

Title: Constitution of Yenepoya Ethics Committee-1 (YEC-1); Selection, Roles and Responsibilities of the YEC-1 Members

SOP Code: SOP02/v4

Effective Date: 01/07/2023

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Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with Date <i>[Signature]</i> 7/6/23
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Details of superseded SOP02

Name of the subcommittee convenor	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 & NABH assessment

Details of current SOPv4

SOP subcomm convenor	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 The tenure of YEC-1 and YEC-1 members specified and aligned with DCGI EC registration letter Criteria for layperson as per ICMR guidelines Introductory training for members specified to include national ethical guidelines and regulations More details on responsibilities of specific roles in the ethics committee

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1. Purpose:

- 1.1. The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provide the framework for constitution, selection, roles and responsibilities of YenePOYA Ethics Committee - 1 (YEC-1) and its members.

2. Scope:

- 2.1. This SOP describes processes related to the constitution of YEC-1, selection, roles and responsibilities of members (including terms of reference for appointment of members).

3. Responsibility

3.1. The Vice Chancellor, YenePOYA deemed to be University (YU) will:

Approve the selection of Chairperson, Member-Secretary and other members of YEC-1 as per national regulations and guidelines, gender balance and institutional representation.

3.2. The Registrar, YU will:

Notify the constitution of YenePOYA Ethics Committee - 1 and ensure that the same is widely known to all through the University or Ethics Committee website/webpage.

3.3. The Chairperson will:

- 3.3.1. Approve and sign the TOR and appointment letters for all members of YEC-1.
- 3.3.2. Accept and approve resignation of any member after exploring alternatives.
- 3.3.3. Ensure that the newly joined members receive the relevant training within a period of 30 days from the date of joining YEC-1 or before the next scheduled full meeting of YEC-1 whichever is earlier.
- 3.3.4. Receive any complaints or grievances of any of the YEC-1 members and take appropriate action, in consultation with the Member-Secretary.

3.4. The Member-Secretary will:

- 3.4.1. Assist the Chairperson in selecting the members for appointment
- 3.4.2. Prepare individualized terms of reference (appointment letters) for each of the roles of the various members of YEC-1
- 3.4.3. Ensure timely training of the newly joined members in research ethics, research ethics guidelines, regulations, Indian GCP guidelines and SOP training
- 3.4.4. Ensure that all members sign copies of their terms of reference (appointment letters) and sign confidentiality agreement and declaration on conflict of interest
- 3.4.5. Forward resignation letters and complaints of YEC-1 members to the Chairperson
- 3.4.6. Communicate changes to the composition of YEC-1 to the concerned authorities as per the existing rules and regulations in force.

3.5. The YEC-1 Secretariat will:

- 3.5.1. Maintain the files on each of the members and ensure that CVs and training certificates are up to date

3.6. The YEC-1 Members will:

- 3.6.1. Read, understand, follow and perform as per their specific role in the ethics committee
- 3.6.2. Sign the requisite forms before appointment; receive training as specified; and provide updated, signed CVs from time to time

3.7. The Grievance Redressal Committee will:

- 3.7.1. Receive and hear the grievance of any researcher or other persons made against the functioning or decision-making of YEC-1
- 3.7.2. Convene a meeting, discuss the matter and report to the Vice Chancellor, YU

4. Detailed Instructions:

4.1. Organizational structure:

- 4.1.1. The organizational structure both within the University and within the Ethics Committee will be constructed by the Member-Secretary, approved by the Chairperson and University and placed as annexure in this chapter (Ann02/SOP02/v4)

4.2. Constitution of Yenepoya Ethics Committee - 1

- 4.2.1. The YEC-1 will be established by the Board of Management, YU and will be mandated within the bye-laws of YU (refer bye-law 578)
- 4.2.2. The Chairperson and Member-Secretary shall nominate potential members at the time of installation of the new committee or for residuary periods.
- 4.2.3. This will be approved by the Vice Chancellor, and notified by the Office of the Registrar.
- 4.2.4. The tenure of the YEC-1 will be for a period specified in the registration letter of the DCGI.
- 4.2.5. After notification by the Registrar, the Member-Secretary will inform the changes in the composition of YEC-1 to the concerned governmental authorities.

4.3. General composition of YEC-1:

- 4.3.1. YEC-1 will be multidisciplinary in composition and include a combination of medical and non-medical, scientific and non-scientific persons with required qualifications as prescribed by current regulations/guidelines and also include lay person(s) to represent the different regional points of view.

