



YENEPOYA
[DEEMED TO BE UNIVERSITY]
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YENEPOYA ETHICS COMMITTEE 2
DHR registration No.: EC/NEW/INST/2023/KA/0276
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Constitution of YEC2
YEC2/SOP02/v3
Effective Date: 25.02.2023

Title: Constitution of YEC2, Selection, Role and Responsibilities of the member

SOP Code: YEC2/SOP02/v3

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Notified by:

Registrar, Yenepoya (Deemed to be university) Notification No: Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date <i>Prasanna Keshava B</i> 25/02/23
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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 2 (YEC2) and its members and procedures for maintaining confidentiality of all activities and documents.

2. Scope:

2.1. This SOP describes processes related to the constitution of YEC2, selection, roles and responsibilities of members of YEC2 and maintenance of confidentiality of all activities and documents.

3. Responsibility

3.1. The Vice Chancellor, Yenepoya (Deemed to be University) will:

Approve the selection of Chairperson, Member-Secretary and all other members of YEC2 keeping in mind, gender balance and institutional representation.

3.2. The Registrar, Yenepoya (Deemed to be University) will:

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

3.3. The Grievance Redressal Committee will:

- 3.3.1. Receive and hear the grievance of any researcher or other persons made against the functioning or decision-making of YEC2.
- 3.3.2. Convene a meeting, discuss the matter and report to the Vice Chancellor

3.4. The YEC2 Members will:

3.4.1. Read, understand, follow and respect all the SOPs, in force, from time to time.

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 University and placed as annexure in this chapter (YEC2/Ann02/SOP02/v3)

4.2. Constitution of Yenepoya Ethics Committee 2

4.2.1. The YEC2 will be established by the Board of Management, Yenepoya (Deemed to be university) and will be mandated within the bye-laws of Yenepoya (Deemed to be University)

4.2.2. The Chairperson and Member-Secretary will nominate potential members at the time of installation of the new committee and 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 YEC2 will be for a period of 5 years from the date of registration letter of the DCGI

4.3. General composition of YEC2

4.3.1. YEC2 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 persons to represent the different regional points of view.

- 4.3.2. The YEC2 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 CDSCO and ICMR requirements, the YEC2 will consist of at least 7 members and upto a maximum of 15 members.
- 4.3.4. YEC2 members must have the expertise, time and commitment to perform all functions as detailed in this SOP.
- 4.3.5. 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, Yenepoya (Deemed to be University).

4.4. Non- member representation in YEC2

- 4.4.1. YEC2 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 included as independent consultants to review the protocol and related documents.
(YEC2/SOP04/V3)

4.5. The specific composition shall be at least as follows:

- 4.5.1. Chairperson (non-affiliated to the institution): Will be from among the external members in the YEC2, serving under any category, but

preferably from the healthcare sector and should preferably have prior experience in working on an ethics committee.

- 4.5.2. Co-Chairperson (optional) (non-affiliated to the institution): Will be from among the external members in the YEC2, serving under any category.
- 4.5.3. Member-Secretary (affiliated to the institution): Will be from Yenepoya (Deemed to be University), be a qualified postgraduate teacher, having qualification/training in research ethics, and preferably have work experience as ethics committee member.
- 4.5.4. One or more members from basic medical science (preferably pharmacologist, especially if reviewing drug, device, vaccine or biological)
- 4.5.5. One or more clinicians from the various constituent of the university.
- 4.5.6. One legal expert (a senior advocate or retired judge) (non-affiliated)
- 4.5.7. One social scientist or representative of non-governmental agency
- 4.5.8. One philosopher, ethicist or theologian
- 4.5.9. One or more lay persons from the community

Note: All members must receive initial and continuous training in human research ethics and documentary proof of this should be filed with the Secretariat(ICH-GCP training is valid upto 3years).

4.6. Criteria for selection of members of YEC2

4.6.1. Chairperson and Co-Chairperson (optional):

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4.6.1.1. The Chairperson must be from outside the institution, and preferably be from the healthcare sector whereas, the Co-Chairperson need not 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 previous experience as an EC member.

4.6.1.4. He/she is eligible for re-appointment as Chairperson for a maximum of 1 additional term of 5 years.

4.6.2. Member-Secretary:

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. He/she would be desirous to have altruistic attitude, capacity and good communication skills.

