


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

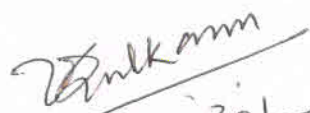
**SOP Code:** SOP02/v2

**Effective Date:** 01/08/2016

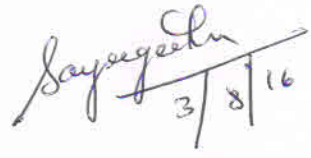
**Prepared by:**

<p>Dr. Ravi Vaswani Member, YUEC</p>	<p>Signature with date  3/7/16</p>
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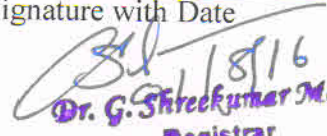
**Reviewed by:**

<p>Dr. Uma Kulkarni Secretary, YUEC</p>	<p>Signature with Date  30/07/2016</p>
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**Approved by:**

<p>Dr. Sayeegeetha Hegde Chairperson, YUEC</p>	<p>Signature with Date  3/8/16</p>
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**Notified by:**

<p>Registrar, Yenepoya University vide Notification No. YUreg/ACA/YUEC/FERCAP/01/2016</p>	<p>Signature with Date  Dr. G. Shreekrumar Menon Registrar Yenepoya University Mangaluru - 575 018</p>
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**Title: Constitution of Yenepoya Ethics Committee-1 (YEC-1), Selection, Roles and Responsibilities of the Members**

**SOP Code: SOP02/v2**

**Effective Date: 01/08/2016**

**Prepared by:**

Dr. Ravi Vaswani Member, YEC-1	Signature with date
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**Reviewed by:**

Dr. Uma Kulkarni Secretary, YEC-1	Signature with Date
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**Approved by:**

Dr. Vikram Shetty Chairperson, YEC -1	Signature with Date
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**Notified by:**

Registrar, Yenepoya (deemed to be University) vide Notification No. YU/REG/ACA/YEC-1/FERCAP/01/2016 dated 01/08/2016	Signature with Date
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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 Ethics Committee - 1 (YEC-1) and its members and procedures for maintaining confidentiality of all activities and documents.

## **2. Scope**

This SOP describes processes related to the constitution of YEC-1, selection, roles and responsibilities of members of YEC-1 and maintenance of confidentiality of all activities and documents.

## **3. Responsibility**

The selection of Chairperson, Member-Secretary and all other members of YEC-1 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 YEC-1 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 Ethics Committee - 1**

4.2.1 The YEC-1 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. The Chairperson, Member-Secretary and YEC-1 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 YEC-1 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 YEC-1 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 YEC-1 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 YEC-1, serving under any category.
- Co-Chairperson (optional) (non-affiliated to the institution): Will be from among the external members in the YEC-1, 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 YEC-1**

##### **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 YEC-1.
- 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 YEC-1 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 YEC-1 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, YEC-1. (Ann3B/SOP02/v2)
- 4.5.3 The Secretariat will obtain the signature of the YEC-1 Chairperson on the Confidentiality form.
- 4.5.4 The Secretariat shall provide YEC-1 members photocopies of the confidentiality form for their records (duly signed and dated by them and YEC-1 Chairperson) and acknowledge the receipt.

4.5.5 The Member-Secretary will keep the original copies of the signed agreements in the YEC-1 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 Ethics Committee - 1 members will be nominated by the Member-Secretary/It Secretary, in consultation with the Chairperson approved by the Vice Chancellor and notified by the Registrar, Yenepoya deemed to be 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 ICH-GCP 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 Yenepoya Ethics Committee - 1, 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 Yenepoya Ethics Committee - 1. 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 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.
- 4.9.2 Disqualification for not attending YEC-1 meetings: A member may be disqualified from YEC-1 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 YEC-1 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 YEC-1.
- 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 YEC-1 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 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.

- 4.9.2.5 The Chairperson or Member-Secretary will inform the YEC-1 members about the cessation of membership by a confidential written communication to other members of YEC-1 or at the next meeting of YEC-1.
- 4.9.2.6 A member may be disqualified from continuance should YEC-1 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 YEC-1 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 YEC-1 member.
- 4.9.2.10 The Chairperson may call for an extraordinary meeting of the YEC-1 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 YEC-1 will be required to attend one meeting as an 'Observer' before being inducted as a member.

