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1. Purpose

The purpose of this SOP is to describe the training, assessment and feedback of Yenepoya Ethics Committee-1 (YEC-1) members and the secretarial staff

2. Scope

This SOP applies to initial and continuing training and assessment of YEC-1 members and secretarial staff in research ethics including but not limited to research ethics, research methodology, ethics committee functioning, ethical review process, SOPs, guidelines, standards, regulations and emerging fields in research and ethics.

The SOP also applies to obtaining feedback from YEC-1 members.

3. Responsibility

3.1. YEC-1 Chairperson will:

- 3.1.1. Ensure that there is a system in place to perform adequate initial and continuing training of the YEC-1 members and the secretarial staff as per the scope of this SOP.
- 3.1.2. Approve the calendar prepared by the Member-Secretary, for the training and assessment sessions
- 3.1.3. Evaluate the training and assessment program to identify areas of weaknesses and recommend corrective measures.
- 3.1.4. Take note of the feedback from the YEC-1 and ensure action wherever deemed necessary

3.2. YEC-1 Member -Secretary will:

- 3.2.1. Arrange for initial training of the new members
- 3.2.2. Prepare the calendar (schedule) for continuing training, get it approved by the Chairperson and arrange for the conduct of these training programs
- 3.2.3. Prepare the assessment schedule for the members, get it approved by the Chairperson and make arrangements for the conduct of these exercises.
- 3.2.4. Prepare the self-assessment schedule and disseminate this information among the members, giving them ample time to respond.
- 3.2.5. Evaluate the training and assessment program, identify areas that need corrective measures and take corrective measures.
- 3.2.6. Issue annual certification for all the members and the secretarial support staff
- 3.2.7. Provide feedback forms, for the YEC-1 members to use and take corrective measures based on such feedback.

3.3. YEC-1 members (including Chairperson and Member-Secretary) will:

- 3.3.1. Take note of and abide by the calendar for training and assessment sessions

for YEC-1 members.

- 3.3.2. Undertake the initial and continuing training sessions organized for the YEC-1 members
- 3.3.3. Take part in the assessment sessions conducted for the YEC-1 members
- 3.3.4. Take part in the self-assessment at scheduled intervals
- 3.3.5. Take part in the feedback sessions and provide feedback for identifying areas of weakness that require corrective action

3.4. YEC-1 Secretarial staff will:

- 3.4.1. Assist the Member-Secretary to develop a calendar for training and assessment programs for the year and remind the Member-Secretary from time to time to conduct these exercises.
- 3.4.2. Communicate the training and assessment schedule to the YEC-1 members and make necessary logistic arrangement
- 3.4.3. Maintain the record (including annual certificate) of training of members and the secretarial staff
- 3.4.4. Maintain the feedback provided by the members in a separate file
- 3.4.5. Take part in the assessment sessions organized by the YEC-1
- 3.4.6. Take part in the self-assessment at scheduled intervals

4. Detailed instructions:

4.1. Topics for training of YEC-1 members (including but not limited to):

- 4.1.1. Basics of research methodology and research ethics
- 4.1.2. Relevant and currently applicable ethical and regulatory guidelines applicable to research on human participants, NABH and FERCAP standards.
- 4.1.3. Structure and content of the SOPs of YEC-1
- 4.1.4. Review process of protocols and protocol-related documents and use of reviewer's checklists and other templates
- 4.1.5. Roles of YEC-1 members as appointed in the YEC-1 (layperson, lawyer, basic scientist, clinician, social scientist, member-secretary, chairperson)
- 4.1.6. Responsibilities of YEC-1 members in the designated roles reviewers, site monitors and sub-committee members
- 4.1.7. **Corrective and Preventive Actions (CAPA) for sustain and enhance quality**
- 4.1.8. Recent developments in health care, research and ethics

4.2. Topics for training of the Secretarial staff (in addition to 4.1):

- 4.2.1. Computer skills including Microsoft Word, Excel, YEC-1 office software and email
- 4.2.2. Communication skills: written, electronic and verbal
- 4.2.3. Use of templates, preparation of agenda, minutes and reports
- 4.2.4. Confidentiality
- 4.2.5. Maintenance of YEC-1 database and its security
- 4.2.6. Maintenance of archival room and access log
- 4.2.7. Maintenance of files
- 4.2.8. Audits
- 4.2.9. Fire safety drill
- 4.2.10. **Corrective and Preventive Actions (CAPA) for sustain and enhance quality**