4.6.2.6. He/she is eligible for re-appointment as Member-Secretary for a maximum of one additional term of 5 years.

4.6.3. Members:

- 4.6.3.1. Will be selected in their personal capacities based on their qualifications, experience, interest, ethical and scientific knowledge and/or expertise, without any known record of professional misconduct or criminal charges.
- 4.6.3.2. Medical scientists, 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 YEC2.
- 4.6.3.4. Conflicts of interest should be avoided, and a process laid down to declare such conflicts in a transparent manner (YEC2/ SOP02/v3)
- 4.6.3.5. Members are eligible for re-appointment for a maximum of 2 terms as per YU bye laws.

4.7. Hierarchy:

- 4.7.1. The Chairperson will head the committee.
- 4.7.2. In his/her absence, Co-Chairperson (optional) will head the committee.
- 4.7.3. If a Co-Chairperson is not appointed, the acting Chairperson will head the committee. (For details on acting Chairperson, refer 3.13.1.5 below)
- 4.7.4. The Member Secretary will be the guardian of all documents in the possession of the committee and the expenses incurred.
- 4.7.5. Other YEC2 members will be regular committee members with equal ranking.

4.8. Membership agreement, confidentiality agreement and Declaration of Conflict of interest agreement

- 4.8.1. It is the responsibility of each YEC2 member, at the time of joining the EC, to read, understand the terms of reference given to him/her based on his/her role in the ethics committee YEC2/Ann02/SOP02/v3.
- 4.8.2. It is the responsibility of each YEC2 member, at the time of joining to accept and sign membership agreement (YEC2/Ann03/SOP/02/v3).
- 4.8.3. It is the responsibility of each YEC2 member, at the time of joining to read, understand their role, accept & sign confidentiality agreement YEC2/Ann01/SOP02/v3
- 4.8.4. It is the responsibility of each YEC2 member, at the time of joining the EC, to read, understand their role, accept and sign the declaration of conflict of interest agreement (YEC2/Ann01/SOP02/v3)
- 4.8.5. The Secretariat shall provide YEC2 members photocopies of the agreement forms and hand over one copy to the members.
- 4.8.6. The Secretariat will keep the originals of the signed agreements (terms of reference, membership agreement, confidentiality agreement and conflict of interest declaration)

4.9. Tenure of membership:

- 4.9.1. The tenure of membership will be for a period of five years from the date of appointment
- 4.9.2. The members may be re appointed for two more years.

4.10. Appointment of new members:

- 4.10.1. The Chairperson and Member-Secretary shall, after discussion with the other YEC2 members, nominate members to the YEC2 which is notified by the Registrar, Yenepoya (Deemed to be University).
- 4.10.2. The Chairperson and Member-Secretary shall, after discussion with the other YEC2 members, nominate members for appointment, based on the current regulatory and National guidelines, the vacancy position.
- 4.10.3. New members can be inducted in the following situations:
 - 4.10.3.1. When a member completes his/her tenure
 - 4.10.3.2. When a member resigns the ethics committee before tenure completion (in which case the new member will be appointed for the residuary period)
 - 4.10.3.3. 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)
 - 4.10.3.4. When the membership requirements need to be met (4.2 above)

4.11. Conditions to be fulfilled by a member after appointment

- 4.11.1. Members must submit an updated CV, duly signed, along with a recent passport-size photograph.
- 4.11.2. Members should also submit self-attested photocopies of any or all documents pertaining to training in bioethics, research ethics and/or GCP-ICH training.
- 4.11.3. If not trained, members should be encouraged to undergo such training

within 9 months from the date of joining, and submit the relevant documents for the purpose of keeping records.

4.11.4. Members must be willing to have their name and affiliation publicly linked to Yenepoya Ethics Committee 2, as on letterhead, website, etc.

4.11.5. Members must sign a confidentiality agreement (YEC2/Ann3A/SOP02/v3) and to the best of their ability maintain confidentiality regarding the deliberations and other business matters in the meeting, the content of research proposals, details on participants, and any other matter directly or indirectly related to the research protocols or the ethical review process.

4.11.6. Members must read, understand accept and comply with the conflict of interest policy of Yenepoya Ethics Committee 2 and sign CoI form (YEC2Ann01/SOP02/v3).

4.11.7. The following qualities are expected in the YEC2 members

- a. Experience and education
- b. Interest and motivation
- c. Commitment and availability
- d. Respect for divergent opinions
- e. Integrity and diplomacy

4.12. Resignation of Members:

4.12.1. A member may resign from YEC2 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 Registrar,

Yenepoya (Deemed to be University).

