

Title: Constitution of Yenepoya University Ethics Committee (YUEC), Selection, Roles and Responsibilities of the Members

SOP Code: SOP02/v2

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1. Purpose

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 University Ethics Committee (YUEC) and its members and procedures for maintaining confidentiality of all activities and documents.

2. Scope

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

3. Responsibility

The selection of Chairperson, Member-Secretary and all other members of YUEC will be approved by the Vice Chancellor, Yenepoya University, keeping in mind, gender balance and institutional representation. The same will be notified by the Office of the Registrar, Yenepoya University, and will be made widely known to all through the University website. It is the responsibility of all the YUEC members and the Secretariat to read, understand, follow and respect all the SOPs, in force, from time to time.

4. Detailed Instructions

4.1 Organizational structure

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 (Ann02/SOP02/v2)

4.2 Composition of Yenepoya University Ethics Committee

4.2.1 The YUEC will be established by the **Board of Management**, Yenepoya University and will be mandated within the bye-laws of Yenepoya University. The Chairperson, Member-Secretary and YUEC members can suggest names of potential members at the time of

installation of the new committee and for residuary periods. These will be approved by the Vice Chancellor.

4.2.2 The YUEC will be multidisciplinary and multi-sectoral in composition. As per current CDSCO and ICMR requirements, the EC will consist of at least 7 members and upto a maximum of 15 members.

4.2.3 The members will

- ✓ include a combination of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.
- ✓ have differing backgrounds to promote complete and adequate review of research.
- ✓ have the required qualifications as prescribed by applicable regulations and guidelines from time to time.
- ✓ have the expertise, time and commitment to perform all functions as detailed in this SOP.

4.2.4 YUEC will have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community/society.

4.2.5 The committee should include at least one member whose primary area of expertise is in a non-scientific area, a clinician and at least one member who is independent of the institution/research site.

4.2.6 YUEC may invite member(s) of specific patient groups or other special interest groups for an EC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (Ann02/SOP05/v2) and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/Observer' and will not have right to vote. (See SOP05/v2)

4.2.7 The composition shall be at least as follows:

- Chairperson (non-affiliated to the institution): Will be from among the external members in the YUEC, serving under any category.
- Co-Chairperson (optional) (non-affiliated to the institution): Will be from among the external members in the YUEC, serving under any category.

- Member-Secretary (affiliated to the institution): Will be from Yenepoya University and having qualification/training in research ethics.
- Joint Member-Secretary (optional) (institutional): Will be from Yenepoya University and having qualification/training in research ethics.
- One or more members from basic medical science (preferably a pharmacologist, especially if overseeing a drug, device vaccine or biological)
- One or more clinicians from various institutions
- One legal expert (a senior advocate or retired judge) (non-affiliated)
- One social scientist or representative of non-governmental agency
- One philosopher, ethicist or theologian
- One or more lay persons from the community

4.3 Criteria for selection of members of YUEC

4.3.1 Chairperson:

- The Chairperson must be from outside the institution.
- He/she should be a person of good-standing in society.
- He/she should preferably have some experience of serving on an ethics committee.

4.3.2 Co-Chairperson (optional): Same criteria as the Chairperson

4.3.3 Member-Secretary and Joint Member-Secretary (optional):

- Should be a full time faculty member of Yenepoya University.
- Should preferably be a postgraduate faculty member in an institution doing biomedical research
- Should have a state medical council recognized graduate or postgraduate degree or an equivalent UGC recognized degree
- Should have qualification, training and expertise in biomedical ethics and research.
- He/she would be desirous to have personal interest and capacity, and good communication skills.

4.3.4 Members

- Will be selected in their personal capacities based on their qualifications, experience, interest, ethical, scientific knowledge and/or expertise, without any known record of professional misconduct or criminal charges.
- Medical scientists, scientists and clinicians should possess postgraduate qualifications
- Should be committed and willing to volunteer the necessary time and effort for the work of YUEC.
- Conflicts of interest should be avoided, and a process laid down to declare such conflicts in a transparent manner (See SOP03/v2)

4.4 Hierarchy

- There will be one Chairperson, one Member Secretary and one Joint Member Secretary (wherever applicable) may be appointed from amongst the members.
- The Chairperson will head the committee.
- The Member Secretary and the Joint Member Secretary (wherever applicable) will be the guardian of all documents and funds in the possession of the committee.
- Other YUEC members will be regular committee members with equal ranking.