4.3. Initial training of new YEC-1 members:

- 4.3.1. Every time a new member is inducted into YEC-1, the Member-Secretary should organize an initial training for the new member before taking part in the first meeting as a member.
- 4.3.2. The topics covered should include YEC-1 scope and functioning, YEC-1 SOPs, the applicable ethical and regulatory guidelines, roles and responsibilities of the new members and the review process
- 4.3.3. The new member is required to attend at least one meeting as an 'Observer' before being inducted as a member of the YEC-1 to understand the conduct and proceedings of the YEC-1 meetings.

4.4. Continuing training of the YEC-1 members:

- 4.4.1. The Member-Secretary will prepare the calendar of continuing training schedule and get it approved
- 4.4.2. Continuing training of YEC-1 members will be conducted as per the training schedule
- 4.4.3. Training on essential national guidelines like ICMR and Good Clinical Practice will be conducted at least once in 3 years and whenever the guidelines are revised by the regulatory authorities
- 4.4.4. All the YEC-1 members must be encouraged to actively take part in the continuing training organized by the YEC-1
- 4.4.5. The resource persons will be selected based on the topic from within the YEC-1 or an external resource person may be called, whenever required.

- 4.4.6. The resource persons will be required to circulate handouts or reading material to the YEC-1 members, wherever applicable.
 - 4.4.7. Annual training certification will be provided to the YEC-1 members and secretarial staff
 - 4.4.8. The YEC-1 members will be encouraged to participate in workshops, conferences or other training programs conducted within or outside the University, in areas of research ethics as delegates or resource persons or facilitators.
 - 4.4.9. Yenepoya deemed to be University may sponsor or reimburse the expenses of a YEC-1 member or prospective member(s) for attending conferences, continuing education session workshops and/or training programs in the area of research ethics or ethics committee functioning (as per University norms).
- 4.5. **Assessment of YEC-1 members:**
- 4.5.1. At the end of every third training program, assessment of YEC-1 members will be conducted using evaluation forms prepared by the resource person/Member-Secretary. All assessments will be on topics covered in the last 3 months with few questions on SOPs.
 - 4.5.2. Training will be reinforced if performance is found inadequate (scores <50%)
 - 4.5.3. Assessment of the YEC-1 members is also done by the Chairperson after self-assessment of YEC-1 members
 - 4.5.4. The Member-Secretary will also regularly assess the review timelines and completeness of review forms by YEC-1 members and request the Chairperson to take action, if deemed necessary.
- 4.6. **Self-assessment of YEC-1 members (including Chairperson and Member-Secretary):**
- 4.6.1. All YEC-1 members are required to fill the self-assessment forms biannually or as specified (Ann02/SOP21/v4.1).
 - 4.6.2. The self-assessment forms will include details of the members' involvement in the activities of YEC-1 at the end of every year 6 months.
 - 4.6.3. The self-assessment forms of the Member-Secretary and the Chairperson will include additional points on activities related to their specific roles in the EC. (Ann03/SOP21/v4.1, Ann04/SOP21/v4.1))
- 4.7. **Feedback from the Members of YEC-1:**
- 4.7.1. YEC-1 members will provide their feedback on YEC-1 functioning every 6 months or when deemed necessary on a regular basis (Ann06/SOP21/v4.1)
 - 4.7.2. The feedback will be assessed by the Member-Secretary and the Chairperson and necessary action initiated

- 4.7.3. The feedback forms and assessment will be maintained in the Secretariat.
- 4.7.4. The feedback from members requiring action will be tabled in the next immediate meeting of the YEC-1
- 4.8. **Training of the Secretarial staff:**
 - 4.8.1. The YEC-1 Member-Secretary or other member designated by the Member-Secretary, will train the Secretarial staff on the importance, structure and content of the YEC-1 SOPs.
 - 4.8.2. The secretarial staff will have one initial training and this will be supplemented with continuing training sessions
 - 4.8.3. The secretarial staff will be encouraged to get trained in computer, communication and administrative skills.
- 4.9. **Self-assessment of secretarial staff:**
 - 4.9.1. Secretarial staff will fill out the self-assessment form, on a regular basis, preferably biannually. (Ann05/SOP21/v4.1)
 - 4.9.2. The Chairperson shall record his/her observations in the area so demarcated and initiate action, if necessary
- 4.10. **Maintenance of training records and feedback forms:**
 - 4.10.1. The secretarial staff will maintain a training file of the YEC-1 - which will include - calendar of training and assessment schedules, details of the training and assessment sessions conducted, self-assessment forms duly filled and feedback forms.
 - 4.10.2. The secretarial staff will maintain copies of the training schedules, records and annual certification of all training sessions conducted for the YEC-1 members in the individual members' file. These documents will be shredded as per the shredding protocol after a period of 5 years.
 - 4.10.3. The secretarial staff will also maintain the certificates of workshops and conferences in research ethics attended by the individual YEC-1 members. In addition, if any member is invited as a resource person in a research or research ethics program, the secretarial staff will maintain records of these as well.
 - 4.10.4. The copies of the certificates will be filed in the individual members' files.