- 4.3.2. YEC-1 will be multi-sectoral in composition with differing backgrounds to promote complete and adequate review of research and representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of society.
- 4.3.3. As per current NDCTR-19 and ICMR requirements, the YEC-1 will consist of at least 7 members and up to a maximum of 15 members.
- 4.3.4. More members may be inducted in due course of time if there is a commensurate increase in the workload, or to represent the constituent colleges, with the prior approval from the Vice-Chancellor, YU.
- 4.3.5. YEC-1 members must have the expertise, time and commitment to perform all functions as detailed in this SOP.
- 4.4. **Non- member representation in YEC-1**
 - 4.4.1. YEC-1 may invite member(s) of specific patient groups or special interest groups for EC meeting (based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research, etc.) or independent consultants in particular areas of research for eliciting their views
 - 4.4.2. Experts in certain areas of research may be appointed as independent consultants to review the protocol and related documents. (SOP04/v4)
- 4.5. **The specific composition shall be at least as follows:**
 - 4.5.1. Chairperson (non-affiliated to the institution)
 - 4.5.2. Member-Secretary (affiliated to the institution)
 - 4.5.3. One or more members from basic medical science (at least one pharmacologist, specially if the EC is reviewing drug, device, vaccine or biological studies)
 - 4.5.4. One or more clinicians from the various institutions of the university or outside
 - 4.5.5. 1-2 legal experts (non-affiliated)
 - 4.5.6. 1-2 social scientists or representative of non-governmental agency/philosopher, ethicist or theologian
 - 4.5.7. One or more lay persons from the community as per the national ethical guidelines (non-affiliated, literate person from the community, who has not pursued any medical science or health-related career in the last five years, may be a representative of the community from which the participants are drawn, and is aware of the local language, cultural and moral values of the community. It is desirable if the layperson is involved in social and community welfare activities.)
- 4.6. **Criteria for selection of members of YEC-1**
 - 4.6.1. **Chairperson/Co-Chairperson (if any):**

- 4.6.1.1. The Chairperson/Co-Chairperson must be from outside the institution, and preferably be from the healthcare sector.
- 4.6.1.2. He/she should be a person of good-standing in society.
- 4.6.1.3. He/she should preferably have some experience as a prior EC member
- 4.6.1.4. He/she is eligible for re-appointment as Chairperson/Co-Chairperson for an one additional term

4.6.2. Member-Secretary/Joint Secretary (if any):

- 4.6.2.1. Should be a full time employee of Yenepoya (deemed to be University)
- 4.6.2.2. Should preferably be from a department doing biomedical research
- 4.6.2.3. Should have a state medical or other healthcare council recognized postgraduate degree or equivalent UGC recognized degree
- 4.6.2.4. Should have qualifications, training and expertise in biomedical research and ethics
- 4.6.2.5. Should have personal interest, capacity and good communication skills
- 4.6.2.6. He/she is eligible for re-appointment as Member-Secretary/Joint Secretary for an additional term

4.6.3. Members:

- 4.6.3.1. Selected in their personal capacity based on qualifications, experience, interest, ethical, scientific knowledge and/or expertise, without any known record of professional misconduct or criminal charges.
- 4.6.3.2. Scientists and clinicians should possess postgraduate qualifications
- 4.6.3.3. Should be committed and willing to volunteer the necessary time and effort for the work of YEC-1.
- 4.6.3.4. Members are eligible for re-appointment for two additional terms

4.7. Hierarchy:

- 4.7.1. The Chairperson/Co-Chairperson will head the committee
- 4.7.2. The Member Secretary/Joint Secretary will be the custodian of all the YEC-1 documents, the medium of communication and recorder of the expenses incurred
- 4.7.3. All other YEC-1 members will be regular committee members with equal ranking
- 4.7.4. The Secretarial staff and support staff will ably assist the Secretariat

4.8. Membership agreement, confidentiality agreement and declaration of conflict of interest

- 4.8.1. It is the responsibility of each YEC-1 member, at the time of joining the EC, to read and understand the terms of reference (appointment letter) given to him/her based on his/her role in the ethics committee (Ann02/SOP02/v4)
- 4.8.2. It is the responsibility of each YEC-1 member, at the time of joining, to read, accept and sign a membership agreement (Ann03/SOP02/v4), a confidentiality agreement (Ann01/SOP3B/v4) and a declaration of conflict of interest agreement (Ann01/SOP3A/v4).
- 4.8.3. The Secretariat will keep the originals of the signed agreements (terms of reference, membership agreement, confidentiality agreement and conflict of interest declaration) in the YEC-1 office in the individual member's files.
- 4.8.4. The Secretariat shall provide YEC-1 members photocopies of the agreement forms.

4.9. Tenure of membership:

- 4.9.1. The tenure of membership will be for a period of five years from the date of constitution, as stipulated in the DCGI's letter of recognition. This is liable to change from time to time.

4.10. Appointment of new members:

- 4.10.1. The Chairperson and Member-Secretary shall nominate members for appointment, based on the current regulatory and national guidelines, the workload on the committee and/or the vacancy position.
- 4.10.2. New members can be inducted in the following situations:
 - 4.10.2.1. When a member completes his/her tenure
 - 4.10.2.2. When a member resigns from the ethics committee before tenure completion (in which case the new member will be appointed for the residuary period)
 - 4.10.2.3. When a member ceases to be a member for various reasons including death or disqualification (in which case the new member will be appointed for the residuary period)
 - 4.10.2.4. When the membership requirements need to be met (4.2 above)

4.11. Conditions to be fulfilled by a member at the time of appointment

- 4.11.1. Members must submit an updated CV, duly signed, along with a recent passport-size photograph
- 4.11.2. Members should submit self-attested photocopies of all certificates pertaining to

qualification, training in bioethics, research ethics and ICH-GCP training.