4.13. Disqualification of members:

4.13.1. For not attending YEC2 meetings:

A member shall be relieved of his/her membership in case of

- 4.13.1.1. Conduct unbecoming for a member of the YEC2
- 4.13.1.2. Failure to attend more than 3 consecutive meetings with prior Information (Leave absence annexure).
- 4.13.1.3. Failure to attend more than 6 consecutive YEC2 meeting in a year
- 4.13.1.4. Relocation to another city or any such matter
- 4.13.1.5. In all such situation the Member secretary will inform the Chairperson in writing.
- 4.13.1.6. The Chairperson will initiate the process of review of membership of such a member by including the matter in the agenda of the next regular meeting of the YEC2 (The relieving process will be followed as per the SOP08/v3)
- 4.13.1.7. 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. Alternately, the concerned YEC2 member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson.
- 4.13.1.10. The matter will be discussed and reviewed at the YEC2 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.

4.13.1.11. The Chairperson or Member-Secretary will inform the YEC2 members about the cessation of membership by a confidential written communication to other members of YEC2 or at the next meeting of YEC2.

4.13.2. For inappropriate conduct:

4.13.2.1. A member may be disqualified from continuance should YEC2 determine, by a >50% majority specifically called for the purpose that the member's conduct has been inappropriate.

4.13.2.2. The Chairperson will satisfy himself/ herself that a *prima facie* case exists before initiating action.

4.13.2.3. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of YEC2 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.

4.13.2.4. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of a YEC2 member.

4.13.2.5. The Chairperson may call for an emergency meeting of the YEC2 specifically to discuss this issue. Alternately, the matter will be taken up for discussion in a routine meeting. The meeting convened will follow the usual rules of quorum (SOP08/V3). The allegation will be discussed at the meeting and the member alleged of misconduct provided opportunity to defend himself/herself.

- 4.13.2.6. 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).
- 4.13.2.7. The Chairperson will convey the disqualification to the concerned member through a written communication.

4.14. Research Ethics Training :

- 4.14.1. An individual selected as a new member of YEC2 will be required to attend one meeting as an ‘Observer’ before being inducted as a member.
- 4.14.2. Member Secretary or a YEC2 member will provide introductory training in Research Ethics, GCP & SOPs to the new member.
- 4.14.3. A newly inducted member should submit certificate of training within 9 months. All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- 4.14.4. YEC2 will conduct in-house training sessions on research ethics, GCP and SOPs from time to time to impart training to YEC2 Members.
- 4.14.5. YEC2 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.

4.15. Functions:

4.15.1. Chairperson:

- 4.15.1.1. The Chairperson will be responsible for conducting meetings,

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leading all discussions and deliberations pertinent to the review of research proposals.

- 4.15.1.2. The Chairperson will preside over all administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the YEC2 at various meetings and forums, or if unable to, will request the Member-Secretary to do so.
- 4.15.1.3. The Chairperson will approve the Member-Secretary's signing of all documents and communications related to YEC2 functioning.
- 4.15.1.4. The Chairperson will approve the formation of the SOP Committee from among the members of the YEC2, and will ask the Member-Secretary to communicate the same.
- 4.15.1.5. In case of anticipated absence of the Chairperson at a planned meeting, the Chairperson will in advance and in writing and the Co-Chairperson will function in his/her behalf.
- 4.15.1.6. If a Co-Chairperson is not appointed, the Chairperson will nominate an external member as acting Chairperson or the members present may elect an alternative Chairperson, from among the members present for the meeting
- 4.15.1.7. The acting Chairperson will have all the powers of the Chairperson for that meeting only.
- 4.15.2. **Co-Chairperson: (Whenever applicable)**
 - 4.15.2.1. In the absence of the Chairperson, the Co-Chairperson will have the same functions as the Chairperson

4.15.3. Member-Secretary:

- 4.15.3.1. Through the Secretariat, the Member-Secretary shall receive research proposals on behalf of the YEC2
- 4.15.3.2. Organize efficient tracking procedure for each proposal received and arrange for the same to be displayed in the Secretariat.
- 4.15.3.3. Prepare, maintain and distribute research proposal files. Determine whether a proposal needs an exempt from ethical review or be taken as expedited review or be kept for full review.
- 4.15.3.4. 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.
- 4.15.3.5. The Member-Secretary shall, in consultation with and approval from the Chairperson, schedule and organize YEC2 meetings. The list of meetings for the whole year shall be maintained in the form of a calendar approved and notified by the Registrar, Yenepoya (Deemed to be University), at the start of every calendar year.
- 4.15.3.6. The Member-Secretary shall prepare and maintain meeting agenda and minutes. These shall be approved by the Chairperson before the Member-Secretary circulates among the members.
(YEC2/SOP08/V3)
- 4.15.3.7. The Member-Secretary will draft the minutes of the meeting and after approval from the Chairperson, must be circulated within the