5. **References:**

ICMR's National Ethical Guidelines for Biomedical and Health Research Involving Human Subjects, 2017

Indian GCP Guidelines, 2001

New Drugs and Clinical Trials Rules, 2019 of the Drugs and Cosmetics Act, 1940

6. Annexures

- 6.1. Ann01/SOP21/v4.1: Template for calendar of training schedule
- 6.2. Ann02/SOP21/v4.1: Self-assessment, assessment and feedback for YEC-1 members
- 6.3. Ann03/SOP21/v4.1: Self-assessment form for YEC-1 Member-Secretary
- 6.4. Ann04/SOP21/v4.1: Self-assessment form for YEC-1 Chairperson
- 6.5. Ann05/SOP21/v4.1: Self-assessment form for YEC-1 Secretarial staff
- 6.6. Ann06/SOP21/v4.1: Feedback form of YEC-1 members on YEC-1 functioning
- 6.7. Ann07/SOP21/v4.1: Annual training certification

Ann01/SOP21/v4.1:

Template for calendar of training, assessment and feedback schedule for YEC-1 members

Training schedule				
No	Date	Topic	Faculty	Specific Learning Objective
1	Jan			
2	Feb			
3	Mar			
4	Apr			
5	May			
6	June			
7	July			
8	Aug			
9	Sep			
10	Oct			
11	Nov			
12	Dec			
Training assessment schedule				
	Mar	June	Sept	Dec
Feedback and and self-assessment schedule (Ann02/SOP 21/v4.1)				
	June		Dec	

Signature of the Chairperson/Member-Secretary

Date:

**Ann02/SOP 21/v4.1: Self-assessment form for YEC-1 members
(Every 6 months)**

Name of the YEC-1 member:

Role in YEC-1:

Date of joining YEC-1:

Period of assessment: From

to

Sl No	Self assessment item	Details		
1	Initial training received: (for new members)			
2	Assessment on initial training (including components of SOPs)			
2	Continuous training received: (list the topics)			
	Assessment on training topics (including components of the SOPs)			
3	Number of meetings attended			
4	Number of protocols reviewed (Expedited)			
5	Number of protocols reviewed (Full review)			
6	Ability to meet the review timelines	Sometimes	Often	Always
7	Ability to ensure completeness of review	Sometimes	Often	Always
8	Level of participation in the discussions in the meetings (as per your perception)	Low	Moderate	High
9	Participation in SAE report review process	Yes	No	
10	Participation in site monitoring visits	Yes	No	
11	Other contribution to the field of research ethics (Provide information on presentations, publications, training conducted/organized)			
12	How satisfied are you with your work in the YEC-1	Less than expectations	Meets my expectations	Exceeds my expectations

13	Any other significant point	
	Signature of YEC-1 member and date:	
14	Assessment observations of the Chairperson:	1. Satisfactory 2. Not satisfactory: 3. Corrective action to be taken (if any):
	Signature of YEC-1 Chairperson and date:	

Ann03/SOP 21/v4.1: Self-assessment form of YEC-1 Member-Secretary/Joint Secretary

Name of the YEC-1 Member-Secretary/Joint Secretary:

Date of joining YEC-1:

