


Title: Procedures for allowing Guest/Observer to visit Yenepoya University Ethics Committee or attend Yenepoya University Ethics Committee meeting


SOP Code: SOP05/v2

Effective date: 01/08/2016

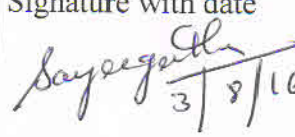
Prepared by:

Dr. Uma Kulkarni Jt Secretary, YUEC	Signature with date  30/07/2016
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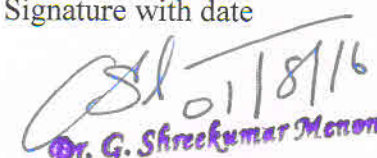
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Dr. Ravi Vaswani YUEC SOP Team	Signature with date  30/7/16
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Approved by:

Dr. Sayeegeetha Chairperson, YUEC	Signature with date  31/8/16
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Notified by:

Registrar, Yenepoya University vide Notification No. YUReg/ACA/YUEC/FERCAP/01/2016	Signature with date  01/8/16 Dr. G. Shree Kumar Menon Registrar Yenepoya University Mangaluru - 575 018
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**Title: Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee - 1
or attend Yenepoya Ethics Committee - 1 meeting**

SOP Code: SOP05/v2

Effective date: 01/08/2016

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Dr. Uma Kulkarni Jt Secretary, YEC-1	Signature with date
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Dr. Ravi Vaswani YEC-1 SOP Team	Signature with date
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Notified by:

Registrar, Yenepoya 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 Standard Operating Procedure (SOP) is to describe procedures to be followed by Yenepoya Ethics Committee - 1 (YEC-1) and the Guest/Observer whenever he/she visits the YEC-1 Office/Secretariat or attends YEC-1 meeting. This SOP is needed to ensure adequate protection of confidentiality of information related to research studies

2. Scope:

2.1 This SOP covers the procedures for allowing a guest/observer to visit the YEC-1 Office/Secretariat and/or observe a meeting in progress.

3. Glossary:

Guest(s)/observer(s) may include a student(s)/trainee(s), member(s) of other ethics committees, surveyor(s), member(s) of regulatory agencies, representative(s) of patient group(s), representative(s) of special interest group(s), representative(s) of accrediting organization(s), representative(s) of Yenepoya University who wish(es) to learn/understand/review/assess the functioning of ethics committees, or to represent participant group(s).

4. Responsibility:

4.1 Member-Secretary:

- 4.1.1 It is the responsibility of the Member-Secretary in consultation with the Chairperson to decide whether the guest/observer intending to attend the YEC-1 office/Secretariat or the YEC-1 meeting, may be allowed.
- 4.1.2 The Member-Secretary will inform the guest/observer to read, understand, agree and sign the agreement letter prior to visiting the YEC-1 office or YEC-1 meeting

4.2 Secretariat:

- 4.2.1 The YEC-1 Secretariat after receiving the request letter from the prospective visitor or guest will inform the Member-Secretary

- 4.2.2 The YEC-1 Secretariat will ensure that the confidentiality letter is duly signed with date by the guest/observer prior to visiting the YEC-1 office or attending the YEC-1 meeting.
- 4.2.3 The YEC-1 Secretariat files this duly signed letter in the respective YEC-1 file

5 Detailed instructions:

5.1 Decision to allow the visitor/observer:

- 5.1.1 On receiving a verbal or written request from a guest intending to visit the YEC-1 office or observe the YEC-1 meeting, the Member-Secretary will inform the Chairperson about the same
- 5.1.2 The request is recorded in the YEC-1 file stating the reason for the visit
- 5.1.3 The Chairperson and Member-Secretary will decide whether the guest or the observer should be allowed to visit the YEC-1 Secretariat or attend the YEC-1 meeting based on the reasons quoted.
- 5.1.4 Once it is decided to allow the guest/observer to visit the YEC-1 Secretariat or attend the YEC-1 meeting, the date and time of visit is informed to the guest via an email.

