

TRAINING ASSESSMENT & FEEDBACK OF MEMBERS

24/02/2024

Title: Training Assessment of Members

SOP Code: YEC2/SOP21/v2

Prepared by:

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Notified by:

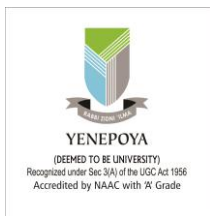
Registrar, Yenepoya (Deemed to be university)	Signature with Date <i>S. Somayajulu</i> Registrar YENEPOYA (Deemed to be University) 24/02/24
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Details of superseded SOP21/v1

Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. Hari Kishore Bhat	v1	14.06.2018	Major revision in the SOP

Details of Current SOP21/v2

Subcommittee Convenor name	Version no	Effective Date (dd/mm/yy)	Describe the main changes
Dr. K. Leena Pramod	v2	24.02.2024	1. Major revision 2. Feedback form added 3. Annexure 1 & 2 Revised, 4. New Annexure added 5. References added 6. Revised Flowchart

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## **1. Purpose**

The purpose of this SOP is to describe the training, assessment and feedback of Yenepoya Ethics Committee-2 (YEC-2) members and the secretarial staff

## **2. Scope**

This SOP applies to initial and continuing training and assessment of YEC-2 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-2 members.

## **3. Responsibility**

It is the responsibility of the YEC 2 Chairperson with the assistance of Member-Secretary to ensure that there is adequate initial and continued training of the YEC 2 members and the Secretariat. The Chairperson is responsible for assessment of all YEC 2 members and completes a self-assessment exercise at prescribed intervals.

### **3.1. YEC-2 Chairperson will:**

3.1.1. Ensure that there is a system in place to perform adequate initial and continuing training of the YEC-2 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 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-2 and ensure action wherever deemed necessary

### **3.2. YEC-2 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 self-assessment schedule and disseminate this information among the members, giving them ample time to respond.

3.2.4. Evaluate the training and assessment program, identify areas that need corrective measures and take corrective measures.

3.2.5. Issue annual certification for all the members and the secretarial support staff 3.2.6. Provide feedback forms, for the YEC-2 members to use and take corrective measures based on such feedback.

**3.3. YEC-2 members (including Chairperson and Member-Secretary) will:**

- 3.3.1. Take note of and abide by the calendar for training sessions for YEC-2 members.
- 3.3.2. Undertake the initial and continuing training sessions organized for the YEC-2 members
- 3.3.3. Take part in the assessment sessions conducted for the YEC-2 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-2 Secretarial staff will:**

- 3.4.1. Assist the Member-Secretary to develop a calendar for training programs for the year and remind the Member-Secretary from time to time to conduct these exercises.
- 3.4.2. Communicate the training schedule to the YEC-2 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 self-assessment at scheduled intervals

**4. Detailed instructions:**

**4.1. Topics for training of YEC-2 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.
- 4.1.3. Structure and content of the SOPs of YEC-2
- 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-2 members as appointed in the YEC-2 (layperson, lawyer, basic scientist, clinician, social scientist, member-secretary, chairperson)

4.1.6. Responsibilities of YEC-2 members in the designated roles reviewers, site monitors and sub-committee members

4.1.7. 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-2 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-2 database and its security

4.2.6. Maintenance of archival room and access log

4.2.7. Maintenance of files

4.2.8. Audits

**4.3. Initial training of new YEC-2 members:**

4.3.1. Every time a new member is inducted into YEC-2, 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-2 scope and functioning, YEC-2 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-2 to understand the conduct and proceedings of the YEC-2 meetings.

**4.4. Continuing training of the YEC-2 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-2 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-2 members must be encouraged to actively take part in the continuing

training organized by the YEC-2

4.4.5. The resource persons will be selected based on the topic from within the YEC-2 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-2 members, wherever applicable.

4.4.7. Annual training certification will be provided to the YEC-2 members and secretarial staff

4.4.8. The YEC-2 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-2 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-2 members:

4.5.1. Assessment of the YEC-2 members is done by the member secretary and Chairperson after self assessment form submission by YEC-2 members

4.5.2. The Member-Secretary will also regularly assess the review timelines and completeness of review forms by YEC-2 members and request the Chairperson to take action, if deemed necessary.

#### **4.6. Self-assessment of YEC-2 members (including Chairperson and Member Secretary):**

4.6.1. All YEC-2 members are required to fill the self-assessment forms biannually or as specified (Ann02/SOP21/v2).

4.6.2. The self-assessment forms will include details of the members' involvement in the activities of YEC-2 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/SOP21/2, Ann04/SOP21/2)

#### **4.7. Feedback from the Members of YEC-2:**

4.7.1. YEC-2 members will provide their feedback on YEC-2 functioning annually or when

deemed necessary on a regular basis (Ann06/SOP21/v2)

4.7.2. The feedback will be assessed by the Member-Secretary and the Chairperson and necessary action initiated

#### **4.8. Training of the Secretarial staff:**

4.8.1. The YEC-2 Member-Secretary or other member designated by the MemberSecretary, will train the Secretarial staff on the importance, structure and content of the YEC-2 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/v2)

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-2 - which will include - calendar of training and assessment schedules, details of the training 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-2 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-2 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/v1: Template for calendar of training schedule**