4.5 Agreement regarding maintenance of confidentiality

- 4.5.1 It is the responsibility of each YUEC member, at the time of joining the EC, to read, understand, accept and sign the agreement contained in the confidentiality form (Ann3A/SOP02/v2).
- 4.5.2 The staff of the secretariat will sign a confidentiality agreement, effective from the date of joining, which will be filed with the Secretariat, YUEC. (Ann3B/SOP02/v2)
- 4.5.3 The Secretariat will obtain the signature of the YUEC Chairperson on the Confidentiality form.
- 4.5.4 The Secretariat shall provide YUEC members photocopies of the confidentiality form for their records (duly signed and dated by them and YUEC Chairperson) and acknowledge the receipt.

4.5.5 The Member-Secretary will keep the original copies of the signed agreements in the YUEC secretariat in a file called ‘Confidentiality Agreement File’ and photocopies of the agreements in the individual members’ files.

4.6 Tenure of membership

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

4.7 Appointment of new members

4.7.1 Yenepoya University Ethics Committee members will be nominated by the Member-Secretary/Jt Secretary, in consultation with the Chairperson approved by the Vice Chancellor and notified by the Registrar, Yenepoya University.

4.7.2 The Chairperson and Secretary shall, after discussion with the other members, suggest names for appointment, based on the composition guidelines in the Schedule Y and ICMR document, the vacancy position and as specified in section 4.2 above.

4.7.3 New members can be inducted in the following situations:

- When a member completes his/her tenure
- When a member resigns before tenure completion
- When a member ceases to be a member for various reasons including death or disqualification
- When the membership requirements need to be met as specified in Section 4.2 above

4.8 Conditions to be fulfilled by a member after appointment

4.8.1 Members must submit an updated CV, duly signed, along with a recent passport-size photograph.

4.8.2 Members should also submit self-attested photocopies of any or all documents pertaining to training in bioethics, research ethics and/or GCP-ICH training.

4.8.3 If not trained, members should be encouraged to undergo such training within a period of 6-9 months from the date of joining, and submit the relevant documents for the purpose of keeping records.

- 4.8.4 Members must be willing to have their name and affiliation publicly linked to Yenepeya University Ethics Committee, such as on the letterhead, in the website, etc.
- 4.8.5 Members must sign a confidentiality agreement (Ann3A/SOP02/v2) 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 the participants, and any other matter directly or indirectly related to the research protocols or the ethical review process.
- 4.8.6 Members must read, accept and comply with the conflict of interest policy of Yenepeya University Ethics Committee. They must sign the conflict of interest form (template provided in SOP03/v2).

4.9 Resignation and Disqualification of Members

- 4.9.1 A member may resign from YUEC 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.
- 4.9.2 Disqualification for not attending YUEC meetings: A member may be disqualified from YUEC membership if the member fails to attend more than 3 regular consecutive meetings without prior intimation. The process conducted will be as follows:
- 4.9.2.1 The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the YUEC without prior intimation.
- 4.9.2.2 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 YUEC.
- 4.9.2.3 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 YUEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson.
- 4.9.2.4 The matter will be discussed and reviewed at the YUEC 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.

- 4.9.2.5 The Chairperson or Member-Secretary will inform the YUEC members about the cessation of membership by a confidential written communication to other members of YUEC or at the next meeting of YUEC.
- 4.9.2.6 A member may be disqualified from continuance should YUEC determine by a two-thirds majority specifically called for the purpose that the member's conduct has been inappropriate.
- 4.9.2.7 The Chairperson will satisfy himself/ herself that a *prima facie* case exists before initiating action.
- 4.9.2.8 If, in the opinion of the Chairperson, the matter is of grave significance where integrity of YUEC could be questioned, the Chairperson may provisionally suspend the membership of the concerned member till final decision is taken.
- 4.9.2.9 During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of a YUEC member.
- 4.9.2.10 The Chairperson may call for an extraordinary meeting of the YUEC 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. The allegation will be discussed at the meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself/herself.
- 4.9.2.11 The member would stand disqualified, if the other members present at the meeting, approve of disqualification by voting (voting by 2/3 of majority of members present in the meeting and voting).
- 4.9.2.12 The Chairperson will convey the disqualification to the concerned member through a written communication.

4.10 Research Ethics Training

- 4.10.1 An individual selected as a new member of YUEC will be required to attend one meeting as an 'Observer' before being inducted as a member.

4.10.2 Member Secretary or a YUEC member will provide introductory training in Research Ethics, GCP & SOPs to the new member.

4.10.3 A newly inducted member should submit certificate of training within 6-9 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.