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stipulated time. A copy of the core minutes should be marked to the Registrar, Yenepoya (Deemed to be University) (YEC2/SOP08/v3)

- 4.15.3.8. The Member-Secretary shall maintain YEC2 documentation on correspondence and communication and archive them.
- 4.15.3.9. Member-Secretary shall have the responsibility of communicating with the YEC2 members, applicants/ investigators and University.
- 4.15.3.10. Member-Secretary shall notify the Principal Investigator regarding YEC2's decisions related to the submitted research proposal.
- 4.15.3.11. The Member-Secretary shall arrange for the training of the personnel and the YEC2 members. In this regard, while preparing the calendar list of meeting dates the Member-Secretary shall also prepare a tentative list of training sessions for the year.
- 4.15.3.12. Organize the preparations, review, revision and distribution of SOPs and guidelines.
- 4.15.3.13. Provide necessary administrative support for YEC2 related activities to the Chairperson.
- 4.15.3.14. Provide updates on relevant and contemporary issues to ethics in health research as well as relevant government circulars/guidelines to the committee members.
- 4.15.3.15. Receive ethics committee review processing fees on behalf of the University and arrange for the issue of official receipt from the University accounts office.

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- 4.15.3.16. Delegate various responsibilities to appropriate and authorized individuals and ensure adherence to SOPs.
- 4.15.3.17. Prepare for audits and inspections
- 4.15.3.18. Prepare and make available for scrutiny by auditors/ inspectors annual reports/ annual financial statements of the YEC2.
- 4.15.3.19 In case of anticipated absence of Member secretary at a scheduled meeting, the Chairperson / Member secretary will nominate an internal member as acting Secretary or the members present may elect an alternative Secretary, from among the members present for the meeting.
- 4.15.3.20. The acting Secretary will have all the powers of the Member-Secretary for that meeting only.
- 4.15.4. YEC2 members:**
- 4.15.4.1. YEC2 members must receive, read and familiarize themselves with a copy of the SOPs relating to the functioning of the YEC2. They must sign a joining letter stating that they will abide by the rules/regulations of the university and YEC2.
- 4.15.4.2. YEC2 members shall attend YEC2 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.
- 4.15.4.3. Actively engage in review, discussion and considerations of the

- ethical issues in research proposals submitted for evaluation.
- 4.15.4.4. Members must sign the confidentiality agreement and abide by it throughout the term of membership and beyond if need be.
 - 4.15.4.5. Monitor serious adverse event reports, as submitted to the YEC2, and recommend appropriate action(s) which will be communicated by the Member-Secretary.
 - 4.15.4.6. Review the progress reports and monitor ongoing studies as appropriate, and recommended by the Chairperson.
 - 4.15.4.7. Carry out site monitoring visits as and when necessary and recommended by the Chairperson and communicated by the Member-Secretary.
 - 4.15.4.8. Evaluate final reports and outcomes in the YEC2 meetings.
 - 4.15.4.9. 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.
 - 4.15.4.10. Participate in continuing education activities in biomedical ethics and biomedical research and submit the certificates for records to the Secretariat.
 - 4.15.4.11. Provide updated CV when requested by the YEC2 secretariat
 - 4.15.4.12. Carry out work delegated by Chairperson, Member-Secretary and assist in the smooth functioning of the YEC2

4.15.5. Secretariat:

- 4.15.5.1. The Secretariat will be composed of administrative support staff. (1-2 second division assistants and 1 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 YEC2
- 4.15.5.2. The Secretariat will support the Member Secretary in all their functions.
- 4.15.5.3. All the staff of the Secretariat will sign the confidentiality agreement which should be filed with YEC2 (YEC2/Ann3B/SOP02/v3)
- 4.15.5.4. The working rules for Secretariat are stated in (YEC2/Ann01/SOP02/v3.)