Period of assessment from to

No	Self assessment item	Details		
1	Continuous training received: (list topics)			
2	Number of meetings attended			
3	Number of protocols reviewed (Expedited)			
5	Number of protocols reviewed (Full)			
6	Level of participation in the discussions in the meetings (as per your perception)	Low	Moderate	High
7	Ability to meet the review timelines	Sometimes	Often	Always
8	Ability to ensure completeness of review	Sometimes	Often	Always
9	Participation in SAE report review process	Yes		No
10	Participation in site monitoring visits	Yes		No
11	Other contribution to research ethics (Provide information on presentations, publications, training conducted/organized)			
12	How satisfied are you with your work in the YEC-1	Less than expectation	Meets my expectations	Exceeds my expectations

13	Number/type of training workshops organized	
14	Number/type of continuing training workshops organized for YEC-1 Secretariat	
15	Any other significant point	
	Signature of YEC-1 member and date:	
	Assessment observations of the Chairperson:	<ol style="list-style-type: none"> 1. Satisfactory 2. Not satisfactory: 3. Corrective action needs to be taken (if any):
	Signature of YEC-1 Chairperson and date:	

Ann04/SOP 21/v4.1 Self-assessment form of YEC-1 Chairperson

Name of the YEC-1 Chairperson:

Date of joining YEC-1:

No	Self assessment item	Details		
1	Continuous training received: (list the topics)			
2	Number of meetings attended			
3	Number of protocols reviewed (Expedited)			
5	Number of protocols reviewed (Full review)			
6	Level of participation in the ethical discussions in the meetings (as per your perception)	Low	Moderate	High
7	Ability to meet the review timelines	Sometimes	Often	Always
8	Ability to ensure completeness of review	Sometimes	Often	Always
9	Participation in SAE report review process	Yes	No	
10	Participation in site monitoring visits	Yes	No	

11	Other contribution to the field of research ethics (Provide information on presentations, publications, training conducted/organized)			
12	How satisfied are you with your work in the YEC-1	Less than expectations	Meets my expectations	Exceeds my expectations
13	Whether quorum requirement fulfillment ensured as per current guidelines in YEC-1 meetings	No	Sometimes	Always
14	Whether considerations related to conflict of interest explored	No	Sometimes	Always
15	Any other significant points			
	Signature of YEC-1 Chairperson and date:			

Ann05/SOP 21/v4.1: Self-assessment form of YEC-1 Secretarial Staff

Name of the YEC-1 Secretarial Staff:

Date of joining YEC-1:

Role in YEC-1:

Period of assessment: From _____ **to** _____

Sl No	Self assessment item	Response
1	Years of service	
2	Status of service	
3	Type of training received: Initial: (including SOPs) Continuous: (including SOPs and CAPA)	
4	Number of meetings assisted Member-Secretary in the current year	
5	Number of days attended work:	
6	Number of protocols handled in the assessment period	
7	Whether Member-Secretary or Chairperson made corrections in the protocol works	
8	Number of SAE report review assisted in:	Yes/No
9	Number of site monitoring visits assisted in:	Yes/No
10	Any other significant contribution to the work in the YEC-1	

11	How satisfied are you with your work in the YEC-1	Less than expectations	Meets my expectations	Exceeds my expectations
	Signature of YEC-1 Secretarial staff and date:			
	Assessment observations of the Chairperson:	<ol style="list-style-type: none"> 1. Satisfactory 2. Not satisfactory: 3. Corrective action to be taken (if any): 		
	Signature (YEC-1 Chairperson) and date:			

Ann06/SOP21/v4.1:

Feedback of the YEC-1 members on the YEC-1 functioning

No	Feature	Yes/ No	Remarks
1	The time allotted for review of expedited protocols is adequate		
2	The time allotted for review of full-review protocols is adequate		
3	The checklist provided for review of protocols is appropriate		
4	Reminders are sent by the Secretarial staff if timeline for review is missed		
5	The SOPs, guidelines and regulations are provided by YEC-1 for reference		
6	Confidentiality of the documents is adequately maintained		
7	Training programs are conducted regularly		
8	Training programs conducted by YEC-1 are useful		
9	The members are free to express their vote of dissent during the decision making		
10	The meetings of the YEC-1 are conducted as per SOP (time, quorum, discussion, decision making)		
11	The YEC-1 manages conflict of interest as per the SOP		
12	The duration of the meetings is adequate for the number of protocols discussed		
13	The functioning and decision making of the YEC-1 is		

	independent		
14	The agenda of the meeting and meeting notes are circulated well ahead of the meeting		
15	The minutes of the meeting are circulated within 7 calendar days of the meeting for approval of the YEC-1 members		
16	The review process includes both scientific and ethical issues in the protocols		
17	Every member is able to freely contribute to discussion and deliberation of protocols in the meeting		
18	The SOPs are clear and practical		
19	The venue and arrangement of the meetings is adequate		
20	What according to you is the strength of the YEC-1?		
21	What according to you needs improvement?		
	Signature of the YEC-1 member with date		
	Assessment of feedback by Member-Secretary and Chairperson	Action needed (if any):	
	Signature of the Member-Secretary with date		
	Signature of the Chairperson with date		