- 4.11.3. If not trained, members should be encouraged to undergo such training 30 days from the date of joining YEC-1 or before the next scheduled full meeting of YEC-1, whichever is earlier, and submit the relevant documents for the purpose of keeping records.
 - 4.11.4. Each new inductee will be assigned - for a three-month period - a senior-serving YEC-1 member as mentor, who will provide support and guidance to the inductee, in matters pertaining to understanding the nuances of the protocol and the business of YEC-1.
 - 4.11.5. Members must be willing to have their name and affiliation publicly linked to Yenepoya Ethics Committee - 1, as on letterhead, website, etc.
 - 4.11.6. Members must sign a confidentiality agreement (Ann3A/SOP02/v4) and comply with it.
 - 4.11.7. Members must read, accept and comply with the conflict of interest policy of Yenepoya Ethics Committee - 1 and sign CoI form (Ann01/SOP3A/v4).
- 4.12. **Specific roles of YEC-1 members:**
- 4.12.1. There will two types of members in YEC-1
 - 4.12.1.1. Scientific
 - 4.12.1.2. Non-scientific
 - 4.12.2. Scientific members will consist of:
 - 4.12.2.1. **Medical:** The roles of the medical members will be to do a medical, scientific and ethical review of the health research (clinical trials) protocol-related documents assigned to them. They will fulfill quorum requirements and take part in the decision-making. As and when nominated they will perform the role of member of SAE, SMV or any other subcommittee of YEC-1.
 - 4.12.2.2. **Non-medical:** The roles of the non- medical members will be to do a scientific and ethical review of the observational, epidemiological and social science research protocol-related documents assigned to them. From this category, the Social Scientist alone will fulfill quorum requirements and take part in the decision-making. As and when nominated they will perform the role of member of SAE, SMV or any other subcommittee of YEC-1

4.12.3. Non-scientific members:

- 4.12.3.1. Legal expert: The legal expert will review the legal documents as described in SOP7A/v4.
- 4.12.3.2. Layperson: The layperson will review the informed consent documents as described in SOP7A/v4. The layperson will also take part in SMV and compensation-related events of clinical trials.
- 4.12.3.3. Theologist/ethicist/non-government organization representatives: These members will review the social, religious, cultural and ethical issues from the point of view of the community and local cultures.

4.13. Resignation of Members:

- 4.13.1. A member may resign from YEC-1 membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson, and approved by the Registrar.

4.14. Disqualification of members:

4.14.1. For not attending YEC-1 meetings:

- 4.14.1.1. A member may be disqualified from YEC-1 membership if they fail to attend more than 3 regular consecutive meetings without prior intimation. The process conducted will be as follows:
- 4.14.1.2. The Member Secretary will inform the Chairperson, if a member has not attended more than three consecutive regular meetings of the YEC-1 without prior intimation.
- 4.14.1.3. Chairperson will initiate the process of review of membership of such a member by including the matter in agenda of the next regular meeting
- 4.14.1.4. A written communication will be sent to the concerned member informing him/her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternatively, the concerned YEC-1 member will be allowed to state his/her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson.
- 4.14.1.5. The matter will be discussed and reviewed at the YEC-1 meeting. The concerned member will be provided adequate opportunity to represent his/her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.
- 4.14.1.6. The Chairperson or Member-Secretary will inform the YEC-1 members/Registrar by a confidential written communication.

4.14.2. For inappropriate conduct:

- 4.14.2.1. A member may be disqualified from continuance should YEC-1 determine, by a >50% majority specifically called for the purpose that the member's conduct has been inappropriate.
- 4.14.2.2. The Chairperson will satisfy himself/ herself that a *prima facie* case exists before initiating action.
- 4.14.2.3. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of YEC-1 could be questioned, the Chairperson may, with approval from the Office of the Registrar, provisionally suspend the membership of the concerned member till the final decision is taken.
- 4.14.2.4. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of a YEC-1 member.
- 4.14.2.5. The Chairperson may call for an emergency meeting of the YEC-1 specifically to discuss this issue. Alternatively, the matter will be taken up for discussion in a routine meeting. The meeting convened will follow the usual rules of quorum (SOP08/v4). The allegation will be discussed at the meeting and the member alleged of misconduct provided an opportunity to defend himself/herself.
- 4.14.2.6. The member would stand disqualified, if the other members present at the meeting approve of disqualification by voting (voting by >50% of members present in the meeting and voting).
- 4.14.2.7. The Chairperson will convey the disqualification to the concerned member through a written communication.

4.15. Research Ethics Training :

- 4.15.1. An individual selected as a new member of YEC-1 will be required to attend at least one meeting as an 'Observer' before being inducted as a member. In addition, he/she will be assigned a mentor.
- 4.15.2. Member Secretary/Joint Secretary or a YEC-1 member or an external experienced faculty will provide introductory training in Research Ethics, GCP, National ethical guidelines & SOPs to the new member.
- 4.15.3. A newly inducted member should submit a certificate of training, within 30 days of joining YEC-1 or before the next scheduled full meeting of YEC-1. All members will be encouraged to receive continued training by participating in workshops, conferences or re-training programs related to research ethics, as delegate, faculty, facilitator, etc.
- 4.15.4. YEC-1 will conduct in-house training sessions on research ethics, GCP and SOPs from time to time to impart continued training to YEC-1 Members.

