Title: Maintenance of Active Study Files

SOP Code : SOP/21/V1.1

Effective date : 24/09/2014

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1. Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the IEC of NIRRH Ethics Committee for Clinical Studies.

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 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 instruction

5.1 Organize the contents of the active study files

- Get the original documents/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 and any updates received during the study.
  - Investigator's brochures or similar documents
  - Approval letters and other correspondence sent to the investigator.
  - Approved documents (protocols, amendment, informed consent form, advertising materials, etc.)
  - Adverse experience reports or Investigational New Drugs safety reports received
  - Continuing review reports
- Use a folder with the following on the cover:
- The name of the principal Investigator /sponsor
- The protocol number
- The number assigned by the IEC Secretariat

Put the following into each folder with the following information:

- 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
- 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

- Correspondence
- Initial Approval with the final version of all above documents (protocol, ICD, CRF etc.)
- Revisions/Amendments
- Adverse Events
- Continuing Review, if applicable
- Final report

5.2 Maintain the active study files

- Assign the approved study files with unique identifiers (on a sheet of paper) established by a member of the IEC Secretariat
- Combine related documents of the approved study files appropriately.
- Attach an identity Label to the package.
- Indicate date when Annual Review is due
- 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.

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

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

7. Reference:

7.1 ICMR guidelines for clinical research. (http://icmr.nic.in/ethical_guidelines.pdf)
7.2 Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006