4.10.4 YUEC will conduct in-house training sessions on ethics in clinical research, GCP and SOPs from time to time to impart training to YUEC Members and faculty members.

4.10.5 YUEC 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.

4.11 Functions

4.11.1 Chairperson:

4.11.1.1 The Chairperson will be responsible for conducting meetings, leading all discussions and deliberations pertinent to the review of research proposals.

4.11.1.2 The Chairperson will preside over all administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the YUEC at various meetings and forums, or if unable to, will request the Member-Secretary to do so.

4.11.1.3 The Chairperson will approve the Member-Secretary's signing of all documents and communications related to YUEC functioning.

4.11.1.4 The Chairperson will approve the formation of the SOP Committee from among the members of the YUEC, and will ask the Member-Secretary to communicate the same.

4.11.1.5 In case of anticipated absence of the Chairperson at a planned meeting, the Chairperson will in advance and in writing nominate a committee member as acting Chairperson or the members present may elect an alternative Chairperson, from among the members present for the meeting (excluding the Member-Secretary).

4.11.1.6 The acting Chairperson will have all the powers of the Chairperson for that meeting only.

4.11.2 Member-Secretary:

- 4.11.2.1 Through the Secretariat, the Member-Secretary shall receive research proposals on behalf of the YUEC
- 4.11.2.2 Organize an effective and efficient tracking procedure for each proposal received and arrange for the same to be displayed in the Secretariat.
- 4.11.2.3 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.
- 4.11.2.4 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.
- 4.11.2.5 The Member-Secretary shall, in consultation with and approval from the Chairperson, schedule and organize YUEC 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 University, at the start of every calendar year.
- 4.11.2.6 The Member-Secretary shall prepare and maintain meeting agenda and minutes. These same shall be approved by the Chairperson before the Member-Secretary circulates among the members.
- 4.11.2.7 The agenda with notes shall be circulated among the members at least 7 days before the meeting date. In the case of clinical trials, the agenda with the accompanying papers shall be circulated at least 15 days in advance.
- 4.11.2.8 Minutes of the meeting shall be prepared by the Member-Secretary and after approval from the Chairperson, must be circulated to all the members within 7 days of the meeting. A copy of the minutes should be marked to the Registrar, Yenepoya University.
- 4.11.2.9 The Member-Secretary shall maintain YUEC documentation on correspondence and communication and archive them.

- 4.11.2.10 The Member-Secretary alone shall have the responsibility of communicating with the YUEC members, applicants/ investigators and the University.
- 4.11.2.11 The Member-Secretary shall notify the Principal Investigator regarding YUEC's decisions related to the submitted research proposal.
- 4.11.2.12 The Member-Secretary shall arrange for the training of the personnel and the YUEC 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.
- 4.11.2.13 Organize the preparations, review, revision and distribution of SOPs and guidelines.
- 4.11.2.14 Provide necessary administrative support for YUEC related activities to the Chairperson.
- 4.11.2.15 Provide updates on relevant and contemporary issues to ethics in health research as well as relevant government circulars/guidelines to the committee members.
- 4.11.2.16 Receive ethics committee review processing fees on behalf of the University and arrange for the issuance of official receipt from the University accounts office.
- 4.11.2.17 Delegate various responsibilities to appropriate and authorized individuals and ensure adherence of YUEC functioning as per SOPs.
- 4.11.2.17 Prepare for audits and inspections
- 4.11.2.18 Prepare and make available for scrutiny by auditors/ inspectors annual reports/ annual financial statements of the YUEC.

4.11.3 Joint Member-Secretary:

The Joint Member Secretary will perform the same functions of Member Secretary in his/her absence.

4.11.4 YUEC members:

- 4.11.4.1 YUEC members must receive, read and familiarize themselves with a copy of the SOPs relating to the functioning of the YUEC. They must sign a joining letter stating that they will abide by the rules/regulations of the university and YUEC.

