




Title: Yenepoya Ethics Committee-1 Members: Training, Assessment and Feedback


SOP Code: SOP 21/v3

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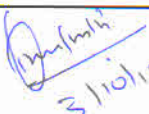
Prepared by:

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature with date  3/10/2019
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Reviewed by:

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with Date  3/10/19
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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date  3/10/19
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Notified by:


Registrar Yenepoya deemed to be University	Signature with Date  3/10
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1. Purpose

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

2. Scope

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

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, continuing assessment, regular self-assessment and feedback 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.

3.2. 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. Create and 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
- 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-1
- 4.1.4. Designing and writing SOPs
- 4.1.5. Review process of protocols and protocol-related documents and use of reviewer's checklists and other templates
- 4.1.6. Roles of YEC-1 members as appointed in the YEC-1 (layperson, lawyer, basic scientist, clinician,
- 4.1.7. Responsibilities of YEC-1 members in the designated roles reviewers, site monitors and sub-committee members
- 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. Confidentiality
- 4.2.4. Maintenance of YEC-1 database and its security
- 4.2.5. Maintenance of archival room and access log
- 4.2.6. Maintenance of files
- 4.2.7. Audits
- 4.2.8. Fire safety drill

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.
- 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 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 training schedule

4.4.2. Continuing training of YEC-1 members is conducted as per the training schedule

4.4.3. All the YEC-1 members including the Chairperson and Member-Secretary must be encouraged to actively take part in the continuing training organized by the YEC-1

4.4.4. 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.

4.4.5. The resource persons will be required to circulate handouts or reading material to the YEC-1 members, wherever applicable.

4.4.6. Annual training certification will be provided to the YEC-1 members and secretarial staff

4.4.7. The YEC-1 members will be encouraged to participate in workshops, conferences or other training programs conducted within or outside the Yenepoya deemed to be University, in the area of research ethics as delegates or resource persons or facilitators.

4.4.8. The 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 workshop and/or training program in the area of research ethics or ethics committee functioning (if applicable).

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

- 4.5.2. Training will be reinforced if assessment found inadequate (50% is the cut off value)
- 4.5.3. Assessment of the YEC-1 members is also done by the Chairperson at the end of the self-assessment forms of YEC-1 members (see below).
- 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 annually or as specified (refer Ann01/SOP21/v3 date).
 - 4.6.2. The self-assessment forms will include details of the member's involvement in the activities of YEC-1
 - 4.6.3. The self-assessment forms of the Member-Secretary and the Chairperson will include additional points to include details of their activities in the roles
- 4.7. **Feedback from the Members of YEC-1:**
 - 4.7.1. Member-Secretary will guide the SOP sub-committee to design the feedback forms and get this approved from Chairperson
 - 4.7.2. Whenever asked for by the members or on a regular basis, these forms will be provided to the members, their feedback taken and the forms maintained in the Secretariat.
 - 4.7.3. The feedback provided by the members 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 annually.
- 4.9.2. The Chairperson shall record his/her observations in the area so demarcated

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
- 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. Annexures

- 5.1. Ann01/SOP21/v3: Template for calendar of training schedule
- 5.2. Ann02/SOP21/v3: Self-assessment form for YEC-1 members
- 5.3. Ann03/SOP21/v3: Self-assessment form for YEC-1 Member-Secretary
- 5.4. Ann04/SOP21/v3: Self-assessment form for YEC-1 Chairperson
- 5.5. Ann05/SOP21/v3: Self-assessment form for YEC-1 Secretarial staff
- 5.6. Ann06/SOP21/v3: Feedback form of YEC-1 members on YEC-1 functioning

Ann01/SOP21/v3: Template for calendar of training schedule for YEC-1 members

From:

To:

S. No	Date and duration	Topic	Faculty	Specific Learning Objectives	Reading material / handouts
1					
2					
3					

Signature of the Chairperson/Member-Secretary

Date:

Ann02/SOP 21/v3: Self-assessment form for YEC-1 members

Name of the YEC-1 member:

