

Title: Maintenance of Active Study Files, Administrative Records of the Ethics Committee,
Archival of Closed Files and Retrieval of Documents

SOP Code: SOP18/v2

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for preparation and maintenance of active study files and other related documents approved by Yenepeya University Ethics Committee (YUEC), administrative documents, archival of closed files and retrieval of documents.

2. Scope

This SOP applies to maintenance, archival and retrieval of all study files and study related documents and YUEC administrative documents by the YUEC Secretariat.

3. Responsibility

It is the responsibility of Member Secretary with assistance of Secretariat to ensure that all active study files and YUEC records are prepared, maintained during the study period and kept securely for a period of five years after the closure/ termination of the project.

4. Detailed instructions

4.1 Maintenance of active study files:

4.1.1 A study master file is the file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the YUEC office.

4.1.2 All related documents of the approved study will be gathered, classified appropriately and placed in the study master file. These could include copies of

1. All original research proposals reviewed and approved
2. Reviewer's assessment forms
3. Study approval letter
4. Reviewed and approved consent documents
5. Amendments and any other correspondence
6. Study progress reports and interim reports
7. Serious adverse event report forms submitted by investigators
8. Any other reports
9. YUEC Correspondence

Soft copies of the above will be maintained in the Secretariat external hard disk drive and password protected with access only to authorized YUEC personnel.

- 4.1.3 Strict confidentiality will be maintained for the contents of all the files (active, closed or archived)
- 4.1.4 All files will be kept secured in file cabinets with restricted and controlled access
- 4.1.5 A log book for accessing the files by authorized staff & members will be maintained
- 4.1.6 The store room/archival room will be kept locked at all times.

4.2 Maintenance of YUEC records

These records will include all of the following:

1. YUEC members' records
 - a. Appointment and acceptance letters of each member
 - b. Signed and dated confidentiality agreements
 - c. Updated Curriculum vitae (hard copy or soft copy)
 - d. Training records for each member (GCP, SOP)
 - e. Documentation of resignations / terminations
2. YUEC membership roster will be maintained in the Secretariat and will contain the following:
 - a. Names of members
 - b. Age
 - c. Gender
 - d. Qualifications
 - e. Role on the ethics committee
 - f. Status of affiliation to Yenepeya University or other institutions
3. YUEC mandate: Copies of the Yenepeya University notifications, byelaws and relevant guidelines
4. Correspondence related to changes in YUEC membership with DCGI, OHRP or any other concerned authority, including correspondence with Yenepeya University
5. Attendance roster, vouchers for honorarium for external members
6. Agenda notice and minutes of the meetings
7. SOPs
8. Templates of forms (participant information sheet, informed consent, SAE report, etc)

9. Documents related to workshops, training programs organized by YUEC (continuing development programs for members & staff)
10. SOP training and distribution logs

4.3 Maintenance of closed study files

- 4.3.1 Once the study file is closed (following completion/premature termination), the related study files will be shifted to the relevant cabinet/cupboard in the archival room and marked for ready retrieval as and when required.
- 4.3.2 All study files relating to regulated clinical trials, patents-related trials and funded research protocols will be archived for a period of five years from the date of closure of the study. All other study files will be stored for a period of three years from the date of closure.
- 4.3.3 A log book for archival of study documents will be maintained (either online or hard copy).

4.4 Accessibility/Retrieval

- 4.4.1 Study files and administrative records will be made available for audit, making photocopies (if requested by the appropriate authorities) or for purpose of research on SAEs on request (*Ann 01/ SOP18/v2*) if authorized by Member Secretary/Chairperson.
- 4.4.2 Requests for reprints of ethical clearance for whatever reason should be discouraged.
- 4.4.3 In case of issuance of fresh ethical clearance on account of protocol changes, the initial ethical clearance certificate should be obtained back from the principal investigator in original, marked "Cancelled – fresh EC issued – date" and archived in the protocol related file.
- 4.4.3 Representatives of regulatory authorities may have access at all times
- 4.4.4 A log book of retrieval of documents will be maintained (either online or hard copy).

4.5 Disposal of closed files and copies of protocols and documents submitted for ethical review

4.5.1 At the end of the prescribed period, the documents from the protocol file will be shredded and properly disposed by authorized YUEC personnel, without any notification to PI, keeping environment protection at the foremost.

4.5.2 Extra copies of protocols and documents submitted for ethical review and any other extra copies will be shredded by authorized YUEC personnel after the YUEC meeting without any notification to PI .

Soft copies of protocol related documents stored in the external hard disk drive will be deleted at the time of shredding of the hard copy as mentioned in 4.5.1.

4.5.3 A formal disposal log will be maintained, providing details of documents that will be disposed. (*Ann02/SOP18/v2*)

5. Annexures

Annexure 1: Ann01/SOP18/v2: Document Request Form

Annexure 2: Ann02/SOP18/v2: Log for disposal of study documents

**Ann01/SOP18/v2
Document Request Form**

Project No.	
Project Title	
Name of Principal Investigator (PI)	
Requested by	
List of documents requested	
Purpose of the request	
Signature and date of requesting person	
Signature and date of Member Secretary/ Chairperson	

**Ann02/SOP18/v2
Log for disposal of study documents**

Project No.	Title	Name of Principal Investigator	No. of files	Date of EC Approval	Date of Study Initiation	Date of Study Closure	Disposed by (Name & Sign) of Authorized Individual

7. Flow Chart

No.	Activity	Responsibility
1	Organize the contents of the active study files	Secretariat
2	Maintain the active study files and administrative documents	Secretariat
3	Archival of study files	Secretariat
4	Authorizing retrieval of archived documents	Member-Secretary/ Chairperson
5	Disposing closed study files and maintaining	Secretariat
6	Document disposal log	Secretariat