- 4.15.5. YEC-1 may nominate and/or request the university to sponsor a member or prospective members for attending conference, continuing education session workshop and/or training program etc.

4.16. Functions:

4.16.1. Chairperson (and Co-Chairperson):

- 4.16.1.1. The Chairperson will be responsible for conducting meetings, leading all discussions and deliberations pertinent to review of research proposals and ensuring equitable distribution of the discussion by all the members.
- 4.16.1.2. In the event of tied vote on a protocol, in addition to his/her initial vote, the Chairperson has a casting vote.
- 4.16.1.3. At the start of every YEC-1 meeting the Chairperson will ensure quorum and ask members for conflict of interest.
- 4.16.1.4. The Chairperson will approve the dates for the meeting, the agenda and the minutes before these are circulated.
- 4.16.1.5. The Chairperson will preside over all administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the YEC-1 at various meetings and forums, or if unable to, will request the Co-Chairperson/Member-Secretary/Joint Secretary to do so.
- 4.16.1.6. The Chairperson will approve the Member-Secretary's signing of all documents and communications related to YEC-1 functioning.
- 4.16.1.7. The Chairperson will approve the formation of any sub-committee from among the members of the YEC-1, and will ask the Member-Secretary to communicate the same.
- 4.16.1.8. In the absence of the Chairperson, the Co-Chairperson will have all the powers and responsibilities of the Chairperson.
- 4.16.1.9. In the event both Chairperson and Co-Chairperson are absent on the day of the meeting, the Chairperson will nominate an external member as acting Chairperson or the members present may elect an alternative Chairperson, from among the external members present for the meeting. The acting Chairperson will have all the powers of the Chairperson for that meeting only.

4.16.2. Member-Secretary:

- 4.16.2.1. Member-Secretary shall receive research proposals, categorize them based on risk (full/expedited/exemption), identify reviewers/ discussants, and ensure that the protocols are sent out within the timelines.
- 4.16.2.2. Organize efficient tracking procedure for each proposal received and

- arrange for the same to be displayed in the Secretariat.
- 4.16.2.3. Identify and allocate research proposal files to the corresponding members based on their field of expertise. In case there are more than one member from a given field the Member-Secretary shall ensure that the distribution of proposals is fair and equitable.
 - 4.16.2.4. In consultation with and approval from the Chairperson, schedule and organize YEC-1 meetings and ensure that these dates are publicized.
 - 4.16.2.5. Prepare and maintain meeting agenda and minutes. These shall be approved by the Chairperson before circulating among the members.
 - 4.16.2.6. Draft the minutes of the meeting and after approval from the Chairperson, circulate within the stipulated time. A copy of the core minutes (without PI identifiers will be marked to the Registrar, YU. (SOP08/v4)
 - 4.16.2.7. Maintain YEC-1 documentation on correspondence and communication and archive them.
 - 4.16.2.8. Member-Secretary shall have the responsibility of communicating with the YEC-1 members, applicants/ investigators and University.
 - 4.16.2.9. Member-Secretary shall notify the Principal Investigator regarding YEC-1's decisions related to the submitted research proposal.
 - 4.16.2.10. The Member-Secretary shall arrange for the training of the personnel and the YEC-1 members, in the areas of research ethics and SOPs. While preparing the calendar list of meeting dates the Member-Secretary shall also prepare a tentative list of training sessions for the year.
 - 4.16.2.11. Organize the preparations, review, revision and distribution of SOPs and guidelines.
 - 4.16.2.12. Provide necessary administrative support for YEC-1 related activities to the Chairperson and the various subcommittees of YEC-1.
 - 4.16.2.13. Provide updates on relevant and contemporary issues to ethics in health research as well as relevant government circulars/guidelines to the committee members.
 - 4.16.2.14. Receive ethics committee review processing fees and a copy of the official receipt from the University accounts office.
 - 4.16.2.15. Delegate various responsibilities to appropriate and authorized individuals and ensure adherence to SOPs.
 - 4.16.2.16. Prepare for audits and inspections.
 - 4.16.2.17. Prepare and make available for scrutiny by auditors/inspectors annual

reports/annual financial statements of the YEC-1.

- 4.16.2.18. Prepare and make available for scrutiny to YEC-1 members a collective assessment of YEC-1 activities including review time and completion, conduct of meetings post-approval activities and training activities.
- 4.16.2.19. Be the custodian for all documents, materials and equipment of YEC-1
- 4.16.2.20. The Joint-Secretary (if any) will have all the powers and responsibilities of the Member-Secretary, in the absence of the Member-Secretary.
- 4.16.2.21. Nominate an internal member as acting Secretary in case Member-Secretary and Joint-Secretary are both absent on the meeting day. The acting Secretary will have all the powers of the Member-Secretary for that meeting only.

