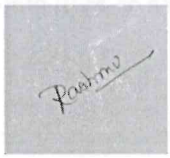
Title: Preparation of Standard Operating Procedure Manual for YEC-4
SOP Code: SOP01/v1
Effective Date: 1.1.2025
Prepared by:

Mrs. Liba Sara Varghese Member, YEC-4 SOP Subcommittee	 22.12.2024 Signature with date

Reviewed by:

Dr. Deeksha Member, YEC-4 SOP Subcommittee	 22.12.2024 Signature with Date

Approved by:

Dr. Rashmi K S, Chairperson, YEC-4	 22.12.2024 Signature with Date

Notified by:

Registrar, Yenepoya (deemed to be University	Signature with Date RS Somayan 27/12/24 Registrar YENEPOYA (Deemed to be University)

Table of Contents:

1. Purpose:

1.1. The purpose of this Standard Operating Procedure (SOP) is to define the process for drafting, reviewing, distributing and amending SOPs of Yenepoya Ethics Committee - 4 (YEC-4).

1.2. The SOPs shall provide clear, unambiguous instructions so that all the activities of the committee are conducted in a standardized, orderly, fair and transparent manner, in accordance with the University rules, and relevant national and international ethical regulations and guidelines.

2. Scope:

2.1. This SOP covers the procedures of drafting, reviewing, distributing and amending the SOPs of YEC-4.

3. Responsibilities:

3.1. The Chairperson will:

3.1.1. Nominate SOP subcommittee(s) to formulate new SOP(s) or to revise/amend existing SOP(s)

3.1.2. Approve the SOP(s)

3.1.3. Sign and date the approved SOP(s)

3.2. The Registrar, Yenepoya deemed to be University will

3.2.1. Notify the SOP subcommittee

3.2.2. Notify the SOP (s) approved by the Chairperson.

3.2.3. Ensure that the SOPs are widely made available to all researchers, on the webpage of YEC-4.

3.3. The Member-Secretary will

3.3.1. Assist the Chairperson to formulate the SOP subcommittee(s)

3.3.2. Coordinate and oversee the activities of drafting, reviewing, approving, distributing and amending SOP(s) and SOP training of members/secretariat

3.3.3. Ensure that all YEC-4 members and involved administrative staff of YEC-4 have access to the SOP(s)

3.3.4. Ensure that all YEC-4 members and involved staff are working according to current version of SOP(s)

3.3.5. Maintain an up-to-date distribution list for each SOP(s) distributed to the YEC-4 members

3.3.6. Consistently refer to the SOP for issues related to the business of YEC-4

3.4. The Secretarial staff will

3.4.1. Assist the Member-Secretary in the coordination of the SOP subcommittee activities

3.4.2. Maintain the current SOP version Master Copy, control copy and other copies

3.4.3. Maintain the superceded SOPs

3.4.4. Upload the current SOP on the website

3.5. SOP subcommittee members will

3.5.1. Assess request(s) for SOP(s) revision in consultation with the Secretariat, Member-Secretary and Chairperson

3.5.2. Propose new/modified SOP(s) as needed

3.5.3. Formulate and/or revise/amend SOP(s) by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the YEC-4.

3.5.4. Draft the SOP(s) in consultation with the YEC-4 members and involved administrative staff of YEC-4

3.5.5. Review the draft SOP(s)

3.5.6. Submit the draft for approval to Chairperson & Yenepoya deemed to be University (YU) authorities

3.6. The YEC-4 members will

3.6.1. Receive, sign and date the approved SOP(s) when they receive it

3.6.2. Maintain a personal file of all the current SOP(s) received

3.6.3. Return all the older versions of the SOP(s) that are in their possession

3.6.4. Delete soft copies of the superceded SOPs

3.6.5. Familiarize themselves with the content of the current SOPs

3.6.6. Maintain adherence to the guidelines in the current SOPs and

3.6.7. Consistently refer to these SOPs while conducting ethical review of protocols

4. Detailed instructions on the structure of the SOPs:

4.1. General SOP chapter structure

4.1.1. Each SOP chapter will be prepared according to the standard template given in Ann01/SOP01/v1 will consist of

4.1.1.1. Title

4.1.1.2. SOP Number

4.1.1.3. Details of SOP preparation and approval

4.1.1.4. Table of contents: *The headings and page numbers*

4.1.1.5. History of the SOP changes

4.1.1.6. **Purpose of the SOP:** *Summarize and explain the objectives of the SOP.*