4.15.6 Scope/ Types of projects reviewed by YEC2:

- 4.15.6.1. The type of studies reviewed by YEC2 will be determined by the University through a notification. YEC2 will review scientific and ethical aspects of all types of research studies involving human participants:
- 4.15.6.2. Regulatory Clinical trials sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in collaborations with international organizations/universities,
- 4.15.6.3. PhD Studies
- 4.15.6.4. Investigator initiated research studies which are self funded
- 4.15.6.5. Research studies which are funded by institutional funding bodies or any other funding agency

4.15.6.6. Review of manuscripts for publications.

4.16. Honorarium to the members:

4.16.1. Members internal to Yenepoya (Deemed to be University) shall do all the duties as provided in the SOP without any remuneration. However, the University will be encouraged to provide for their training in research ethics.

4.16.2. External members of the YEC2 will be provided local transport and an honorarium as per existing rules/norms, from time to time.

4.16.3. The Secretariat will inform the Finance Officer the list of the external members who attended the meeting.

4.16.4. The Finance officer shall transfer the amount to the account number of the external members or provide the same in the form of a cheque after the meeting is concluded

4.16.5. Secretariat will take signature of external members on the receipt voucher.

4.16.6. The receipt copies shall be maintained at the Secretariat.

4.17. Preparing an annual activity report of the YEC2

4.17.1. It is the responsibility of the Member-Secretary to make the annual report.

4.17.2. Once approved by the Chairperson, it shall be circulated among members.

4.17.3. A copy will be sent to the Registrar of Yenepoya (Deemed to be University) and one copy maintained in the secretariat.

4.17.4. This report should contain all the details of the activities of the YEC2 in the calendar year and should at least include information on:-

- Number and dates of the YEC2 meetings
- Number of SAE subcommittee and any other subcommittee
- Numbers and types of proposals reviewed in a year, status of each study proposal whether completed /ongoing / terminated.
- Number of approvals for full/expedited reviews with decisions
- Brief details about workshops, training programmes and other activities undertaken by YEC2 and those attended by members.

4.18. Grievances against the YEC2

- 4.18.1. If any of the stakeholders including researchers, sponsors, participants or any other individual has a complaint or grievance against the YEC2 functioning, they may approach the Grievance Redressal Committee, with a complaint submitted in writing.
- 4.18.2. The YEC2 Grievance Redressal Committee constituted by the Vice Chancellor and will look into the grievances and submit report to the Vice Chancellor recommending appropriate action.

4.19. Appellate authority of the Vice Chancellor, Yenepoya (Deemed to be University):

- 4.19.1. Anyone having a grievance against the recommendation of the Grievance Redressal Committee he/she can appeal against such decision in writing to the Vice Chancellor, Yenepoya (Deemed to be University) with a copy marked to the YEC2 Secretariat.

4.19.2. 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.

4.20. YEC2 (Administrative staff) Secretariat:

4. 20.1. There will be administrative officer (Secretariat) /assistant(s) and attendant(s) /helper(s) who will help the YEC2 Chairperson and Member-Secretary in executing functions of the YEC2.

4. 20.2. 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 YEC2 meeting, which same shall be recorded in the minutes.

4. 20.3. Additional staff may be appointed and duties assigned; as and when deemed necessary by the YEC2, in consultation with the University. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile.

4. 20.4. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of leaves maybe decided by the University from time to time.

4. 20.5. Administrative staff, Secretariat will report to Chairperson and/or Member-Secretary.

4. 20.6. **Duties of the Secretariat:** On behalf of and under the instructions of the Member-Secretary and the YEC2:

- Carry out the correspondence with YEC2 Chairperson, members, external experts, and University officials.

- Communicate with the newly appointed members, the terms of reference, agreement letters, etc
- Communicate with the Principal Investigators
- Assist the Member-Secretary in preparing the agenda, agenda notes and minutes of the YEC2 meetings
- Maintain filing, classifying & archiving of all protocol documents
- Maintain the filing, archiving and maintaining of the SOPs (all versions), member files
- Maintain copies of relevant guidelines, regulations and government circulars related to ethical review of biomedical research
- Maintain, update, backup and protect the electronic database of the YEC2 records
- Respond to general enquiries, attend to telephone calls and emails
- Send email reminders to members who default on review deadline
- Send email reminders to the Principal Investigators for resubmissions/ continuing reports/ completion reports
- Coordinate functions of subcommittees, audits and site monitoring
- Assist in the audit/ inspection of the ethics committee.
- Coordinate training program of the EC members
- Perform any other duties as assigned by the Chairperson, related to the working of the YEC2.