- 4.10.2 Member Secretary or a YEC-1 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 YEC-1 will conduct in-house training sessions on ethics in clinical research, GCP and SOPs from time to time to impart training to YEC-1 Members and faculty members.
- 4.10.5 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.

## **4.11 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 YEC-1 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 YEC-1 functioning.
- 4.11.1.4 The Chairperson will approve the formation of the SOP Committee from among the members of the YEC-1, 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 YEC-1
- 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 YEC-1 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 YEC-1 documentation on correspondence and communication and archive them.

- 4.11.2.10 The Member-Secretary alone shall have the responsibility of communicating with the YEC-1 members, applicants/ investigators and the University.
- 4.11.2.11 The Member-Secretary shall notify the Principal Investigator regarding YEC-1'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 YEC-1 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 YEC-1 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 YEC-1 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 YEC-1.

#### **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 YEC-1 members:**

- 4.11.4.1 YEC-1 members must receive, read and familiarize themselves with a copy of the SOPs relating to the functioning of the YEC-1. They must sign a joining letter stating that they will abide by the rules/regulations of the university and YEC-1.

- 4.11.4.2 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.
- 4.11.4.3 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 YEC-1, 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 YEC-1 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 maintain when requested for by the YEC-1 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 YEC-1.

#### **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 YEC-1 (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 YEC-1**

4.12.1 YEC-1 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 YEC-1 meeting will be held as scheduled provided there is quorum.

4.13.2 For the purpose of YEC-1 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 YEC-1 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 YEC-1**

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 YEC-1 in the calendar year and should at least include information on

- Number and dates of the YEC-1 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 YEC-1 and those attended by YEC-1 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 YEC-1 can submit a grievance in writing to the Vice Chancellor, Yenepoya University, with a copy marked to the YEC-1 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 YEC-1 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 Ethics Committee - 1 (SOP03/v2)  
5.2 Agenda preparation/Meeting procedures/Recording of Minutes (SOP08/v2)

#### **6. Annexures**

- 6.1 Ann01/SOP02/v2 - YEC-1 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 YEC-1 members  
6.4 Ann3B/SOP02/v2 - Confidentiality Agreement Form for Staff of the Secretariat

### **Ann01/SOP02/v2 - YEC-1 administrative staff working rules**

- There will be administrative officer/assistant(s) and attendant(s) /helper(s) who will help the YEC-1 Chairperson and Member-Secretary in executing functions of the YEC-1.
- 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 same shall be recorded in the minutes.
- Additional staff may be appointed and duties assigned; as and when deemed necessary by the YEC-1, 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 YEC-1:

1. Carry out the correspondence with YEC-1 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 YEC-1 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 YEC-1 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.

