Independent
Ethics Committee
(Clinical Research) India

Standard Operating Procedures

(SOP -18/01)

For

Maintenance of Active Project Files

Independent Ethics Committee (Clinical Research) India

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the Independent Ethics Committee (IEC).

2. Scope

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

3. Responsibility

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

4. Flow chart

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

5. Detailed instructions

5.1 Organize the contents of the active study files

The Secretariat will:

- Get the master copy of the study files.
- Gather, classify and combine all related documents together.
- Check if a study file contains, at a minimum, the following documents:
  - Original applications of projects for initial review and any updates received during the study (containing all the list as mentioned in SOP 09/01 Procedures for Review of Amended protocol/Protocol related documents).
  - Investigator's brochures or similar documents

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- Agreements signed by appropriate authorities, such as: Clinical trial agreement, Insurance document.
- Photocopies of statutory permissions as applicable
- Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
- Approval letters for protocol & protocol related documents
- Adverse experience reports or IND safety reports received/SAE reports
- Continuing review reports
- Copy of all original letters received from the Principal Investigator.
- Copy of all correspondence letters sent to the investigator.

- The Administrative Officer will use a folder with the following identity label on the cover of the folder:
  - The name of the sponsor/Principal Investigator
  - The protocol number assigned by the IEC Secretariat

- The Administrative Officer will put the following documents into each folder with the following information:

  - Sponsor details with address and contact phone/e-mail id of contact person, protocol number, investigator name (with address, e-mail, telephone and fax) and title of the study.
  - 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, any other material submitted by the investigator
    1. Correspondence
    2. Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
    3. Revisions/Amendments
    4. Approval of amended protocol/protocol related documents
    5. Adverse Events
    6. Continuing Review, if applicable
    7. Final report

  For studies with multiple study sites, the Administrative Officer should maintain the files with sub-folders to allow easy cross-referencing without unnecessary duplications.

5.2 Maintain the active study files

The Administrative Officer will:
- Combine related documents of the approved study files appropriately.
- Attach an identity Label to the package.

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- Keep all active and potential study packages in a secure file cabinet.
- Maintain the study files in an easily accessible and secure place until the final report is reviewed and accepted by the IEC.
- Send all closed study files to archive.
- Store the closed study files for ***at least 5 years*** after the study closure.

6. Glossary

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.
CRF	Case Record Form or Case Report Form is a printed, optical or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial participant.
IND	Investigational New Drug is a drug that has never been seen in the market because it is under investigation of its efficacy and safety and not yet been approved for marketing by the local authorities. The drug is therefore approved for used only at some certain study sites.
ICD	Informed Consent Document is a written, signed and dated paper confirming participant's willingness to voluntarily participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the participant's decision to participate.
Master file	A file for storage of the originally signed and dated documents