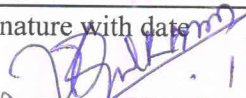


Title: Maintenance, archival, retrieval and disposal of protocols and protocol-related documents


SOP Code: SOP18/v4

Effective Date: 01/07/2023

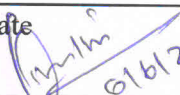
Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date  . 11/6/2023
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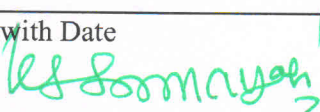
Reviewed by:

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with Date  1/6/23
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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date  01/6/23
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Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with Date  1/6/23
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Details of superseded SOP18/v4

Subcommittee convenor name	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP and NABH assessment

Details of current SOP18/v4

Subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	<ol style="list-style-type: none"> Glossary section added in the SOP More information added to the excel database to capture tracking of post-approval activities Storage requirement for external hard disc for backup is specified

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1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to provide instructions for maintenance, archival, retrieval and disposal of the protocol-related and YEC-1 office documents.
2. **Scope:** This SOP applies to
 - 2.1. The maintenance, archival, retrieval and disposal of all protocol-related files including the pre-approval files, active files, closed files and protocol-related reports and communications
 - 2.2. The maintenance, archival, retrieval and disposal of YEC-1 office documents which include SOPs, guidelines, correspondence, meeting-related documents, YEC-1 subcommittee documents, document access logs, audit/inspection files, membership files, training files, budget/finance and related documents and others.
3. **Responsibility:**
 - 3.1. **YEC-1 Chairperson will**
 - 3.1.1. Oversee the maintenance, archival, retrieval and disposal of documents
 - 3.2. **YEC-1 Member-Secretary will**
 - 3.2.1. Ensure that the maintenance, archival, retrieval and disposal of the YEC-1 protocol-related and YEC-1 office documents is done as per the SOP
 - 3.2.2. Will approve the documents that are ear-marked for shredding and confirm that the same has been entered in the log
 - 3.3. **YEC-1 Secretariat will**
 - 3.3.1. Ensure that the stock of empty files and other stationery is adequate.
 - 3.3.2. Make timely approvals for procurement of stock through the university approved online system, on the designated days.
 - 3.3.3. Maintain the pre-approval and active protocol files separately in the designated cupboards/racks, with appropriate coding, and numbering of the files, in a systematic order.
 - 3.3.4. Archive the closed files separately in cupboards/racks designated for the said files with appropriate coding and numbering of protocol files, in a systematic order.
 - 3.3.5. Maintain the YEC-1 office documents including current and active SOPs, guidelines, communications with authorities, meeting-related files, sub-committee files, document access logs, audit/inspection files, membership files, training files, budget/finance related documents and other any other concerned documents in the designated cupboards/racks with appropriate coding and numbering of files
 - 3.3.6. Archive YEC-1 office documents including old and outdated SOPs, guidelines,

communications with authorities, meeting-related files, sub-committee files, document access logs, audit/inspection files, membership files, training files, budget/finance related documents and other any other concerned documents in the designated cupboards/racks with appropriate coding and numbering of files

- 3.3.7. Retrieve the protocol-related files/ YEC-1 documents on the request by the YEC-1 members, authorized persons, researchers, or other individuals, once duly permitted by the Member-Secretary/Chairperson.
- 3.3.8. Dispose the documents in the closed files after the stipulated time as determined by the current guidelines and as per the procedure laid down in the section on shredding in this SOP.
- 3.3.9. Reuse the usable files for filing new protocols, once the contents have been appropriately disposed

4. **Detailed instructions:**

4.1. **The filing system for protocols:**

- 4.1.1. The Secretariat will assign a folder/file for each protocol, assign the unique protocol number with the numbering system of YYYY/NNN, where “YYYY” stand for the year in which the protocol is submitted and “NNN” the serially progressing number for all protocols submitted to YEC-1. At the start of each calendar year, the numbering will restart from “001”.
- 4.1.2. Protocol packages that are incomplete or lacking documents as provided in the checklist, will not be assigned a number and will be kept in a holding area. The Secretariat will assign the unique YEC-1 number only after receiving the complete protocol package (as per the checklist) and a soft copy by email (ethcom@yenepoya.edu.in) will file all documents and communications pertaining to the protocol from the time of submission to the closure of the study in a chronological manner.
- 4.1.3. The Secretariat will maintain an index of documents and number the documents in order to ensure that all the documents are appropriately filed and maintained. For easy retrieval, the rib of the files may be given a strip with the protocol number.