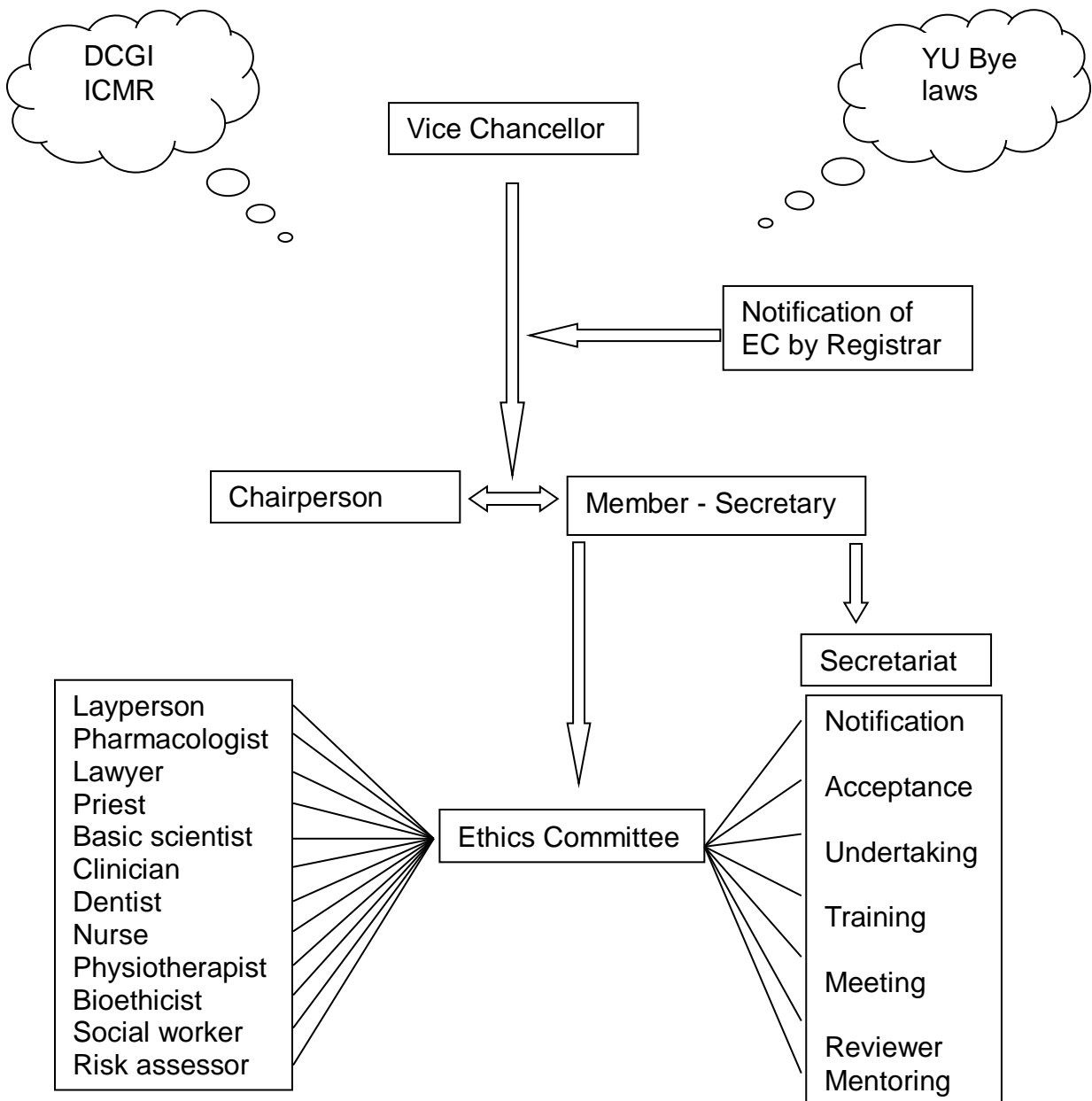
11. Any other duties as assigned by the Chairperson, related to the working of the YEC-1

**Duties of the attender/helper:**

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

**Ann02/SOP02/v2 - Organizational Chart of the Yenepoaya Ethics Committee - 1 and its place in the University**

**CENTRE FOR ETHICS  
 YENEPOYA ETHICS COMMITTEE - 1  
 ORGANIZATIONAL CHART**



### **Ann3A/SOP02/v2 - Confidentiality Agreement Form for YEC-1 members**

In recognition of the fact, that, I \_\_\_\_\_

*(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 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 YEC-1 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.

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 research participants and the undersigned, as a member of YEC-1, 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 YEC-1. All confidential information (and any copies and notes thereof) shall remain the sole property of YEC-1. 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, YEC-1 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 YEC-1. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-1 Chairperson and me

Signature

Date



**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 YEC-1 Secretariat. This agreement encompasses any information deemed confidential provided to the undersigned in conjunction with the duties as a staff of the YEC-1. All confidential information (and any copies and notes thereof) shall remain the sole property of the YEC-1.

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 YEC-1. A copy will be given to the undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-1 Chairperson and me.

Signature \_\_\_\_\_ Date: \_\_\_\_\_

## 7. Flowchart

No.	Activity	Responsibility
1	Composition of Yenepoya Ethics Committee - 1	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	YEC-1 Members and Secretariat
5.	Initiation of the process of appointment	Secretariat
6.	Tenure of Membership	Chairperson, YEC-1 Members and Secretariat
7.	Resignation and disqualification of members	YEC-1 Members and Secretariat
8.	Quorum requirements	YEC-1 Members and Secretariat