


TAGORE MEDICAL COLLEGE & HOSPITAL 	Archiving and Retrieving Documents		Institutional Ethics Committee
			TMCH/IEC/SOP/22
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Archiving and Retrieving Documents

For Institutional Ethics Committee



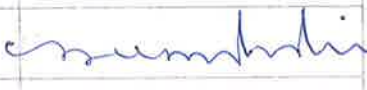
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Issue No : 01
Issue Date : 02.11.2020
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**Copy Holder Name
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1. Purpose

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.

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• 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.
- 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.
- The requestor must also sign and date the log of request.
- Retrieval of documents can only be done when a request is made in the request form 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

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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.




6. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, (Geneva 2000)-
<https://www.who.int/tdr/publications/documents/ethics.pdf> (last accessed 22nd October 2020).
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996-<http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 22nd October 2020).

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3. National Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017

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