

Title: Archival and Retrieval of Documents

SOP Code : SOP/22/V1.1

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1. Purpose

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 IEC Secretariat for maintaining inactive study files and administrative documents.

4. Flow chart

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

5. Detailed instructions

5.1 After receiving the final report

- 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.
 - ✓ Place the file in a storage container
- Keep the files of the multi-center studies active, until all the study sites are closed.
- Place in Archive room.

5.2 When archiving administrative documents

A staff of the IEC Secretariat should

- Perform inventories of miscellaneous administrative documents
- Place the documents in the appropriate storage container so that it may be easily retrieved.
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Note: The IEC Secretariat maintains past board membership information as well as the active administrative documents.

5.3 Retrieving Documents

- Keep in mind the SOP/23/V1.1 (Maintaining Confidentiality of Ethical Review Committee Documents)
- Retrieval of documents can only be done with a request form (AF/EC/01/22/V1.1, see ANNEX 1) signed and dated by the IEC Chairperson or the Member Secretary.
- The requestor must also sign and date the log of request (AF/EC/02/22/V1.1, see ANNEX 2)
- The Secretariat retrieves archived documents and documents in the inventory (register) kept by NIRRH Ethics Committee for Clinical Studies office.
- Return the file back to its place.
- Record, sign and date when the document has been returned and kept.

6. Glossary

Administrative Documents	Documents include official minutes of IEC meetings (as described in SOP/13/V1.0) and the Standard Operating Procedures, both historical files and Master Files as described in SOP/01/V1.0.
Inactive Study Files	Approved and supporting 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 NIRRH Ethics Committee for Clinical Studies Board for which a final report has been reviewed and accepted.

7. References

- 7.1 World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- 7.2 International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996.
- 7.3 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006

8. ANNEX

- ANNEX 1 AF/EC/01/22/V1.1 Document Request Form
ANNEX 2 AF/EC/02/22/V1.1 Log of Requested IEC Documents

ANNEX 1

AF/EC/01/22/V1.1

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: 		
Retrieved by:	Date:	
Returned by:	Date:	
Archived by:	Date:	
Approved by:	Date:	