Role in YEC-1:

Date of joining YEC-1:

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

SI No	Self assessment item	Response	
1	Current tenure		
2	Terms served		
3	Type of training received: Initial: Continuous:		
4	Number of meetings attended in the current year		
5	Number of protocols reviewed per meeting as lead discussant		
6	Number of protocols reviewed per meeting as primary reviewer		
7	Number of protocols reviewed per meeting as secondary reviewer		
8	Level of participation in the ethical discussions in the meetings (your perception as an approximate percentage)	25% 51-75%	26-50 % >75%
8	Participation in SAE report review process	Yes/No	
9	Participation in site monitoring visits	Yes/No	
10	Other contribution to the field of research ethics		
11	How satisfied are you with your work in the YEC-1	25% 51-75%	26-50 % >75%

Signature of YEC-1 member and date:

Assessment observations of the Chairperson:

Signature of the Chairperson and date:

Ann03/SOP 21/v3: Self-assessment form of YEC-1 Member-Secretary

Name of the YEC-1 Member-Secretary:

Date of joining YEC-1:

Period of assessment from _____ to _____

SI No	Self assessment item	Response	
1	Current tenure		
2	Terms served		
3	Training received		
4	Type of training received		
5	Number of meetings attended in the current year		
6	Number of protocols reviewed per meeting as lead discussant		
6	Number of protocols reviewed per meeting as primary reviewer		
7	Number of protocols reviewed per meeting as secondary reviewer		
8	Level of participation in the ethical discussions in the meetings	25% 51-75%	26-50 % >75%
8	Participation in SAE report review process	Yes/No	
9	Participation in site monitoring visits	Yes/No	
10	Number and type of continuing training workshops organized for YEC-1 members		
11	Number and type of continuing training workshops organized for staff of YEC-1 Secretariat		
12	Any other contribution to research ethics		
11	How satisfied are you with your work in the YEC-1	25% 51-75%	26-50 % >75%

Signature of YEC-1 Member-Secretary and date:

Assessment observations of the Chairperson:

Signature of the Chairperson and date:

Ann04/SOP 21/v3 Self-assessment form of YEC-1 Chairperson

Name of the YEC-1 Chairperson:

Date of joining YEC-1:

SI No	Self assessment item	Response
1	Current tenure	
2	Terms served	
3	Training received	
4	Type of training received	
5	Number of meetings attended in the current year	
6	Number of protocols reviewed per meeting as lead discussant	
6	Number of protocols reviewed per meeting as primary reviewer	
7	Number of protocols reviewed per meeting as secondary reviewer	
8	Level of participation in the ethical discussions in the meetings	25% 26-50 % 51-75% >75%
8	Participation in SAE report review process	Yes/No
9	Participation in site monitoring visits	Yes/No
10	Whether considerations related to conflict of interest considered	Yes/No
11	Any other significant contribution to the field of research ethics	



12	Whether quorum requirement fulfillment ensured as per current guidelines in YEC-1 meetings	
13	Whether considerations related to conflict of interest explored	
14	Any other contribution to research ethics	
15	How satisfied are you with your work in the YEC-1	25% 26-50 % 51-75% >75%

Signature of Chairperson and date:

Ann05/SOP 21/v3: 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 _____

SI No	Self assessment item	Response
1	Years of service	
2	Status of service	
3	Type of training received: Initial: Continuous:	
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	25% 26-50 % 51-75% >75%

Signature of YEC-1 Secretarial staff and date:

Assessment observations of the Chairperson:

Signature of the Chairperson and date:

Ann06/SOP21/v3: Feedback of the YEC-1 members on the YEC-1 functioning

S.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			



YENEPOYA

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YENEPOYA ETHICS COMMITTEE-1

SOP 21/v3
MEMBER TRAINING FEEDBACK
03/10/2019

20	What according to you is the strength of the YEC-1?	
21	What according to you needs improvement?	

7. Flowchart