5.2 Signing the Confidentiality agreement from

- 5.2.1 The Secretariat gives the confidentiality agreement form (Ann01/SOP05/v2) to the visitor/observer upon his arrival at the YEC-1 office on the scheduled date and time
- 5.2.2 The guest/observer will read the form carefully prior to the visit to the YEC-1 Secretariat or before commencement of the YEC-1 meeting, whichever is applicable.
- 5.2.3 If there are any doubts, questions, the guest/observer will seek clarifications from the Secretariat/Member-Secretary/member of YEC-1.
- 5.2.4 The guest/observer will enter the specified details stating clearly the purpose for the visit, in the given form and sign the confidentiality agreement form in the presence of at least one member of the YEC-1, or one administrative staff of the YEC-1 Secretariat.
- 5.2.5 Chairperson/Member-Secretary will counter sign the confidentiality agreement form
- 5.2.6 A photocopy of the duly signed and dated document will be provided to the guest/observer
- 5.2.7 The guest/observer will acknowledge the receipt of the photocopy.

5.3 Filing of the confidentiality agreement forms

- 5.3.1 The Secretariat will file the original duly signed confidentiality agreement form in the YEC-1 file for confidentiality agreement forms for visitors of the YEC-1
- 5.3.2 The file is maintained in the secure storage of the YEC-1

5.4 Ensuring confidentiality

The guest /observer must implement the clauses of the signed Confidentiality Agreement form.

6 Annexures:

- 6.1 Ann02/SOP05/v2: Request letter to visit YEC-1 or attend YEC-1 meeting
- 6.2 Ann01/SOP05/v2: Confidentiality Agreement for Guest/Observer to YEC-1 /YEC-1 Meeting

Ann01/SOP05/v2

Request letter to visit YEC-1 or attend YEC-1 meeting

To

The Member-Secretary, Yenepoya Ethics Committee - 1

Yenepoya deemed to be University

Sir/Madam,

I request you to permit me to visit YEC-1 office/YEC-1 meeting. Following are my details:

Name:

Designation:

Institution:

Address:

Phone number:

Email address:

Desired date and time of visit:

Purpose of visit:

Thanking you, Yours sincerely,

Signature with Name and date

Ann02/SOP05/v2

**Confidentiality Agreement Form for Guest / Observer Attendees to YEC-1 Secretariat/
YEC-1 Meetings**

Confidentiality agreement

I have read carefully and understood the terms of confidentiality agreement provided by the YEC-1 Secretariat for visiting the YEC-1 Secretariat/office on (date) _____ at (time) /attending YEC-1 meeting on (date) _____ at (time) _____ at (venue)_____

I understand that I am being allowed to visit YEC-1 office/attend YEC-1 meeting only as a guest/observer. I may become aware of some confidential information during my visit to YEC-1 / during the course of the YEC-1 meeting. I ensure that any confidential information that I come across will be kept confidential through reasonable measures.

I ensure that I will only observe the functioning of the YEC-1 Secretariat/office and/or meeting without interfering with the discussion in the meeting or disrupting the office material.

I agree to all the terms and conditions.

Signature:

Name

Institution

Date:

Signature of the Chairperson/Member-Secretary

Date:

Acknowledgment:

I, _____ (name) acknowledge that I have received a copy of the agreement signed by the Chairperson YEC-1 and me.

Signature of guest with date

7 Flowchart

SI No	Activity	Responsibility
1	Receiving request from guest/ observer	YEC-1 Secretariat/ Member/ Member-Secretary
2	Allowing a guest/ observer	Chairperson
3	Informing guest/ observer about visit/ meeting date and time	YEC-1 Secretariat
4	Read the text carefully and thoroughly, sign the confidentiality agreement	Guest/observer
5	Filing of signed confidentiality form in YEC-1 records	YEC-1 Secretariat