

Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRH Ethics Committee for Human Studies

Title: Archival and Retrieval of Documents

SOP Code: 24/V1.2 Dated: 8th November 2024 Page Nos : 266 to 271

24.1. 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.

24.2. 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 to auditors and inspectors. After the timeframe of 5 years, the Ethics Committee will maintain a soft copy of the file for records Copying files and documents for or by authorized representatives of the national authority is allowed when required.

24.3. Responsibility

The IEC Secretariat is responsible for maintaining inactive study files and administrative documents.

24.4. Flow chart

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

24.5. Detailed instructions

24.5.1 After receiving the final report

- a. IEC Secretariat and Members will review the Final Report of the study.
- b. A member of the Secretariat should
 - i Remove the contents of the entire file from the active study filing area.
 - ii Verify that all documents are present in an organized manner.
 - iii Place the file in a storage container
- c. Keep the files of the multi-center studies active, until all the study sites are closed.
- d. Place in Archive room.

24.5.2 When archiving administrative documents

A staff of the IEC Secretariat should

- a. Perform inventories of miscellaneous administrative documents
- b. Place the documents in the appropriate storage container so that they may be easily retrieved.

Note: The IEC Secretariat maintains past board membership information as well as active administrative documents.

24.5.3 Retrieving Documents

- a. Keep in mind the SOP/25/V1.2 (Maintaining Confidentiality of Ethical Review Committee Documents)
- b. Retrieval of documents can only be done with a request form (**AF/01/24/V1.2**, see ANNEX 1) signed and dated by the IEC Chairperson or the Member Secretary.
- c. The requestor must also sign and date the log of request (**AF/02/24/V1.2**, see ANNEX 2)
- d. The Secretariat retrieves archived documents and documents in the inventory (register) kept by ICMR-NIRRH Ethics Committee for Human Studies office.
- e. Return the file back to its place.
- f. Record, sign and date when the document has been returned and kept.

24.6. ANNEX

ANNEX 1	AF/01/24/V1.2	Document Request Form
ANNEX 2	AF/02/24/V1.2	Log of Requested IEC Documents
ANNEX 3	AF/03/24/V1.2	Document History

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:

Log of Requested IEC Documents

#	Document	Requester	Date Requested	Retrieved by	Archived by	Returned Date

Page No.....

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	23 rd March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	24 th September 2014	Sop no. changed from 15 to 22
Dr. Beena Joshi	Version 1.2	1 st May 2019	Sop no. changed from 22 to 24 Document History added