4.2. **The filing system for YEC-1 office documents**

- 4.2.1. The Secretariat will file the YEC-1 office documents (guidelines, SOPs, correspondence with university and other authorities, members’ files, meeting agenda and minutes, various logs, reports, members’ assessment forms, feedback forms, training files, and other sundry documents) in appropriate files in appropriate cabinets, such that retrieval is quick and efficient.
- 4.2.2. The Secretariat will maintain one copy of each version of the old and current SOPs, and each of the old and revised guidelines, acts, regulations, etc.

4.3. The archival room:

- 4.3.1. The YEC-1 will have a specified archival room with security for maintenance of all the confidential documents related to YEC-1 functioning.
- 4.3.2. The archival room will be earmarked as “restricted access” and will be accessible only to the Member-Secretary, Joint Secretary and the Secretariat, and if required -with permission from the Member-Secretary - to the current YEC-1 members who need to access protocol for review, within the archival room.
- 4.3.3. The Secretariat will maintain a log of YEC-1 members who access the archival room with purpose, date and time.

4.4. Maintenance of pre-approval incomplete protocol files:

- 4.4.1. The pre-approval protocol files identified as incomplete submissions will be filed separately for easy access of the Secretariat.
- 4.4.2. The as-yet-unnumbered incomplete protocol files will be maintained in a systematic manner for easy access.

4.5. Maintenance of working protocol files:

- 4.5.1. The working pre-approval protocol files under review at various stages (awaiting categorization, under initial review, awaiting resubmissions/clarifications from the researchers will be filed in separate cupboards/cubbyholes designated for these files.
- 4.5.2. The working post-approval protocol files under review at various stages (continuing review, amendment review, and those files awaiting issue of approval letters) will be filed in separate cupboards/cubbyholes designated for these files.
- 4.5.3. In the case of regulated clinical trials submitted in the form of bound books, the same will be stored with the protocol number written boldly en face and all the associated pre-approval, approval and post-approval correspondence will be filed in a separate file bearing the same protocol number.
- 4.5.4. The files will be maintained in a systematic manner for easy access

4.6. Maintenance of active protocol files:

- 4.6.1. The active protocol files which are approved and the study is ongoing, will be filed in separate cupboards designated for these files, year-wise in a systematic order as per the numbering of the files.
- 4.6.2. The active files will contain the study protocol, reviewer’s assessment forms, all correspondence and email communications, scanned copy of the approval letter, amendments and amendment approval letters, if any, continuing review forms, interim reports, reminder letters, serious adverse event forms and

reports, site monitoring and its report(s) and any other reports.

- 4.6.3. If required, in view of too many document papers, multiple files may be made for each protocol and numbered as sections.
- 4.6.4. In the case of regulatory clinical trials submitted in the form of bound books, the same will be stored with the protocol number written boldly en face and all the associated pre-approval, approval and post-approval correspondence will be maintained in a separate file bearing the same protocol number.

4.7. Maintenance of closed protocol files:

- 4.7.1. All the closed protocol files for which study completion report has been submitted will be maintained in a separate cupboard designated for the same in a systematic manner as per the numbering.
- 4.7.2. In the interest of space constraints and environment protection, the hard-cover of the closed files whose documents are to be shredded, may be removed and reused for new protocols.
- 4.7.3. The closed files relating to regulated clinical trials, patents-related trials and funded research protocols will be maintained in the designated cupboard for the stipulated period as determined by the current applicable regulations.

4.8. Maintenance of the YEC-1 office documents:

- 4.8.1. The Secretariat will maintain all YEC-1 office documents in a separate cupboard/rack earmarked for this purpose.
- 4.8.2. One hard copy of the active and current SOPs, one hard copy each, of the current national and international guidelines, membership files for the current tenure and all other files for the current calendar year including communications with authorities (both university and external), meeting-related files for the current calendar year, sub-committee files, document access logs, various other logs, all current year reports, members' assessment forms, feedback forms, current year training files, audit/inspection files, current version of updated CVs of members, budget/finance and related documents for the current year and other sundry files will be maintained in the cupboard/rack designated for this purpose.
- 4.8.3. One hard copy each, of the previous versions of the national and international guidelines, one hard copy of the previous versions of YEC-1 SOPs, previous membership files and all other files for the previous calendar years including communications with authorities (both university and external), past meeting related documents, various logs, various reports, members' assessment forms, feedback forms, training files, members' files, meeting-related files, sub-committee files, document access logs, audit/inspection files, training files, old CVs of members, budget/finance and related documents and other sundry documents will be maintained in the cupboard/rack designated for this purpose.

