

Title: Training and Assessment of Ethics Committee Members

SOP Code: SOP 21/v2

Effective Date: 01/08/2016

Prepared by:

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Reviewed by:

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Approved by:

Dr. Sayeegeetha Hegde Chairperson, YUEC	Signature with Date <i>Sayeegeetha</i> 3/8/16
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Registrar Yenepeya University vide Notification No. YURBQ/ACA/YUEC/FERCAP/01/2016	Signature with Date <i>Dr. G. Shree Kumar Menon</i> 01/8/16 Dr. G. Shree Kumar Menon Registrar Yenepeya University Mangaluru - 575 018
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Dr. Ravi Vaswani Member, YEC-1 SOP team	Signature with Date
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Approved by:

Dr. Sayeegetha Hegde 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 SOP is to describe requirements and methodology for training and performance assessment of Yenepoya Ethics Committee-1 (YEC-1) members and the Secretariat

2. Scope

The SOP applies to all the YEC-1 members and the Secretariat.

3. Responsibility

It is the responsibility of the YEC-1 Chairperson with the assistance of Member-Secretary to ensure that there is adequate initial and continued training of the YEC-1 members and the Secretariat. The Chairperson is responsible for assessment of all YEC-1 members and complete a self-assessment exercise at prescribed intervals.

4. Detailed instructions:

4.1 Topics for training:

YEC-1 members should have knowledge of the following:

- Relevant research ethics and regulatory guidelines
- Roles and responsibilities of YEC-1 members
- Review of protocol and related documents, including concepts of risk-benefit assessment, equity in recruitment, autonomy, confidentiality and privacy
- Recent Developments in relevant health science specialities
- SOPs of YEC-1

The Secretariat should have knowledge and relevant skills for conducting the following activities:

- Competency in working on Microsoft word, Excel, YEC-1 office software
- Maintenance of YEC-1 database
- Communication skills- written and verbal
- Knowledge about the SOPs

4.2 Training of new YEC-1 members:

- 4.2.1 Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided.
- 4.2.2 An individual selected as a new member of the YEC-1 will be required to attend one meeting as an ‘Observer’ before being inducted as a member of the YEC-1. Member Secretary or a YEC-1 member will provide an introductory training to the new member. The new YEC-1 members would be encouraged to undergo EC training program too.
- 4.2.3 The Chairperson, YEC-1 Member-Secretary, and members will be encouraged to receive continued training by participating in workshop, conference and/or re-training program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- 4.2.4 The YEC-1 will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the YEC-1 Members to the institutional faculty members.
- 4.2.5 The YEC-1 may sponsor or reimburse the expenses of a member or prospective member(s) for attending conference, continuing education session workshop and/or training program in the area of bioethics (if applicable).

4.3 Training of the Secretariat:

- 4.3.1 The YEC-1 Member Secretary along with other members will train the Secretariat on SOPs.
- 4.3.2 There will be initial training and at least one training session per year on SOPs.
- 4.3.3 The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

4.4 Assessment of YEC-1 members:

4.4.1 The YEC-1 members' performance should be evaluated once a year using an assessment form (*Ann01/SOP 21/v2*) by the Chairperson.

4.4.2 The Chairperson should do self-assessment once a year

4.5 Maintenance of training records of the YEC-1 Members and the Administrative Staff

4.5.1 The Secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual YEC-1 members.

4.5.2 The copies will be filed in the individual members' files.

4.5.3 The records regarding training copies of the Secretariat will also be maintained in their respective files

5. Annexures

Ann01/SOP 21/v2: Self Assessment Form for YEC-1 Member-Secretary/ Member

Ann02/SOP21/v2: Self Assessment form for YEC-1 Chairperson

Ann01/SOP 21/v2 Self Assessment Form for YEC-1 Member-Secretary/Member

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 projects reviewed per meeting as primary reviewer	
7	Number of projects reviewed per meeting as secondary reviewer	
8	Participation in SAE report review process	Yes/No
9	Participation in site monitoring visits	Yes/No
10	For Member-Secretary: Number and type of continuing training	

	workshops organized for YEC-1 members	
11	For Member-Secretary: Number and type of continuing training workshops organized for staff of YEC-1 Secretariat	
12	Any other significant contribution to the field of research ethics	

Signature of YEC-1 member and date:

Remarks of the Chairperson:

Singature of the Chairperson and date:

**Annexure 2: Ann02/SOP 21/v2
Self Assessment Form for YEC-1 Chairperson**

SI No	Self assessment item	Response
1	Current tenure	
2	Terms served	
3	Training received	
4	Type of training received	
5	Number of meetings held in the current year	
6	Number of meetings attended	
7	Whether quorum requirement fulfillment ensured as per schedule Y in YEC-1 meetings	Yes/No
8	Whether considerations related to conflict of interest considered	Yes/No
11	Any other significant contribution to the field of research ethics	
12	Any other comments	

Signature of the Chairperson and date:

7. Flow Chart

No.	Activity	Responsibility
1	Ensuring Training of YEC-1 members	Chairperson/Member-Secretary
2	Training of Secretariat	YEC-1 Member-Secretary/ Members
3	Assessment of performance of members	YEC-1 Chairperson
4	Assessment of performance of Chairperson	YEC-1 Chairperson (self assessment)