6.2. Ann02/SOP21/v2: Self-assessment for YEC-2 members

6.3. Ann03/SOP21/v1 : Self-assessment form for YEC-2 Member-Secretary

6.4. Ann04/SOP21/v2: Self-assessment form for YEC-2 Chairperson

6.5. Ann05/SOP21/v1: Self-assessment form for YEC-2 Secretarial staff 6.6.

Ann06/SOP21/v1: Feedback form of YEC-2 members on YEC-2 functioning

6.7. Ann07/SOP21/v1: Annual training certification.





**YENEPOYA**  
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Recognized under Sec. 3(A) of the USC Act 1956  
Accredited by NAAC with 'A' Grade

**YENEPOYA ETHICS COMMITTEE 2**  
**TRAINING ASSESSMENT & FEEDBACK OF MEMBERS**

**YEC2/SOP 21/v2**  
**24/02/2024**

**Ann01/SOP21/v2:**

**Template for calendar of training, assessment and feedback schedule for YEC-2 members**

<b>Training schedule</b>				
<b>No</b>	<b>Date</b>	<b>Topic</b>	<b>Faculty</b>	<b>Specific Learning Objective</b>
1	Jan			
2	Feb			
3	Mar			
4	Apr			
5	May			
6	June	WORKSHOP/SEMINAR		
7	July			
8	Aug			
9	Sep			
10	Oct			
11	Nov			
12	Dec	WORKSHOP/SEMINAR		
<b>Training assessment schedule</b>				
	Mar	June	Sept	Dec
<b>Feedback and and self-assessment schedule (Ann02/SOP 21/v2)</b>				
	June		Dec	

Signature of the Chairperson/Member-Secretary

Date

**Name of the YEC-2 member:**

**Role in YEC-2:**

**Date of joining YEC-2:**

**Period of assessment: From**

**to**

Sl No	Self assessment item	Details		
1	Initial training received: (for new members)			
2	Continuous training received: (list the topics)			
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)			



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**YENEPOYA ETHICS COMMITTEE 2                      YEC2/SOP 21/v2**  
**TRAINING ASSESSMENT & FEEDBACK OF MEMBERS    24/02/2024**

12	How satisfied are you with your work in the YEC-2	Less than expectations	Meets my expectations	Exceeds my expectations
13	Any other significant point			
	Signature of YEC-2 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-2 Chairperson and date:			

**A**

**nn03/SOP 21/v2 : Self-assessment form of YEC-2 Member-Secretary, Name of the YEC-2 Member-Secretary**

**Date of joining YEC-2:**

**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)			



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**YENEPOYA ETHICS COMMITTEE 2**  
**TRAINING ASSESSMENT & FEEDBACK OF MEMBERS**

**YEC2/SOP 21/v2**  
**24/02/2024**

12	How satisfied are you with your work in the YEC-2	Less than expectation	Meets my expectations	Exceeds my expectations
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13	Number/type of training workshops organized	
14	Number/type of continuing training workshops organized for YEC-2 Secretariat	
15	Any other significant point	
	Signature of YEC-2 member and date:	
	Assessment observations of the Chairperson:	<ol style="list-style-type: none"> <li>1. Satisfactory</li> <li>2. Not satisfactory:</li> <li>3. Corrective action needs to be taken (if any):</li> </ol>
	Signature of YEC-2 Chairperson and date:	

**Ann04/SOP 21/v2 Self-assessment form of YEC-2 Chairperson**

**Name of the YEC-2 Chairperson:**

**Date of joining YEC-2:**

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-2	Less than expectations	Meets my expectations	Exceeds my expectations
13	Whether quorum requirement fulfillment ensured as per current guidelines in YEC-2 meetings	No	Sometimes	Always
14	Whether considerations related to conflict of interest explored	No	Sometimes	Always
15	Any other significant points			
	Signature of YEC-2 Chairperson and date:			

**Ann05/SOP 21/v2: Self-assessment form of YEC-2 Secretarial Staff**

**Name of the YEC-2 Secretarial Staff:**

**Date of joining YEC-2:**

**Role in YEC-2:**

**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			
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-2			
11	How satisfied are you with your work in the YEC-2	Less than expectations	Meets my expectations	Exceeds my expectations
	Signature of YEC-2 Secretarial staff and date:			
	Assessment observations of the Chairperson:	1. Satisfactory 2. Not satisfactory: 3. Corrective action to be taken (if any):		
	Signature (YEC-2 Chairperson) and date:			

**Ann06/SOP21/v2:**

**Feedback of the YEC-2 members on the YEC-2 functioning**

<b>No</b>	<b>Feature</b>	<b>Yes/ No</b>	<b>Remarks</b>
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-2 for reference		
6	Confidentiality of the documents is adequately maintained		
7	Training programs are conducted regularly		
8	Training programs conducted by YEC-2 are useful		
9	The members are free to express their vote of dissent during the decision making		
10	The meetings of the YEC-2 are conducted as per SOP (time, quorum, discussion, decision making)		
11	The YEC-2 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-2 is		



**Ann07/SOP21/v2: Annual training certification**

**Yenepoya Ethics Committee-2**

This is to certify that (Name and designation in YEC-2), has successfully undergone the following training in YEC-2 during the year conducted by YEC-2

S. No	Date	Topic

**Signature of the Chairperson**

**Date**

**7. Flow Chart**