- 4.11.4.2 YUEC members shall attend YUEC 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.
- 4.11.4.3 Actively engage in review, discussion and considerations of the ethical issues in research proposals submitted for evaluation.
- 4.11.4.4 Members must sign the confidentiality agreement and abide by it throughout the term of membership and beyond if need be.
- 4.11.4.5 Monitor serious adverse event reports, as submitted to the YUEC, and recommend appropriate action(s) which will be communicated by the Member-Secretary
- 4.11.4.6 Review the progress reports and monitor ongoing studies as appropriate, and recommended by the Chairperson.
- 4.11.4.7 Carry out on-site visits as and when necessary and recommended by the Chairperson and communicated by the Member-Secretary.
- 4.11.4.8 Evaluate final reports and outcomes in the YUEC meetings.
- 4.11.4.9 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.
- 4.11.4.10 Participate in continuing education activities in biomedical ethics and biomedical research and submit the certificates for records to the Secretariat.
- 4.11.4.11 Provide an updated CV when requested for by the YUEC secretariat
- 4.11.4.12 Carry out the work delegated by Chairperson, Member-secretary or Jt. Member-Secretary and assist in the smooth functioning of the YUEC.

4.11.5 Secretariat:

- 4.11.5.1 The Secretariat will be composed of administrative support staff.
- 4.11.5.2 The Secretariat will support the Member Secretary and Joint Member Secretary (if any) in all their functions

4.11.5.3 All the staff of the Secretariat will sign confidentiality agreement which should be filed with YUEC (Ann3B/SOP02/v2)

4.11.5.4 The working rules for the Secretariat are stated in Ann01/SOP02/v2.

4.12 Types of projects reviewed by YUEC

4.12.1 YUEC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by pharmaceutical companies, sponsored by Government of India / NGOs, studies in collaborations with international organizations/universities, all dissertation projects (postgraduate students :MD, MS, MCh, DM, Mch, DNB, PhD, MSc, MPTh, MOTH, Nursing, dental and any other course run by Institution as applicable), research projects of undergraduate students carried out under guidance of teachers (e.g. Indian Council for Medical research studentship or any other) and investigator initiated research studies which are self funded / funded by institutional funding bodies.

4.12.2 The Member-Secretary shall decide based on the ICMR guidelines whether the research proposal is fit for exempt from review, or expedited review or full review.

4.13 Quorum requirements

4.13.1 The YUEC meeting will be held as scheduled provided there is quorum.

4.13.2 For the purpose of YUEC meeting with a regulatory clinical trial in the agenda, quorum will consist of at least 5 members with the following representations:

- One clinician
- One legal expert
- One basic scientist (preferably a pharmacologist)
- One social scientist/representative of non- governmental voluntary agency/philosopher/ethicist/theologian or a similar person
- One layperson from the community, **apart from**
- Member Secretary and
- Chairperson (in absence any other member chosen from among those present)

4.13.3 Without satisfying the above condition (4.13.2), any decision taken by the committee with regard to regulatory clinical trial, shall be considered null and void.

4.13.4 For all other research proposals any quorum of five members is sufficient.

4.14 Honorarium to the members

4.14.1 Members internal to Yenepoya 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.

4.14.2 External members of the YUEC will be provided local transport and an honorarium as per existing rules/norms, from time to time. The Secretariat shall provide this amount after the meeting is concluded and will take their signature on the receipt voucher.

Copies of these same shall be maintained at the Secretariat.

4.15 Preparing an annual activity report of the YUEC

It is the responsibility of the Member-Secretary to make the annual report. Once approved by the Chairperson, the same shall be circulated among the members. A copy will be sent to the University and one copy maintained in the Secretariat. This report should contain all details of the activities of the YUEC in the calendar year and should at least include information on

- Number and dates of the YUEC meetings
- Number of SAE subcommittee and any other subcommittee
- Numbers and types of proposals (Pharmaceutical/Government sponsored/ Dissertations/ investigator initiated) reviewed in a year, status of each study proposal whether completed/ongoing/terminated.
- Number of approvals for full review/expedited review with decisions
- Brief details about workshops, training programmes and other activities undertaken by the YUEC and those attended by YUEC members

4.16 Appellate authority of the Vice Chancellor, Yenepoya University:

- 4.16.1 In the event of anyone having a grievance against the functioning of the YUEC can submit a grievance in writing to the Vice Chancellor, Yenepoya University, with a copy marked to the YUEC Secretariat. 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.
- 4.16.2 In the event that the Chairperson or Member-Secretary YUEC perceive a need to conduct an extra-ordinary meeting within 24 hours, this same needs prior approval from the Vice Chancellor. This does not cover Serious Adverse Events reporting which follows the regulations as laid down in SOP12/v2, based on the regulations in Schedule Y of the Drugs and Cosmetics Act 1940.