4.1.1.7. **Scope:** *State the range of activities that the SOP applies to.*

4.1.1.8. **Definitions, if any**: *Define terms relevant to the SOP for easy understanding of the procedures*

4.1.1.9. **Responsibilities:** *Refers to person(s) assigned to perform the activities involved in the SOP*

4.1.1.10. **Detailed instructions:** *Describes the procedures step by step in short and clear sentences in numbered bullets*

4.1.1.11. **References:** *List of all other SOPs referred to in the current SOP and the latest international and national guidelines*

4.1.1.12. **Annexures:** *Forms or templates or letters to capture information pertaining to the SOP instructions numbered serially*

4.1.1.13. **Abbreviations:** *List of abbreviations used in the SOP manual for easy reference*

4.1.1.14. **Flowchart:** *Simplified representation of the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*

4.1.1.15. **Glossary**: *List of terminologies for easy reading*

4.1.2. Each page of the SOP will bear a header which will consist of

4.1.2.1. The YU logo

4.1.2.2. YEC-4 name

4.1.2.3. Brief title of the SOP

4.1.2.4. SOP number/version

4.1.2.5. Effective date (*dd/mm/yyyy*).

4.1.3. Each page will have a footer that will bear the page number as page p of q (total) pages.

4.2. Naming & numbering of the SOPs:

4.2.1. Each function/activity of the YEC-4 will have a separate SOP chapter and all the SOP chapters together will be called the SOP Manual

4.2.2. Each SOP chapter will be given a title that is self-explanatory

4.2.3. Each SOP will be given a unique code in the format SOP"xx"/v"y" where:

4.2.3.1. "xx" will be a two-digit number assigned specifically to each activity-based SOP

4.2.3.2. "y" is a number identifying the version.

4.2.4. Thus the first SOP of the current version would be SOP01/v1

4.3. Annexures for the SOP:

4.3.1. Each SOP may have annexures which are forms or templates to be

used by YEC-4 members, Principal Investigators (PI) or other stakeholders.

4.3.2. Each annexure will be given a unique code number with the format Ann"pp"/SOP"xx"/v"y". "Ann" refers to the annexure form, "pp" is a two-digit number, in serial order for the various annexures, and "xx"/v"y" refers to the SOP number and its version. For example, Ann01/SOP01/v4 means annexure form/template number 1 from SOP01/v1

5. Detailed instructions on the preparation and implementation of the SOPs

5.1. Review and revision of current SOP chapter or need for a new SOP chapter:

5.1.1. The YEC-4 will review the SOPs at least once in every 3 years.

5.1.2. Revision of SOP may also be done after an audit/ inspection/ accreditation of YEC-4 as suggested/ recommended by them

5.1.3. Revision of SOPs may also be required with changes in the national regulations and guidelines governing the Ethics Committees or changes in the guidelines on research on human participants

5.1.4. Revision of SOPs may also be considered in the background of advancement in scientific research methodologies

5.1.5. Apart from these, any member of the YEC-4 or Secretariat who feels the requirement of a revision or notices an inconsistency/discrepancy /has any suggestions on how to improve the existing SOP(s) or requests to design an entirely new SOP can put forth a formal request to the YEC-4 Chairperson either as an email/letter/verbal request in a meeting.