4.21.7. Duties of the attender/helper:

- 4.21.7.1. Assisting the Secretariat in arranging the YEC2 meetings
- 4.21.7.2. Dispatching study documents to YEC2 members and ICs
- 4.21.7.3. Dispatch of post and couriers of the YEC2
- 4.21.7.4. Receiving the study related documents from and dispatching the YEC2 letters to concerned parties
- 4.21.7.5. Assist the Secretariat in filing, archiving and maintaining of files
- 4.21.7.6. Assisting the Secretariat during YEC2 meetings
- 4.21.7.7. Any other work as assigned by the Chairperson, related to the working of the YEC2.

5. Reference to other SOP chapters:

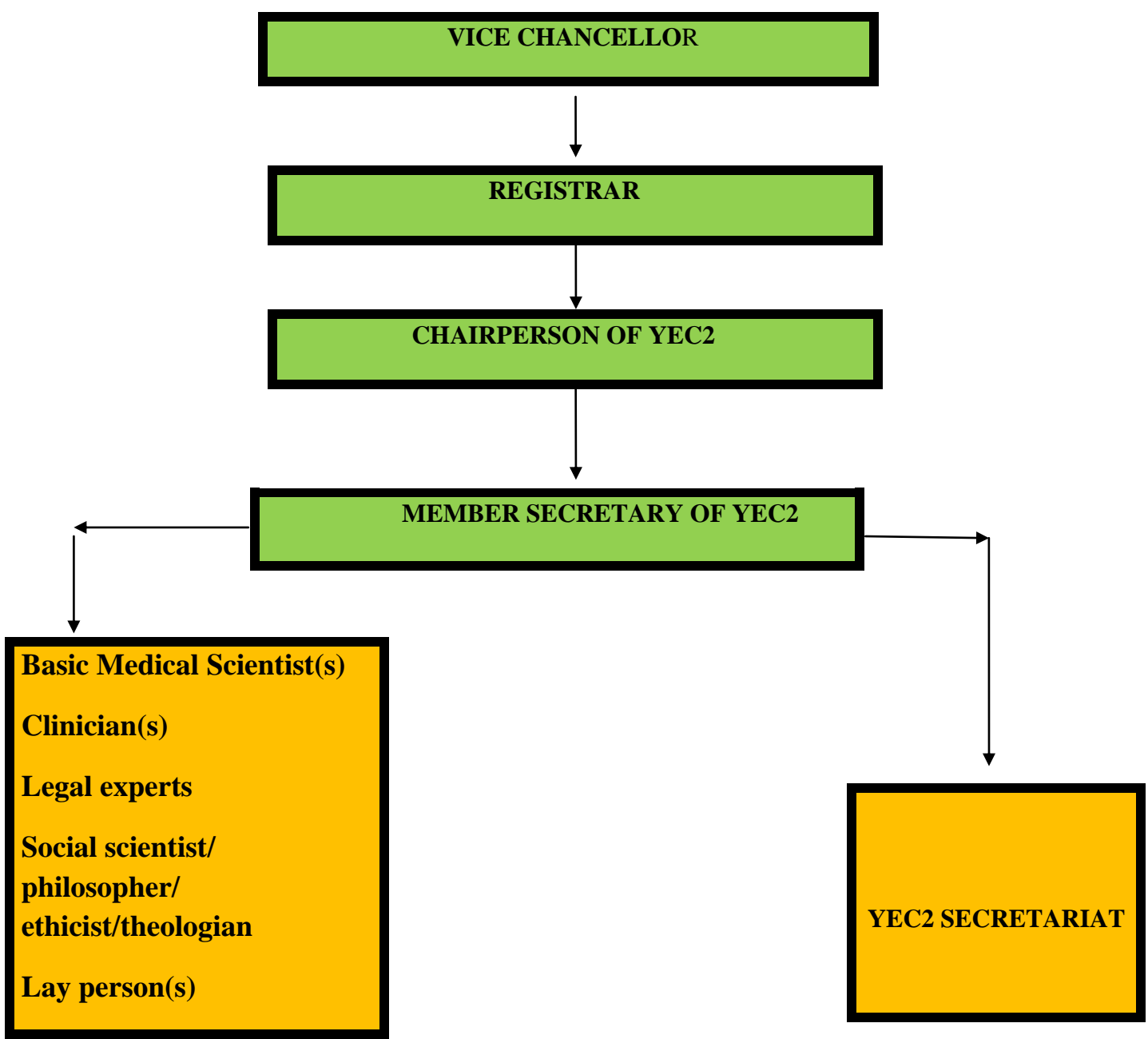
- 5.1. Conflict of interest policy for Yenepoya Ethics Committee 2 (SOP02/v3)
- 5.2. Agenda preparation/Meeting procedures/Recording of Minutes (SOP08/v3)

