**Title:** Maintenance of Active Project Files **SOP**

**Code: SOP 18/V1 dated 18th February 2017**

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## 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 Institutional 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

***Organize the contents of the active study files***

The Secretariat will:

- Preserve one original set (hard copy and soft copy) of the entire file (called as master file) and rest of the five sets will be shredded following the IEC meeting in which the initial review of a study is done.
- Gather, classify and combine all related documents together.
- Check if a study file contains, at a minimum, the following documents:
  - Original application form with the initial protocol submitted for initial review and any updates received (containing the entire list as mentioned in SOP 09/01 Procedures for Review of Amended protocol/Protocol related documents).
  - Investigator's brochures or similar documents.
  - Agreements signed by appropriate authorities, including 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 event reports, IND safety reports received and/ or SAE reports.
- Continuing review reports.
- A copy of every original letter/ communication received from the Principal Investigator.
- A copy of every letter/ communication sent to the investigator.

- The Administrative Officer will use a folder for each study file and affix an identity label on the folder cover:
  - 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: Name 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.
  - IEC Application form duly filled in and signed by the investigator at the time of initial submission.
  - Initial and various versions of the Protocol, Case Record 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.
  - Correspondence with the investigator.
  - Initial Approval with the final version of all above documents. (Protocol, ICD, CRF etc.)
  - Revisions/Amendments.
  - Approval of amended protocol/protocol related documents.
  - Protocol deviations / violations
  - Hard copies of Adverse Events and SAEs at this site,
  - Soft copy (CD) of SAEs at other site/s, CIOMS, SUSAR, Appendix XI reports and Safety reports
  - Continuing Review, if applicable.
  - 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.

***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.
- Keep all active and potential study packages in a secure place.
- Maintain the study files in an easily accessible, but secure place until the final report is received, reviewed and accepted by the IEC or the matter will be discussed at Full Board by IEC.
- Send all closed study files to the archive.

## 6. Glossary

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|---|---|
| **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 |