5.2. Initiating the action on revision of current SOP/preparation of a new SOP chapter:

5.2.1. Once need for revision is discussed in the YEC-4 meeting the Chairperson approves the need for revision if the majority of members agree to the request

5.2.2. The Chairperson will nominate SOP subcommittee(s) to initiate the action

5.3. Appointment of the SOP subcommittee(s):

5.3.1. The Chairperson will nominate members to the SOP subcommittee(s) consisting of the Member-Secretary, two or more members of YEC-4, and based on inputs from Member-Secretary two or more members from within Yenepoya (deemed to be University) (optional), who have a thorough understanding of the ethical review process.

5.3.2. The Registrar will notify the subcommittee

5.4. Drafting of the SOPs:

5.4.1. The SOP subcommittee will assign the various SOP drafts to different members.

5.4.2. The SOP subcommittee members will prepare the new SOP or make changes in the current SOP based on the requirement

5.4.3. The SOP subcommittee members will keep the current regulatory guidelines and the local rules and regulations while drafting the SOPs

5.5. Review of the draft SOP:

5.5.1. The draft SOP written by one or more members of the SOP subcommittee will be reviewed by another member(s) of the SOP subcommittee.

5.5.2. The Member-Secretary will include it in the agenda of the subsequent YEC-4 meeting for review by other YEC-4 members

5.5.3. The suggestions that are agreed upon by the members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.

5.6. Approval of the SOPs:

5.6.1. The SOP draft will be approved by the YEC-4 members in the YEC-4 meeting

5.6.2. The authors and the reviewers will sign and date the SOPs

5.6.3. The Chairperson will approve the SOPs and sign and date the SOPs

5.6.4. The extract of the relevant resolution of the YEC-4 meeting minutes will be appended to the SOP

5.7. Notification of the SOPs:

5.7.1. Once the SOPs are approved by the YEC-4 members and the YEC-4 Chairperson, they are forwarded to the Registrar, YU

5.7.2. The SOPs are then notified by the Registrar, YU.

5.8. Effective date of the SOPs:

5.8.1. The authors and reviewers will sign and date the SOP on the first page of the SOP document.

5.8.2. The Chairperson will sign the date of approval.

5.8.3. The date of approval signed by the Chairman will be declared as the effective date from which the SOP will be implemented. The time gap between 5.8.1 and 5.8.2 should be sufficient to complete the SOP training of the members (if required)

5.8.4. The same page will also bear the signature of the Registrar, YU as having accepted the document for notification.

5.9. Supersession of previous SOP(s):

5.9.1. If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History as an annexure (Ann02/SOP01/v4)

along with description of the main change(s).

5.10. Distribution of SOPs

5.10.1. The approved SOP(s) will be distributed to YEC-4 members (as soft copies) and whenever required as hard copy, a log will be maintained as per annexure (Ann"xx"/SOP"yy"/v"z"). In this case, it will be Ann 04/SOP 01/v1.

5.10.2. When the revised version is distributed, all the YEC-4 members will be requested to destroy their earlier version.

5.10.3. The SOP manual will also be uploaded to YEC-4 website for easy access to all research stakeholders including the YEC-4 members, researchers, sponsors, independent consultants, auditors, and others.

5.11. Filing of SOPs:

5.11.1. One complete original set of current SOP will be filed in the SOP Master file, by the YEC-4 Secretariat in the YEC-4 office and marked as the controlled copy as per the SOP20/v1

5.11.2. An additional 'uncontrolled' copy will be available in YEC-4 for easy access

5.11.3. One copy of the earlier version will be filed in the file entitled 'Past SOPs of the YEC-4' by the YEC-4 Secretariat in the YEC-4 office, in the Master File.

5.11.4. Old versions of the SOPs will be marked as "Superseded" to indicate they are not effective anymore.

5.12. Training of YEC-1 members and secretariat:

5.12.1. The Member-Secretary will discuss the approved SOP(s) with the involved administrative staff of the EC and instruct them to implement it accordingly.