6. Annexures:

- 6.1.** Ann01/SOP02/v3: Organizational Chart of the YEC2 and place in Yenepoya (Deemed to be University)
- 6.2.** Ann02/SOP02/v3: Terms of reference for the members
- 6.3.** YEC2/Ann03/SOP02/v3: Membership Agreement Form for YEC2 members

YEC2/Ann01/SOP02/v3

Organization chart for the Yenepoya Ethics committee 2 (YEC2)



YEC2/Ann02/SOP02/v3:
Terms of reference for the members at the time of appointment

All members	<p>Appointment to YEC2 with designation Term of office Training in 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 guidelines applicable 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</p>
External members	<p>Encourage and guide YEC2 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 YEC2 in its smooth functioning</p>
Chairperson	<p>Head the YEC2 Lead the discussions and deliberation Preside over the administrative matters of the YEC2 Ensure adherence to SOPS and guidelines Ensure a timely ethical review process</p>

Member-Secretary	Receive, categorize, allocate and sign the approval of the protocols Prepare and maintain the agenda and minutes of the meeting Plan training activities Schedule and conduct post-approval activities Prepare and respond to audits and inspections of the YEC2 Maintain the archival of files Coordinate with members the activities of the YEC2
Legal expert	Ethical review of protocol Emphasis on legal issues, compensation, agreements, MoUs, Insurance, Indemnity, permissions and other documents in the protocol
Social scientist/ theologian/bioethic	Ethical review (emphasis on social, cultural & religious issues)
Layperson	Ethical review of protocol (emphasis on informed consent document)
Clinician	Ethical review of protocol (emphasis on clinical aspects, complications, management of complications issues in the protocol)
Basic scientist	Ethical review of protocol (emphasis on basic scientific issues, IND details, clinical trial phases, genomic/laboratory research, etc)

YEC2/Ann01/SOP02/v3

Confidentiality Agreement Form for YEC 2 members

In recognition of the fact, that, I

(*Member's name, his/her position on YEC 2 and affiliation*) herein referred to as the “undersigned”, have been appointed as a member of Yenepoya Ethics Committee 2

(YEC 2). I understand the confidentiality policy of the YEC2 and agree that,

1. All the data and information (and any copies and notes thereof) that I read, hear or discuss, shall remain the sole property of YEC2.
2. All the data and information that is shared with me, as a YEC2 member, in the course of the functioning of the YEC-1, will remain in my trust or confidence.
3. I shall use the documents/information shared with me, only for the express purpose of smooth functioning of the YEC2
4. I shall not share the documents or the information from within them, with the PI or sponsor or any third uninterested person/party.
5. I shall not photocopy/photograph any of the documents accessed by me from the archives of YEC2
6. I shall delete all the documents from my email/computer/mobile/electronic storage/cloud/prints after the decision on the protocol is completed.
7. I shall ensure that all e-documents are deleted annually/at the end of my term in YEC-1, whichever is earlier.
8. I understand that, Every second Saturday YEC2 has a offline meet only if there is a genuine reason i can be excused from the meeting after prior information to YEC2 office and submitting of leave letter
9. I understand that tenure of appointment of 5 years and I am willing to give service to the ethics committee for at least 3 years.

10. I understand that as per the SOP, If i don't attend the 3 consecutive YEC2 meet and A total of 6 in year my membership can be terminated .

11. I understand that as a member of YEC2 , I will be reviewing protocols for review for which i have to reply within a period of 7 days .

12. If member has genuine reason due to which he/she not able to review the protocol send to them they should inform YEC2 secretariat within 2 days of receiving email

13. If I fail to review the 5 protocol send to me within the time frame given my membership can be terminated.

14. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of YEC2 and may include:

a. The protocol/protocol-related documents sent to me for review by email:

b. The agenda and minutes of the meeting sent to me by email

c. Proceedings of the YEC2 meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the YEC2 meeting: d. The protocol/protocol-related documents/YEC2 files accessed from the archives

e. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review:

f. Any other, if applicable

9. This agreement is binding on me beyond the boardroom meetings as well as beyond my tenure as a YEC2 member, for a reasonable time, considering that research studies often remain active for years.