4.16.3. YEC-1 members:

- 4.16.3.1. YEC-1 members must receive, read and familiarize themselves with a copy of the SOPs relating to the functioning of the YEC-1.
- 4.16.3.2. They must sign the appointment letter (terms of reference) stating that they will abide by the rules/regulations of the university and YEC-1.
- 4.16.3.3. YEC-1 members shall attend YEC-1 meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at. In case of inability, the member must submit a leave note in writing and the absence of the member should be recorded in the minutes.
- 4.16.3.4. Actively engage in review, discussion and considerations of the ethical issues in research proposals submitted for evaluation.
- 4.16.3.5. Members must sign the confidentiality agreement and abide by it throughout the term of membership and beyond if need be.
- 4.16.3.6. Monitor SAE reports, as submitted to YEC-1, and recommend appropriate action(s) which will be communicated by Member-Secretary.
- 4.16.3.7. Review the progress reports and monitor ongoing studies as appropriate, and recommended by the Chairperson.
- 4.16.3.8. Participate in any role in the YEC-1 subcommittees, whenever requested
- 4.16.3.9. Approve the agenda and minutes of the YEC-1 meetings.
- 4.16.3.10. Declare any conflict of interest in writing to the Chairperson, if any, at each meeting. In case they fail to do so in writing, they can announce the same at the start of the meeting when the Chairperson asks for it.
- 4.16.3.11. Participate in continuing education and training activities in biomedical ethics and biomedical research and submit the certificates for records to

the Secretariat and attend and submit the certificate of initial training within 30 days from the date of joining YEC-1 or before the next scheduled full meeting of YEC-1.

- 4.16.3.12. Provide updated CV when requested by the YEC-1 secretariat
- 4.16.3.13. Carry out work delegated by Chairperson, Member-Secretary and assist in the smooth functioning of the YEC-1.

4.16.4. Secretariat:

- 4.16.4.1. The Secretariat will be composed of administrative support staff. (1-2 second division assistants and 1 or more office assistant). Hereinafter, for the purpose of all the SOP chapters in this version of the manual, the term Secretariat will mean the support staff – not including the office assistant – assigned to the YEC-1
- 4.16.4.2. The Secretariat will maintain the database of protocols in one or more Excel spreadsheets and update these regularly. They will ensure backup of the database into an external hard disk drive at one fixed time of the week.
- 4.16.4.3. The Secretariat will ensure that the desktop computers and external hard disk drive are stored securely and the password to access these are updated frequently. The external hard disk drive shall in addition be stored in a safe deposit locker, at a site away from the YEC-1 Secretariat.
- 4.16.4.4. The Secretariat will maintain the logs of all the activities of the YEC-1 including the shredding, despatch and end-user assistance.
- 4.16.4.5. Secretariat will support the Member Secretary in all their functions
- 4.16.4.6. All the staff of the Secretariat will sign the confidentiality agreement which should be filed with YEC-1 (Ann3B/SOP02/v4)
- 4.16.4.7. The working rules for Secretariat are stated in Ann01/SOP02/v4.

4.17. Scope/ Types of projects reviewed by YEC-1:

- 4.17.1. The type of studies reviewed by YEC-1 will be determined by the University through a notification. YEC-1 will review scientific and ethical aspects of all types of research studies involving human participants:
 - 4.17.1.1. Regulatory Clinical trials sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in collaborations with international organizations/universities
 - 4.17.1.2. PhD Studies
 - 4.17.1.3. Investigator-initiated clinical trials which are self funded (aka Academic Clinical Trial)

- 4.17.1.4. Research studies which are funded by institutional funding bodies or any other funding agency
- 4.17.1.5. Research studies submitted by faculty members, research scholars, doctoral, post-graduate and under-graduate students
- 4.17.1.6. Review of manuscripts for publications

4.18. Honorarium to the members:

- 4.18.1. Internal members shall do all the duties as provided in the SOP with or without any remuneration, as decided by the University, from time to time.
- 4.18.2. External members of the YEC-1 will be provided local transport and an honorarium as per existing rules/norms, from time to time.
- 4.18.3. The Secretariat will inform the Finance Officer the list of the external members who attended the meeting after every meeting.
- 4.18.4. Finance Officer shall transfer the amount to account number of the external members or provide a cheque after the meeting is concluded
- 4.18.5. The Secretariat will take signatures of external members on the receipt vouchers and file them.

4.19. Preparing an annual activity report of the YEC-1

- 4.19.1. It is the responsibility of the Member-Secretary to make the annual report.
- 4.19.2. Once approved by the Chairperson, it shall be circulated among members.
- 4.19.3. A copy will be sent to the Registrar, and one copy maintained in the Secretariat.
- 4.19.4. This report should contain all the details of the activities of the YEC-1 in the calendar year and should at least include information on
 - 4.19.4.1. Membership details including changes in the membership
 - 4.19.4.2. Number and dates of the YEC-1 meetings
 - 4.19.4.3. Number of SAE subcommittee and any other subcommittee
 - 4.19.4.4. Numbers and types of proposals reviewed in a year, status of each study proposal whether completed /ongoing / terminated.
 - 4.19.4.5. Number of approvals for full/expedited/exempted reviews with decisions
 - 4.19.4.6. Brief details about workshops, training programmes and other activities undertaken by YEC-1 and those attended by members

4.20. Grievances against the YEC-1

- 4.20.1. If any of the stakeholders including researchers, sponsors, participants or any other individual has a complaint or grievance against the YEC-1 functioning,

they may approach the Grievance Redressal Committee, with a complaint submitted in writing.