4.8.4. The YEC-1 will prominently display the notification of YEC-1 accreditation status, calendar of meetings, important notifications and flow charts in the YEC-1 office and on its website.

4.9. Maintenance of ‘controlled’ documents:

4.9.1. YEC-1 will maintain one hardcopy set of original “controlled” or “master” copy of the following documents at all times: current SOPs, copy of registration of YEC-1 with the regulatory authorities, and notification of the YEC-1 reconstitution by the University.

4.9.2. These documents will not be issued to any person other than Chairperson/ Member-Secretary/Secretariat and that too in exigent circumstances.

4.9.3. For ready access of SOPs and other documents, YEC-1 will maintain duplicate copies of the same “uncontrolled” and these may be accessed by authorized persons after entering details in the access log, updated by the Secretariat..

4.10. Maintenance of E- or Soft copies

4.10.1. The Secretariat will maintain the soft copies of all documents related to the protocols (including an excel spreadsheet database of all protocols received and processed, and scanned copy of PI-signed EC approval letter) or YEC-1 members, or YEC-1 functioning and communications in separate folders in the computer exclusively assigned for the above purpose. This will be stored in a safe place under security with restricted access, only to authorized personnel.

4.10.2. The excel sheet containing the database will contain information of the history of every protocol including title, investigator details, dates of submission, details of review process, reviewer names and review dates, reminders to reviewers, communications with the researchers, reminders to researchers, resubmission, approval date and duration, post-approval review like amendments, deviations, continuing reviews, site monitoring, and closure, date of shredding of documents.

4.10.3. For the purpose of backing up, the Secretariat will maintain an external hard disk drive with password protected access only to the authorized YEC-1 personnel. This will be updated on a regular basis every weekend and stored in a safe place under security outside of the premises of the Secretariat of the YEC-1, in a room outside of YEC-1 in a password-protected, safe locker meant exclusively for Yenepoya Ethics Committee-1 with restricted access only to authorized YEC-1 personnel.

4.10.4. YEC-1 will have an exclusive email id which will be password protected and the email will be accessed strictly by the authorized YEC-1 personnel only.

4.10.5. The protocol documents sent to the reviewers by email and the communications, thereof, will not be shared with any unauthorized person/institution and will be deleted by the YEC-1 members, from the email

and from the personal computers/laptops/mobiles on a regular basis or at least at the end of the calendar year or at the end of the term of the members, whichever is earlier. This will be mentioned in the terms of reference and the confidentiality agreement forms of the members at the time of joining YEC-1.

4.11. Retrieval of the YEC-1 protocol files/ other documents:

- 4.11.1. The Chairperson, Member-Secretary/Joint Secretary and the Secretariat shall have unrestricted access to all the documents maintained by the YEC-1. For all other YEC-1 members, retrieval of files will be done with maintenance of strict confidentiality after signing the document access log book. Any other person(s) wishing to access the documents will do so after following the procedure laid down in SOP05 (Ann02/SOP05/v4).
- 4.11.2. Every retrieval of any file/document will be entered in the access log with details like name, purpose, time and date of access and return
- 4.11.3. Retrieval of files will be permitted under the following circumstances
 - 4.11.3.1. External audit/ inspections of YEC-1 by authorized persons
 - 4.11.3.2. Trainees, students and other observers wishing to know the functioning of YEC-1 after due permissions.
 - 4.11.3.3. Internal audit by YEC-1 members
 - 4.11.3.4. For site monitoring visits by the YEC-1 members
 - 4.11.3.5. For research on YEC-1 functioning like SAE reports, site monitoring reports, etc after due written permission from the YEC-1 Chairperson.
- 4.11.4. All YEC-1 files retrieved must be returned on the same working day, but in exceptional circumstances may be returned within 24 hours with due permission from the YEC-1 Chairperson/Member-Secretary.

4.12. Submission of copies of the YEC-1 documents to authorities:

- 4.12.1. Any document required to be submitted to authorized persons like auditors/inspectors/regulatory bodies/university must be done by YEC-1 after receiving a request/instruction from the concerned authority.
- 4.12.2. The submission of these documents, the purpose and the authority to which the documents are submitted must be entered in the document access log with signature, date and time by the Member-Secretary/ designated YEC-1 member.
- 4.12.3. While doing so, confidentiality of the information must be utmost and the procedure laid down in SOP3B/v4 must be adhered to.

4.13. Issue of duplicate YEC-1 approval letter:

- 4.13.1. For each approved protocol, YEC-1 will issue only one original EC approval letter, in the name of the Principal Investigator.