Ann07/SOP21/v4.1: Annual training certification

Yenepoya Ethics Committee-1

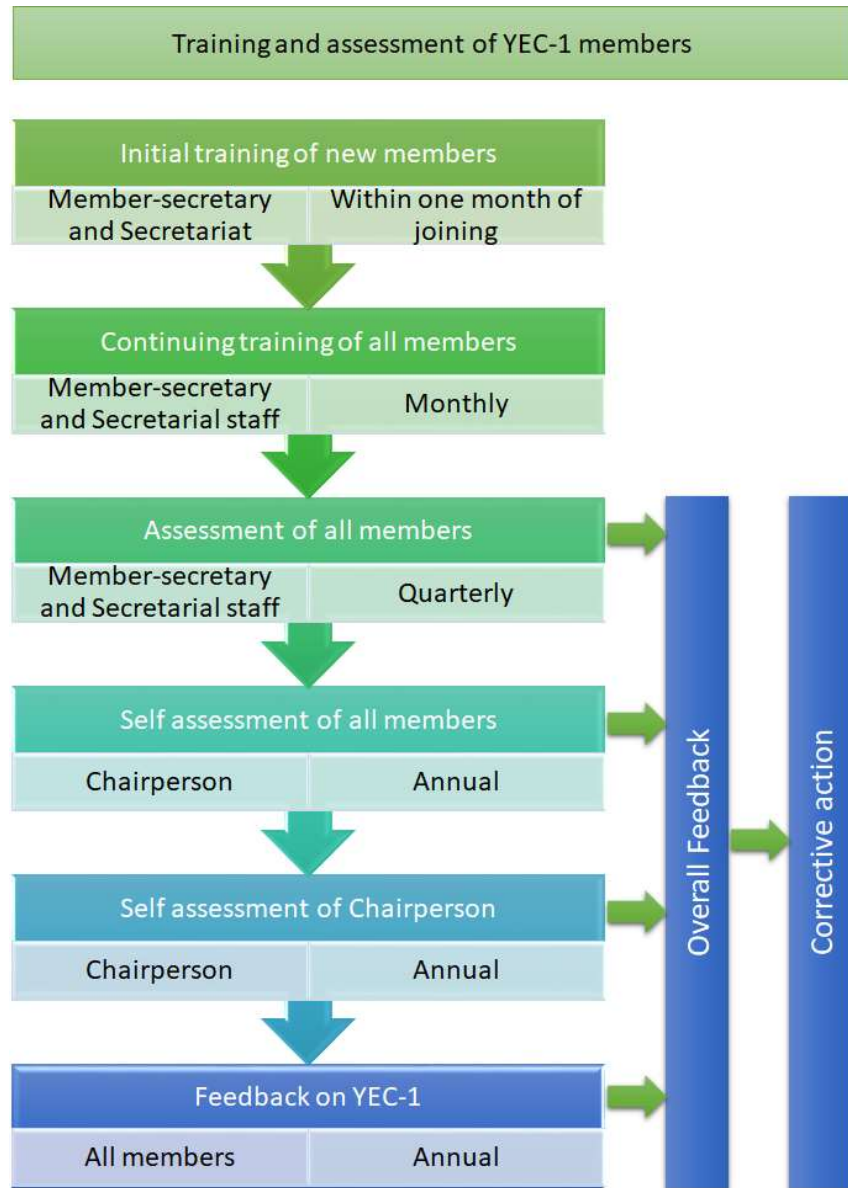
This is to certify that (Name and designation in YEC-1), has successfully undergone the following training in YEC-1 during the year conducted by YEC-1

S. No	Date	Topic

Signature of the Chairperson

Date

7. Flowchart



8. Glossary:

GCP: Good Clinical Practice

ICMR: Indian Council of Medical Research

NDCTR: New Drugs and Clinical Trials Rules