

Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRH Ethics Committee for Human Studies

Title: Maintenance of Active Study File

SOP Code: 23/V1.2 Dated: 8th November 2024 Page Nos : 262 to 265

23.1. Purpose

To provide instructions for preparing and maintaining active study files and other related documents approved by the IEC of ICMR-NIRRH Ethics Committee for Human Studies.

23.2. Scope

This SOP applies to all active study files and their related documents that are maintained in the IEC office.

23.3. Responsibility

It is the responsibility of IEC Secretariat to ensure that all study files are prepared, maintained and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

23.4. Flow chart

Sr. No.	Activity	Responsibility
1	Organize the contents of the active study files	IEC Secretariat
2	Maintain the active study files	IEC Secretariat

23.5. Detailed instruction

23.5.1 Organize the contents of the active study files

- a. Get the original documents/copy of the study files.
- b. Gather, classify, and combine all related documents.
- c. Check if a study file contains, at a minimum, the following documents:
 - iOriginal applications and any updates received during the study.
 - iiInvestigator's brochures or similar documents
 - iii Approval letters and other correspondence like meeting minutes, reviewer's comments sent to the investigator & reply received from the investigator.
 - iv Approved documents (protocols, amendment, informed consent form (in English as well as local language), advertising materials (in English as well as local language), MoU/MTA, Approval of collaborating centers etc.)
 - vAdverse experience reports or Investigational New Drugs safety reports received
 - viContinuing review reports
- d. Use a folder with the following on the cover:
- e. The name of the principal Investigator /sponsor
- f. The protocol number
- g. The number assigned by the IEC Secretariat

Put the following into each folder with the following information:

1. Sponsor with address and contact phone/e-mail id of contact person, protocol number, investigator name (with address, e-mail, telephone and fax) and title

2. Application form of the IEC Protocol, Case Report Form, Investigator's Brochure (drug studies), Informed consent documents with translations in the relevant languages, advertising material and recruitment procedures, investigator bio data along with GCP certificate (with in last 3 years), any other material submitted by the investigator
 - a. Correspondence
 - b. Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
 - c. Revisions/Amendments
 - d. Adverse Events/ Unexpected Adverse Event/ Serious Adverse Events
 - e. Continuing Review, if applicable
 - f. Final / Completion report

23.5.2 Maintain the active study files

1. Assign the approved study files with unique identifiers (on a sheet of paper) established by a member of the IEC Secretariat
2. Combine related documents of the approved study files appropriately.
3. Attach an identity Label to the package.
4. Indicate date when Annual Review is due
5. Keep all active and potential study packages in a secure file cabinet.
6. Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the IEC.
7. Send all closed study files to archive.
8. Store the closed study files for **at least 5 years** after the study closure.
9. After this period save an electronic version of the entire file and discard the hard copy after appropriate approvals

Note: For studies with multiple study sites, a member Secretariat should maintain the files to allow cross-referencing without unnecessary duplications.

23.6 ANNEX

ANNEX 1 AF/EC/01/23/V1.2 Document History

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1.0	23 rd March 2013	Final approved copy
Dr. Ragini Kulkarni	Version 1.1	24 th September 2014	Sop no. changed from 14 to 21
Dr. Beena Joshi	Version 1.2	1 st May 2019	Sop no. changed from 21 to 23 Document History added