

Title: Training and Assessment of Ethics Committee Members

SOP Code: SOP 21/v2

Effective Date: 01/08/2016

Prepared by:

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Approved by:

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Notified by:

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| Registrar Yenepoya University vide Notification No. YU/REG/ACA/YUEC/FERCAP/01/2016 dated 01/08/2016 | Signature with Date |
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Table of Contents:

| No. | Content | Page No. |
|------------|-----------------------|-----------------|
| 1 | Purpose | 3 |
| 2 | Scope | 3 |
| 3 | Responsibility | 3 |
| 4 | Detailed Instructions | 3 |
| 5 | Annexures | 5 |
| 6 | Flowchart | 7 |

1. Purpose

The purpose of this SOP is to describe requirements and methodology for training and performance assessment of Yenepoya University Ethics Committee (YUEC) members and the Secretariat

2. Scope

The SOP applies to all the YUEC members and the Secretariat.

3. Responsibility

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

4. Detailed instructions:

4.1 Topics for training:

YUEC members should have knowledge of the following:

- Relevant research ethics and regulatory guidelines
- Roles and responsibilities of YUEC 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 YUEC

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

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

4.2 Training of new YUEC 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 YUEC will be required to attend one meeting as an 'Observer' before being inducted as a member of the YUEC. Member Secretary or a YUEC member will provide an introductory training to the new member. The new YUEC members would be encouraged to undergo EC training program too.
- 4.2.3 The Chairperson, YUEC 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 YUEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the YUEC Members to the institutional faculty members.
- 4.2.5 The YUEC may sponsor or reimburse the expenses of a member or prospective member(s) for attending conference, continuing education session workshop and/or training program (if applicable).

4.3 Training of the Secretariat:

- 4.3.1 The YUEC 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 YUEC members:

4.4.1 The YUEC 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 YUEC 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 YUEC 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

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

Annexure 2: Ann02/SOP21/v2: Self Assessment form for YUEC Chairperson

Annexure 1: Ann01/SOP 21/v2 Self Assessment Form for YUEC 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 | |

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

Signature of YUEC member and date:

Remarks of the Chairperson:

Singature of the Chairperson and date:

**Annexure 2: Ann02/SOP 21/v2
Self Assessment Form for YUEC 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 YUEC 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 YUEC members | Chairperson/Member-Secretary |
| 2 | Training of Secretariat | YUEC Member-Secretary/ Members |
| 3 | Assessment of performance of members | YUEC Chairperson |
| 4 | Assessment of performance of Chairperson | YUEC Chairperson (self assessment) |