- 4.20.2. The YEC-1 Grievance Redressal Committee constituted by the Vice Chancellor, will look into the grievances and submit a report to the Vice Chancellor recommending appropriate action.

4.21. Appellate authority of the Vice Chancellor, YU:

- 4.21.1. Anyone having a grievance against the recommendation of the Grievance Redressal Committee he/she can appeal against such a decision in writing to the Vice Chancellor, YU with a copy marked to the YEC-1 Secretariat.
- 4.21.2. The Vice Chancellor can consider the matter by hearing both sides and taking a decision, keeping in mind the laws, regulations and guidelines in current use in the country. The Vice Chancellor's decision will be final.

4.22. YEC-1 Secretarial staff:

- 4.22.1. There will be an administrative officer (Secretariat) /assistant(s) and attendant(s) /helper(s) who will help the YEC-1 Chairperson and Member-Secretary in executing functions of the YEC-1.
- 4.22.2. The administrative staff will be appointed as per the University rules/regulations prevailing from time to time. However, the Chairperson may recommend names to the University after due discussion in the YEC-1 meeting, which shall be recorded in the minutes.
- 4.22.3. Additional staff may be appointed and duties assigned; as and when deemed necessary by the YEC-1, in consultation with the University. Eligibility criteria for staff to be appointed will be laid down depending on the required job profile.
- 4.22.4. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of leaves may be decided by the University from time to time.
- 4.22.5. Administrative staff will report to the Chairperson and/or Member-Secretary.

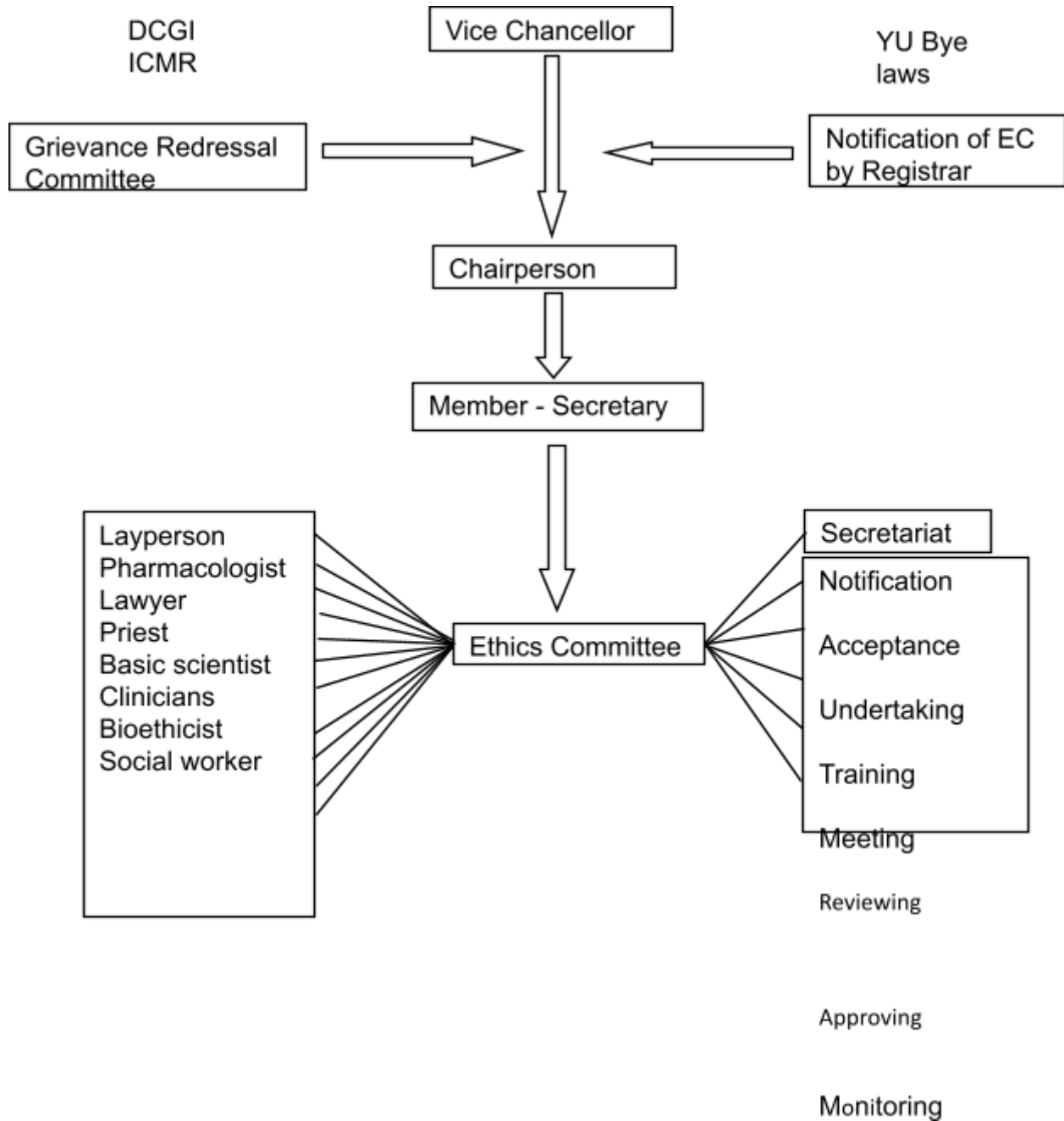
4.23. Duties of the Secretariat: On behalf of and under the instructions of the Member-Secretary and the YEC-1:

