IEC secretariat
3	Disposal of closed files and copies of protocols and documents submitted for IEC review	IEC secretariat

5. Detailed instructions:

5.1 After receiving the notification of termination, completion / final report:

- IEC Secretariat and Members will review the termination, completion / final report of the study.
- A member of the Secretariat should:
 - Remove the contents of the entire file from the active study folder (soft copy) to the archived study folder.
 - Remove the contents of the entire file from the active study cupboard (hard copy) to the archived study cupboard in the archival room.
 - Verify that all documents are present in an organized manner.
 - The soft archived study files will be password protected and will be accessible only to the IEC secretariat.
 - The cupboard where hard copies of the archived study files are kept will be kept in a lock and key and will have controlled access only to the secretariat.

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- If any IEC member/ non-members of IEC (auditor or other authorized person) wants to have access, they can access the project file with the help of secretariat after the permission of chairperson.
- 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.

5.2 Retrieving 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 16/V5*
- The requestor must also sign and date the log of request. (*AX 02/SOP 16/V5*)
- Retrieval of documents can only be done when a request is made in the request form (*AX 01/SOP 16/V5*) 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.

5.3 Disposal of closed files and copies of protocols and documents submitted for IEC review.

- The trial master file will be maintained in the IEC office for complete period of the study and for five years following closure of the study. After completion of the archival period the closed files will be shredded and disposed off in the IEC office shredding facility. However, all the copies of the research projects and documents submitted for IEC review will be shredded by the authorized IEC personnel after the IEC meeting without any notification to the Principal Investigator. A log book of disposed documents will be maintained.\

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6. Glossary

Administrative Documents	Documents include official minutes of Board meetings and the Standard Operating Procedures, both historical files and Master Files as.
Closed Study File	Any approved protocol, supporting documents, records containing Communications and reports that correspond to a study which is completed or terminated or discontinued or suspended or not initiated.

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 July 2017)
- [2] International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed July 2017).

8. Annexure


Annexure 1	AX 01/SOP 16/V5	Document Request Form
Annexure 2	AX 02/SOP 16/V5	Log of Requested IEC Documents

Annexure 1 AX 01/SOP 16/V5 Document Request Form

Name of Document requested:
Requested by: Name: -----
<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:

Signature of person requesting and date

Signature of Member Secretary/ Chairperson and date

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Annexure 2
AX 02/SOP 16/V5
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	Retrieve d by (Name, Signatur e and Date)	Returned Date	Archived by (Name, Signature and Date)