- 4.13.2. Upon receiving a written request from the PI, with suitable justification stated, and with due approval from the Chairperson, YEC-1 may issue a duplicate copy of the original EC approval - a copy will be in the e-copy archives.
 - 4.13.3. The request letter should be signed by the PI or the co-I (or guide)
 - 4.13.4. The copy of the scanned YEC-1 approval letter will be marked with a stamp - "duplicate copy" - signed and dated by the Member-Secretary/Chairperson
 - 4.13.5. A fee, as determined by the University, will be charged from the Principal Investigator/applicant before issuing the duplicate copy and the receipt of the same will be issued.
 - 4.13.6. On no account will a fresh EC approval letter be issued to the Principal Investigator or any other Co-I, unless this is for rectification of errors in the issued approval letter, in which case, the previously issued approval letter will be deposited in YEC-1 at the time of issue of the fresh approval letter.
 - 4.13.7. The Secretariat will maintain a log of issue of duplicate YEC-1 approvals, in the same book used for regular EC approvals.
- 4.14. **Disposal of closed files and copies of protocols and documents submitted for ethical review:**
- 4.14.1. At the end of the prescribed period, the hard copy documents from the protocol file will be shredded and appropriately disposed of by authorized YEC-1 personnel as per the University policy of waste disposal.
 - 4.14.2. The closed files of academic protocols and related documents will be archived for a period of 3 years from the date of completion report/termination report of the study and will then be eligible for shredding.
 - 4.14.3. Closed files of clinical trials (regulatory), patent-related trials and funded research protocol files and related documents will be archived for a period of 5 years from the date of study completion report/termination report and will thereafter be eligible for shredding.
 - 4.14.4. Extra copies of protocols and documents submitted for ethical review and any other extra copies will be shredded by authorized YEC-1 personnel after the YEC-1 meeting without any notification to PI
 - 4.14.5. At the time of disposal of protocol files, the YEC-1 secretariat will maintain a soft copy of only the approval letters (initial, extension, amendments) of all protocols and maintain these copies for records for an indefinite period.
 - 4.14.6. The Secretariat will maintain and regularly update the Excel spreadsheet with protocol numbers and dates of completion reports which will serve as a reminder for timely shredding.
 - 4.14.7. All files eligible for shredding will be verified by checking the date of the

completion report, and a list will be sent to the Chairperson for approval and will be included in the agenda of the meeting for ratification by the members.

- 4.14.8. A formal disposal log will be maintained, providing details of documents that will be disposed of. (Ann02/ SOP18/v4). The protocol numbers will be entered in a protocol shredding register, maintained in the Secretariat.
- 4.14.9. The files will then be shredded and the shreds will be sent for disposal as per University norms keeping in mind the environmental protection
- 4.14.10. Confidentiality will be maintained for the contents of all files shredded
- 4.14.11. Shredding will be carried out by the YEC-1 secretariat with email any notification to PI and Co-Is to remind them of disposal of the research data from their side.
- 4.14.12. 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, and the same will be entered in the appropriate column in the register with the following details: protocol number, title of the protocol, date of EC approval, date study completion, date of shredding.

5. References:

- 5.1. ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017

6. Annexures:

- 6.1. Ann01/SOP18/v4: Document Request Form
- 6.2. Ann02/SOP18/v4: Log for disposal of study documents
- 6.3. Ann03/SOP18/v4: Log for document disposal
- 6.4. Ann04/SOP18/v4: Form for confirming deletion of softcopies
- 6.5. Ann05/SOP18/v4: Template for PI intimation of shredding of protocol documents

Ann01/SOP18/v4

Document Request Form

Protocol No.	
Title	
Name of the PI	
Requested by	
List of documents requested	
Purpose of the request	
Signature of requesting person with date	
Date and signature of Member Secretary/ Chairperson	

Ann02/SOP18/v4

Document access log

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

Ann03/SOP18/v4

Log for document disposal

Prot No.	Title	Name PI	No. of files	Clinical trial/non-clinical trial	EC approval date	Date of Study Initiation	Date of Study Closure	Date of completion report	e-copy deleted (Yes/No)

Date of shredding:

Signature of shredding personnel:

Confirmed and verified by: Chairperson/Member-Secretary

Ann04/SOP18/v4

Form for confirming deletion of softcopies related to YEC-1 protocols

I, _____, Member of YEC-1, hereby confirm that I have deleted the soft copies of all protocols and protocol-related documents, the review forms and communications related to the YEC-1 functioning including meeting details and subcommittee reports received so far, from my laptop/other electronic devices and my email id. I confirm that I have maintained strict confidentiality and have not shared these documents with any unauthorized third party.