I, Dr/Mr/Ms _____ (Member name, YEC2 designation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from the ethics committee and/or liable to legal actions from the Yenepoya deemed to be University, if confidentiality is will fully breached by me.

Constitution of YEC2,
YEC2/SOP02/v3
Date:25.02.2023

Signature

Date

Chairperson's Signature

Date

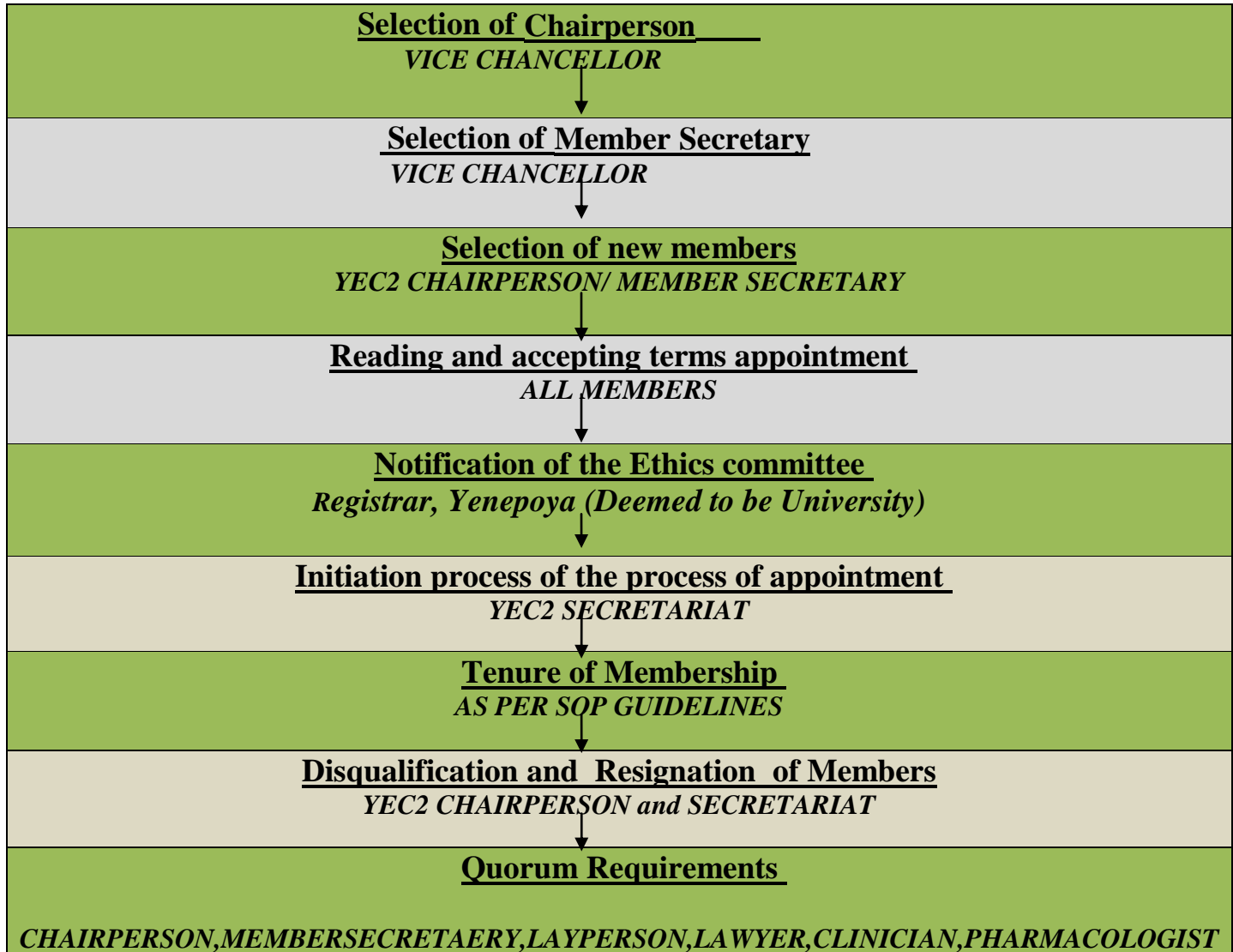
[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat YEC2 A copy will be given to the Undersigned.]

I acknowledge that I have received a copy of this Agreement signed by the YEC2 Chairperson and me

Signature

Date

7. Flow chart



8. References:

Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf