

Institutional Review Board, Tata Memorial Centre (IRB, TMC)

**Title: Maintenance of Active Project Files, Archival /
Disposal of closed files and Retrieval of documents**

SOP Code: SOP 10/V1 Date : 05/09/2012 Pages: 1 to 7

10.1 Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the IRB, TMC, and storage/archival of closed files and retrieval of documents.

10.2 Scope

This SOP applies to all active protocol/study files, closed files and their related documents that are maintained in the IRB office and archival site.

10.3 Responsibility

It is the responsibility of IRB staff to ensure that all study files are prepared, maintained, and kept securely for a period of three years after the closure of the project (under a proper system that ensures confidentiality and facilitates retrieval at any time).

10.4 Active study files maintenance & archival of closed files

A Study Master File is the file comprising all essential documents and correspondence related to the study/protocol. Study master files should be established at the time of initial submission in the IRB office.

- The study files are assigned unique identifiers (serial project no.)
- All documents related to the study file are gathered, classified and combined together appropriately.
- All active files are kept in a secured file cabinet with controlled access. Only authorized individuals' i.e. IRB Secretariat, will have access to the files. The study files are maintained in an easily accessible and secure place for at least 3 years after the study closure.
- All closed study files are separately archived.
- IRB staff will arrange for the closed project files to be archived once the completion/status reports are reviewed by the IRB. The completed/closed project files will be stored in archive boxes that are clearly labeled with the project number and title, Principal Investigator and disposal date. The archive boxes will be sent to a secure, dry location. The access to the files should be restricted to the IRB and the regulatory authorities. The details of the archiving location should be recorded in a location register stored in the IRB office. This register should record the project number and title, Principal Investigator and the disposal date. This procedure should be carried out in accordance with TMH regulations.

10.5 Disposal of closed files and copies of protocols and documents submitted for IRB review.

The trial master file will be maintained in the IRB office for a period of three years

following closure of the study. After completion of the archival period the closed files will be shredded and disposed off in the central shredding facility. However, all the copies of the research projects and documents submitted for IRB review will be shredded by the authorized IRB personnel after the IRB meeting without any notification to the Principal Investigator. A log book of disposed documents will be maintained.

10.6 Accessibility / Retrieval

Master files will be made available for inspection and copying by authorized representatives of regulatory authorities after receiving the request in writing.

In case any investigator needs a copy of any document from the master file, he/she should make a written request. (AX1 –V1/SOP10/V1). The IRB staff will furnish a copy of the required document within a week with the IRB Secretary's consent. The IRB will issue a copy of the following documents on formal written request.

Archived boxes may be retrieved from storage by the IRB as per TMH regulations.

For administrative purposes, the IRB Secretariat can retrieve archived file(s) without requiring the Chairperson's approval. For this purpose the IRB Secretary can authorize a staff member of the IRB secretariat to physically retrieve a file. Whenever an item is retrieved from the archives, the date, item and person retrieving the item should be documented, together with the date returned to the archives.

10.7 Final Disposal of Master files

The master files will be disposed off by the IRB secretariat after the archival period of 3 years. A formal written off register (AX2- V1/SOP 10/V1) will be maintained, providing details of the documents being written off / disposed off after notification to IRB in IRB meeting.

Glossary

Active Study File: Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.

Closed Study File: Any approved protocol, supporting documents, records containing communications and reports that correspond to a study which is completed or terminated or discontinued or suspended or not initiated.

Annexe

AX1 –V1/SOP10/V1

Document Request Form

Project No :	Project Title:
Name of Principal Investigator/Requesting Person:	Date:
Documents requested: Purpose of request:	
Principal Investigator / Requesting person' s sign & date	
Permission of the Secretariat: Yes/No	
Signature of IRB Secretariat:	

AX2 –V1/SOP10/V1

Format of written off/disposal register

Project No.	Title	PI	No. of files	IRB approval Date	Study Initiation Date	Study Closure Date	Name & Sign of Authorized Individual

Flow Chart