5. Reference to other SOP chapters:

- 5.1 Conflict of interest policy for Yenepoya University Ethics Committee (SOP03/v2)
5.2 Agenda preparation/Meeting procedures/Recording of Minutes (SOP08/v2)

6. Annexures

- 6.1 Ann01/SOP02/v2 - YUEC administrative staff working rules
6.2 Ann02/SOP02/v2 - Organizational Chart of the Yenepoya University Ethics Committee and its place in the University
6.3 Ann3A/SOP02/v2 - Confidentiality Agreement Form for YUEC members
6.4 Ann3B/SOP02/v2 - Confidentiality Agreement Form for Staff of the Secretariat

Annexure 1: Ann01/SOP02/v2 - YUEC administrative staff working rules

- There will be administrative officer/assistant(s) and attendant(s) /helper(s) who will help the YUEC Chairperson and Member-Secretary in executing functions of the YUEC.
- 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 YUEC meeting, which same shall be recorded in the minutes.
- Additional staff may be appointed and duties assigned; as and when deemed necessary by the YUEC, in consultation with the University. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile.
- 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.
- The administrative staff will report to the Chairperson and/or Member-Secretary.

Duties of the administrative staff:

On behalf of the Member-Secretary and the YUEC:

1. Carry out the correspondence with YUEC Chairperson, members, external experts, and University officials.
2. Communicate with the Principal Investigators
3. Assist the Member-Secretary in preparing the agenda, agenda notes and minutes of the YUEC meetings
4. Filing, classifying and archiving of study-related documents
5. Filing, archiving and maintaining of SOPs (all versions), member files
6. Maintaining copies of all the relevant guidelines, regulations and governmental circulars related to ethical review of biomedical research
7. Maintain, update, backup and protect the electronic database of the YUEC records
8. Respond to general enquiries, attend to telephone calls and general emails
9. Send email reminders to members who default on the review deadline
10. Send email Principal Investigators of research proposals where the ethical clearance is due to expire.

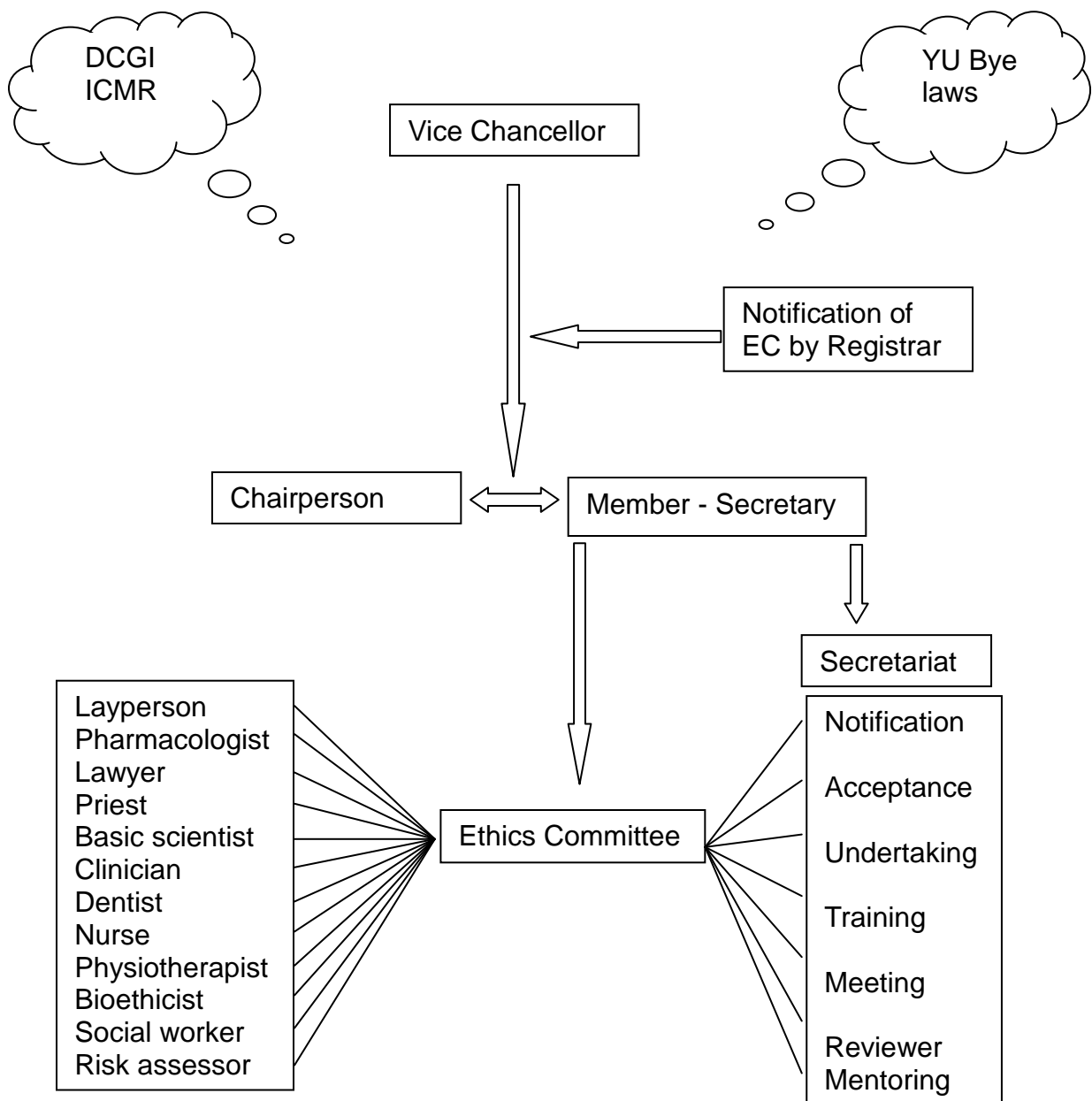
11. Any other duties as assigned by the Chairperson, related to the working of the YUEC