- 4.23.1. Carry out the correspondence with YEC-1 Chairperson, members, external experts, and University officials.
- 4.23.2. Communicate with the newly appointed members, the terms of reference, agreement letters, etc
- 4.23.3. Communicate with the Principal Investigators
- 4.23.4. Assist the Member-Secretary in preparing the agenda, agenda notes and minutes of the YEC-1 meetings

- 4.23.5. Maintain filing, classifying & archiving of all protocol documents
- 4.23.6. Maintain the filing and archiving of the SOPs (all versions), member files
- 4.23.7. Maintain copies of relevant guidelines, regulations and government circulars related to ethical review of biomedical research
- 4.23.8. Maintain, update, backup and protect the electronic database of YEC-1 records
- 4.23.9. Respond to general enquiries, attend to telephone calls and emails
- 4.23.10. Send email reminders to members who default on review deadline
- 4.23.11. Send email reminders to the Principal Investigators for resubmissions/ continuing reports/ completion reports
- 4.23.12. Coordinate functions of subcommittees, audits and site monitoring
- 4.23.13. Assist in the audit/ inspection of the ethics committee.
- 4.23.14. Coordinate training program of the EC members
- 4.23.15. Perform any other duties assigned by Chairperson, related to working of YEC-1
- 4.24. **Duties of the attender/helper:**
 - 4.24.1. Assisting the Secretariat in arranging the YEC-1 meetings
 - 4.24.2. Dispatching study documents to YEC-1 members and ICs
 - 4.24.3. Dispatch of post and couriers of the YEC-1
 - 4.24.4. Receiving documents from and dispatching letters to concerned parties
 - 4.24.5. Assist the Secretariat in filing, archiving and maintaining of files
 - 4.24.6. Assisting the Secretariat during YEC-1 meetings
 - 4.24.7. Any other work as assigned by the Chairperson, related to the working of YEC-1
5. **References:**
 - 5.1. Conflict of interest policy for YenePOYA Ethics Committee - 1 (SOP03/v4)
 - 5.2. Agenda preparation/Meeting procedures/Recording of Minutes (SOP08/v4)
6. **Annexures:**
 - 6.1. Ann01/SOP02/v4: Organizational Chart of the YEC-1 and place in YU
 - 6.2. Ann02/SOP02/v4: Terms of reference for the members
 - 6.3. Ann03/SOP02/v4: Membership Agreement Form for YEC-1 members

Ann01/SOP02/v4

Organizational Chart of the Yenepoya Ethics Committee - 1 and its place in the University



Ann02/SOP02/v4: Terms of reference for the members at the time of appointment

All members	<p>Appointment to YEC-1 with designation Term of office Train in SOPS, Research Ethics, GCP Submit updated Curriculum Vitae and training certificates Conduct scientific and ethical review of protocols, adhere to timelines Adhere to SOPs Follow the current applicable guidelines Attend meetings regularly Contribute actively to the deliberations and discussions in the meetings Participate in the subcommittees, whenever required Participate in the post-approval activities, whenever required Abide by the confidentiality agreement Abide by the conflict of interest declaration agreement Maintain good conduct and integrity as a member</p>
External members	<p>Encourage and guide YEC-1 to take an independent and free decision Provide details of bank account and PAN for the purpose of remuneration and reimbursement of travel expenses</p>
Internal members	<p>Assist the YEC-1 in its smooth functioning</p>
Chairperson	<p>Head the YEC-1 Lead the discussions and deliberation during the meetings Preside over the administrative matters of the YEC-1 Ensure adherence to current SOPS and guidelines Ensure a timely ethical review process</p>
Member-Secretary	<p>Receive, categorize, allocate the protocols Sign the approval of the protocols Prepare and maintain the agenda and minutes of the meeting Plan and conduct training activities Schedule and conduct post-approval activities Prepare and respond to audits and inspections of the YEC-1 Maintain the archival of files Coordinate with members the activities of the YEC-1</p>
Legal expert	<p>Review of protocol with emphasis on legal issues, compensation, agreements, MoUs, Insurance, Indemnity, permissions and other documents in the protocol</p>
Social scientist/ theologist/bioethicist	<p>Review of protocol with emphasis on ethical, social, cultural & religious issues</p>
Layperson	<p>Review of protocol with emphasis on informed consent document- language, content and translation with local communities in mind</p>
Clinician	<p>Review of protocol with emphasis on ethical and clinical aspects, complications, management of complications issues in the protocol</p>
Basic scientist	<p>Ethical review of protocol (emphasis on basic scientific issues, IND details, clinical trial phases, genomic/laboratory research, etc)</p>