5.12.2. The Member-Secretary will organize training of the YEC-4 members on a regular basis so as to train them on the SOPs, as in SOP21/v1

5.13. Implementation of SOPs:

5.13.1. The approved SOP(s) will be implemented from the effective date (read with 5.8.3 above)

5.13.2. All procedures including forms, templates, procedures and timelines will be adhered to by all the YEC-4 members including the independent consultants and the Secretariat.

5.13.3. Any challenges faced in the implementation of the SOPs is brought to the notice of the Member-Secretary/ Chairperson who in turn will plan an action for better implementation and smooth functioning of the YEC-4

6. **Annexures:**

6.1. Ann01/SOP01/v1 - Template for SOPs

6.2. Ann02/SOP01/v1 - Documentation of History of the SOPs

6.3. Ann03/SOP01/v1 - Log of the YEC-4 members receiving SOPs

6.4. Ann04/SOP01/v1- List of National and International guidelines

Annexure 1: Ann01/SOP01/v1
Template for Standard Operating Procedures

Logo of institution Title of the SOP	YEC-4 **Effective date:** *aa/bb/cccc*	**SOP Code:** SOP xx/vy

Title: Title which is self-explanatory and easily understood
SOP Code: SOP xx/vy
Effective date: *aa/bb/cccc*

Prepared by : xxxxxxxxx **Signature with date** ----------

Reviewed by: xxxxxxxx **Signature with date** ----------

Approved by: xxxxxxxxx **Signature with date** ----------

Notified by: xxxxxxxxxx **Signature with date** ----------

Document Table of Contents:

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4. **Detailed instructions**: *Describes procedures step by step in short and clear sentences in numbered list*
5. **References:** To other SOPs, Annexures, published guidelines or published literature
6. **Annexure**: *Forms to capture information pertaining to the SOP instructions*
7. **Flow chart:** *Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*

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Annexure 2: Ann02/SOP01/v1
Documentation of History of the SOPs

Details of superseded SOP

Name of the subcommittee convenor	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)

Details of current SOP

Name of the SOP subcommittee convenor	Version	Effective date (dd-mm-yyyy)	Describe the main change(s)

Annexure 3: Ann03/SOP01/v1

Log of the YEC-4 members receiving SOPs

No.	Name of Recipients	Designation	SOP code number	Hard/ soft copy	Signature	Date

Ann04/SOP1/v1:
List of Current National and International Research Ethics guidelines applicable to ethical review of research protocols

S.No.	Title of the guideline	Web Link
1.	Ministry of Health and Family Welfare's New Drugs and Clinical Trials Rule 2019	https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf
2.	Indian Council of Medical Research's National Ethical Guidelines for Biomedical and Health Research involving human participants 2017	https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf
3.	ICMR's National Ethical Guidelines for ECs reviewing biomedical and health research during COVID-19 pandemic 2020	https://www.icmr.gov.in/pdf/covid/techdoc/EC_Guidance_COVID19_06052020.pdf
4.	Indian Council of Medical Research's National Guidelines for Stem cell research 2017	https://dbtindia.gov.in/sites/default/files/National_Guidelines_StemCellResearch-2017.pdf
5.	Ministry of Health and Family Welfare's Indian Good Clinical Practice Guidelines 2018	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ==

	World Medical Association's Declaration of Helsinki 2013	https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2013-JAMA.pdf
7.	WHO's Standards and operational guidance for ethics review of health-related research	https://www.who.int/publications/i/item/9789241502948
8.	Good Clinical Practices for Clinical Trials on Ayurveda, Siddha, Unani medicines 2011	http://siddhacouncil.com/ccrs/wp-content/uploads/2018/10/GCP-Guidelines.pdf
9.	International Ethical Guidelines for health related research involving humans 2016	https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

8. Glossary:

CDSCO: Central Drug Standards Control Organization
CIOMS: Council for International Organizations of Medical Sciences
GCP: Good Clinical Practice
ICMR: Indian Council of Medical Research
SOP: Standard Operating Procedure
WHO: World Health Organization
WMA: World Medical Association