Duties of the attender/helper:

1. Assisting the Secretariat in arranging the YUEC meetings
2. Dispatching sets of study documents to YUEC members and external experts
3. Dispatch of post and couriers of the YUEC
4. Receiving the study related documents from and dispatching the YUEC letters to concerned parties
5. Assisting the Secretariat in filing, archiving and maintaining of files
6. Assisting the Secretariat during YUEC meetings
7. Any other work as assigned by the Chairperson, related to the working of the YUEC

Annexure 2: Ann02/SOP02/v2 - Organizational Chart of the YenePOYA University Ethics Committee and its place in the University

**CENTRE FOR ETHICS
YENEPOYA UNIVERSITY ETHICS COMMITTEE
ORGANIZATIONAL CHART**





Annexure 3: Ann3A/SOP02/v2 - Confidentiality Agreement Form for YUEC members

In recognition of the fact, that, I _____
(Member's name, his/her position on YUEC and affiliation) herein referred to as the "undersigned", have been appointed as a member of Yenepoya University Ethics Committee (YUEC) and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines. The appointment of the undersigned as a member of the YUEC is based on individual merits and not as an advocate or representative of a home province, territory, or community, nor as a delegate of any organization.

YUEC 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 research participants and the undersigned, as a member of YUEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This agreement encompasses any information deemed confidential provided to the undersigned in conjunction with the duties as a member of YUEC. All confidential information (and any copies and notes thereof) shall remain the sole property of YUEC. The undersigned herewith agrees to hold all confidential information in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review shall not be copied or retained.

I, _____ (Member name, YUEC designation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to legal actions from the University, if confidentiality is willfully breached by me.

Signature _____ Date _____

Chairperson's Signature _____ Date _____

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

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

Signature _____ Date _____



Annexure 4: Ann3B/SOP02/v2 - Confidentiality Agreement Form for Staff of the Secretariat

I, _____ (Staff name & designation) herein referred to as the “undersigned”, have been appointed as a staff of the YUEC Secretariat. This agreement encompasses any information deemed confidential provided to the undersigned in conjunction with the duties as a staff of the YUEC. All confidential information (and any copies and notes thereof) shall remain the sole property of the YUEC.

The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him/her during the tenure of his/her service and beyond if necessary.

I, _____ (Staff name & designation) have read and accept the conditions as explained in this agreement.

Signature

Date

Chairperson’s signature

Date

[The original (signed and dated agreement) will be kept on file in the custody of the YUEC. A copy will be given to the undersigned.]

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

Signature

Date:

7. Flowchart

No.	Activity	Responsibility
1	Composition of Yenepoya University Ethics Committee	Vice Chancellor, via notification by Office of Registrar, with inputs from Chairperson and Member-Secretary
2	Selection of Chairperson	Vice-Chancellor, via notification by Office of Registrar, with inputs from Chairperson and Member-Secretary
3	Selection of new members	Chairperson
4	Conditions of appointment	YUEC Members and Secretariat
5.	Initiation of the process of appointment	Secretariat
6.	Tenure of Membership	Chairperson, YUEC Members and Secretariat
7.	Resignation and disqualification of members	YUEC Members and Secretariat
8.	Quorum requirements	YUEC Members and Secretariat