Ann03/SOP02/v4

Membership Agreement Form for YEC-1 members

I, Dr/Mr/Ms _____ (*Member's name, his/her position on YEC-1 and affiliation*) herein referred to as the "undersigned" have been appointed as a member of Yenepoya Ethics Committee - 1 (YEC-1) and have been asked to carry out ethical review of research studies involving human participants in order to ensure that such studies are conducted in a humane and ethical manner, adhering to the highest standards of care as per the international national and local regulations/guidelines and institutional policies. I understand that my appointment as member of YEC-1 is based on individual merits and not as an advocate or representative of a territory, or community, nor as a delegate of any organization. I am aware that YEC-1 must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of participants and that as a member of YEC-1, I will meet the standards of ethical behavior to carry out its mandate. I agree to sign the confidentiality agreement and abide by it. I agree to the Conflict of interest declaration policy of YEC-1 and abide by it. I have been given the current SOP manual (Soft copy). I agree to take part in the training programs organized by the YEC-1 for the members. I agree to take part in the review process and adhere to the timelines.

Signature of the member with date

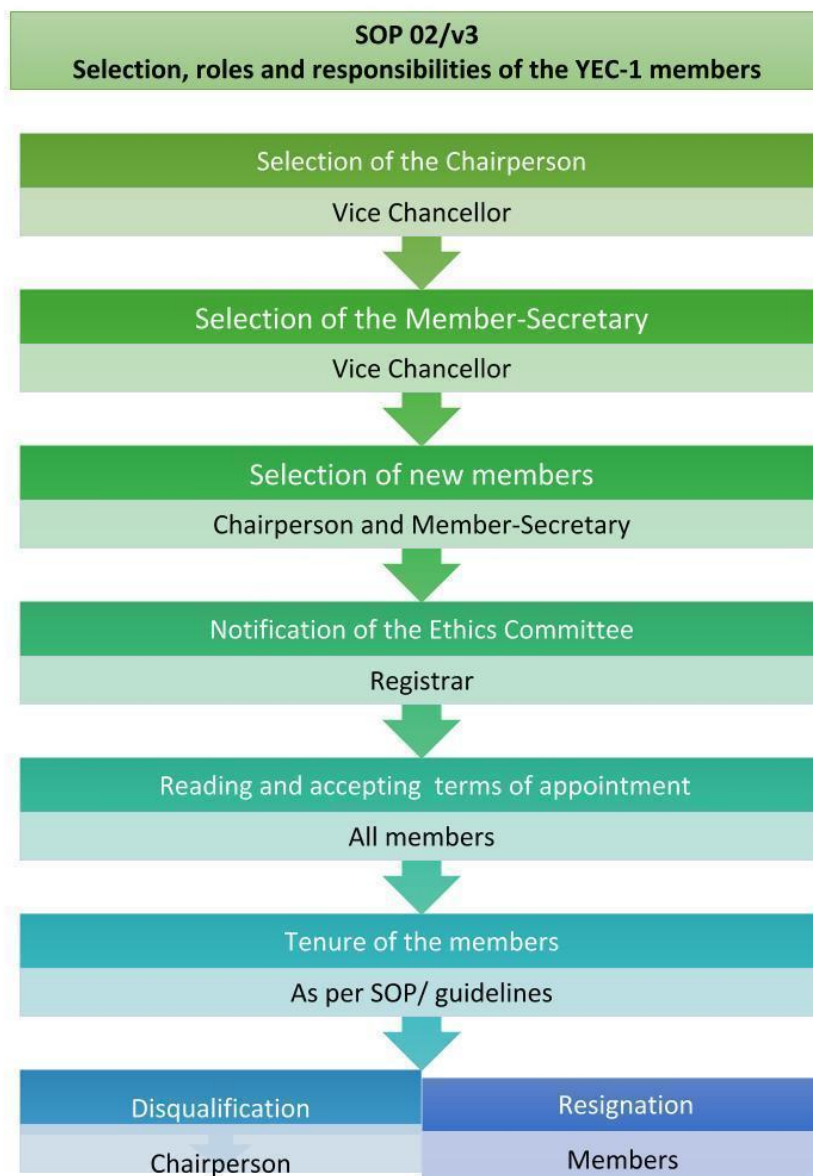
Chairperson's Signature with date

[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat YEC-1. A copy will be given to the Undersigned.]

I acknowledge that I have received a copy of the signed Membership Agreement

Signature with date

7. Flowchart:



8. Glossary:

- CDSKO: Central Drugs Standard Control Organization
- GCP: Good Clinical Practice
- ICH-GCP: International Committee for Harmonization - Good Clinical Practice
- ICMR: Indian Council of Medical Research
- NDCTR-19: New Drugs and Clinical Trials Rules 2019
- SAE: Serious Adverse Event
- SOP: Standard Operating Procedure
- ToR: Terms of Reference