Name of the YEC-1 member

Signature

Date

Signature of the Chairperson/ Member-Secretary

Date

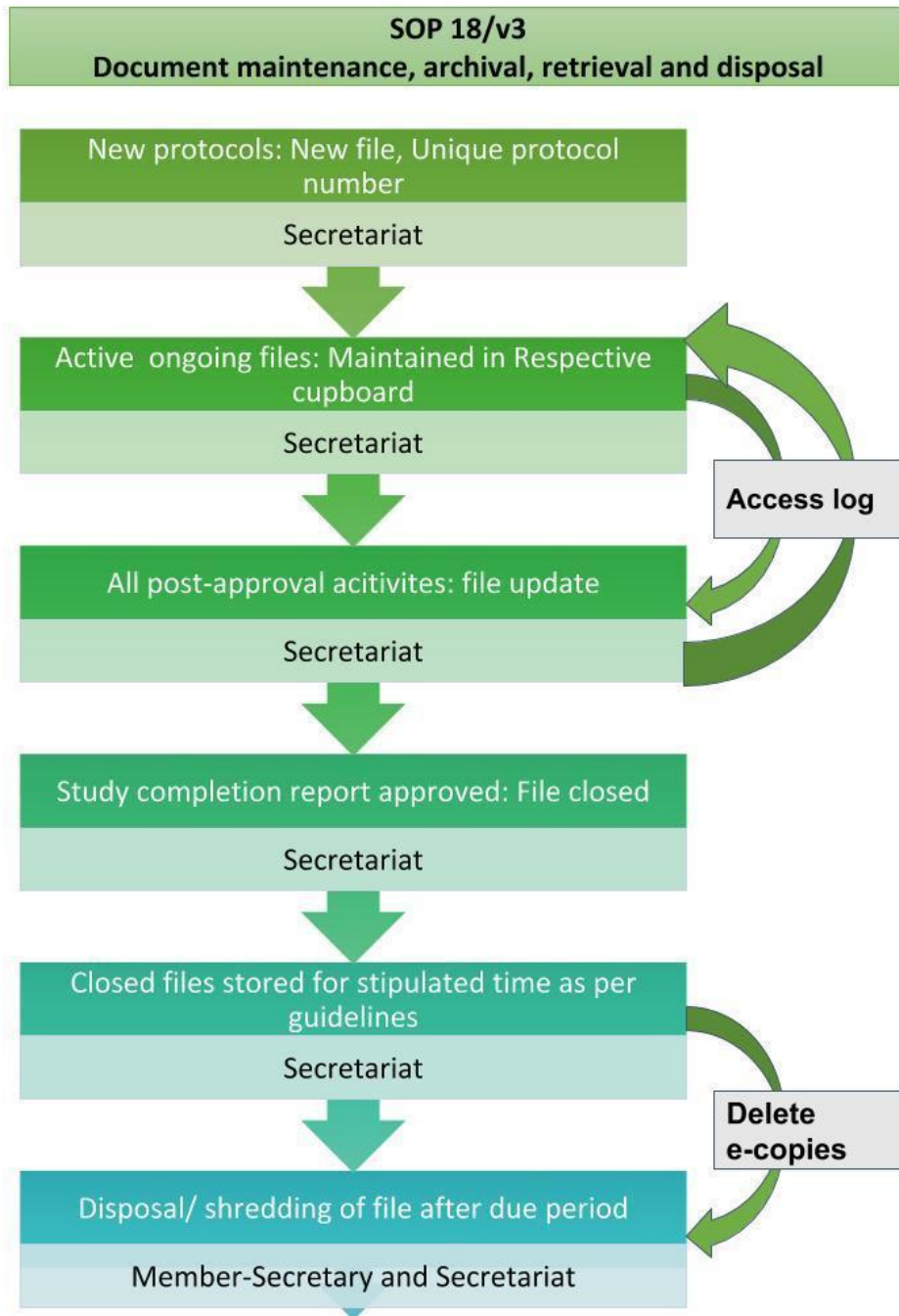
Ann05/SOP18/v4:

Template for PI intimation of shredding of protocol documents

Dear PI/Co-I

This is to inform you that your Protocol no: YEC-1/ _____ titled _____ which approved and ratified your study completion report in the YEC-1 meeting held on _____ is shredding of hard copies and deletion of soft copies in the YEC-1 office as per YEC-1 SOPs. This email also serves to remind you to dispose of the same from your side.

7. Flowchart



8. Glossary:

- EC: Ethics Committee
- ICMR: Indian Council of Medical Research
- PI: Principal Investigator