



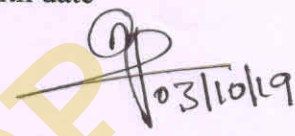
YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

Title: Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee - 1 or attend meeting

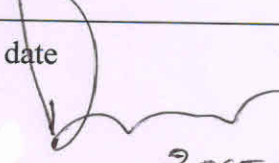
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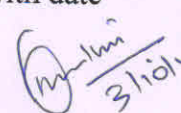
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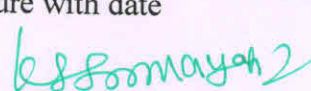
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Table of Contents:

Sl No	Content	Page No.
1	Purpose	3
2	Scope	3
3	Glossary	3
4	Responsibility	3
5	Detailed Instructions	5
6	Reference to other SOPs	7
7	Annexures	7
8	Flowchart	10

1. Purpose:

1.1. 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.

1.2. This SOP is needed to ensure adequate protection of confidentiality of information related to research studies, yet allow for YEC-1 accreditation, inspection audit or training.

2. Scope: 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:

3.1. Guest(s)/observer(s) may include any individual (s) who visit the YEC-1 as a

3.1.1. A student(s)/trainee(s),

3.1.2. Prospective member(s) of YEC-1 who are yet to be inducted,

3.1.3. Member(s) of other ethics committees, secretarial staff of other ethics committees

3.1.4. Surveyor(s)

3.1.5. Member(s) of regulatory agencies

3.1.6. Representative(s) of patient group(s)

3.1.7. Representative(s) of special interest group(s)

3.1.8. Representative(s) of accrediting organization(s)

3.1.9. Representative(s) of YU who wish(es) to learn/understand/ review/assess the functioning of ethics committees

3.1.10. Representatives of participant group(s)

3.1.11. Principal Investigator invited to the YEC-1 meeting

3.1.12. And should not have any interest – direct or indirect – in any of the active protocols currently at the YEC-1, to be tabled in the agenda of that meeting.

4. Responsibility:

4.1. The Chairperson will:

- 4.1.1. Read the request received to visit the YEC-1 office/ attend the YEC-1 meeting
- 4.1.2. Approve the request if found to be appropriate

4.2. The Member-Secretary will:

- 4.2.1. Review the request of the individual to visit the YEC-1 office/ meeting and decide whether the guest/observer intending to attend the YEC-1 office/Secretariat or the YEC-1 meeting, may be allowed. Should the Member-Secretary – in consultation with the Chairperson – decide not to accede to the request of a guest/observer/visitor, the same should be communicated in writing to the guest stating reasons why the visit is not permitted. The decision of the Chairperson/Member-Secretary will be final and binding.
- 4.2.2. 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

4.3. Secretariat will:

- 4.3.1. Inform the Member-Secretary when a request letter from the prospective visitor or guest is received
- 4.3.2. 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.
- 4.3.3. Ensure that a copy of the approval letter - stating what the guest can and cannot do – is handed over to the guest, and the receipt acknowledged.
- 4.3.4. Ensure that the study of the guest/observer is not tabled on the agenda of the meeting when the guest/observer will be attending.

- 4.3.5. Ensure that the communications from the guest/observer and the related records are maintained and archived.

5. Detailed instructions:

5.1. Decision to allow the visitor/observer:

- 5.1.1. The guest/observer will enter the specified details stating clearly the purpose for the visit, in the given form (*Ann01/SOP05/v3*)
- 5.1.2. On receiving a 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
- 5.1.3. The request is recorded in the YEC-1 file stating the reason for the visit
- 5.1.4. 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.
- 5.1.5. 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 form

- 5.2.1. The Secretariat will give the confidentiality agreement form (*Ann03/SOP3B/v3*) to the visitor/observer upon his/her 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 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. The 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. Attending the YEC-1 meeting**
 - 5.4.1. The guest observers are permitted to sit through the deliberation of the protocol, but will not take part in the decision making or voting
 - 5.4.2. The guest observers who are attending the meeting for a specific protocol (participant representatives, ICs, PIs) will attend the meeting only during the discussion of the concerned protocol
 - 5.4.3. The guest/observer will sign the attendance sheet for the YEC-1 meeting and the same will be included in the minutes of the meetings.
- 5.5. Visiting the YEC-1 office:**
 - 5.5.1. The guest observers are permitted to visit the YEC-1 office only when accompanied by the Secretariat/ Member-Secretary or other member of the YEC-1
 - 5.5.2. The guest observers are permitted to access any documents only after entering into the log book
- 5.6. Interacting with YEC-1 members:**

5.6.1. The guest observers will speak to or interview the YEC-1 members/Secretariat about the functioning of the YEC-1 and will not enquire about any individual protocol/ decision of the YEC-1

5.7. Ensuring confidentiality:

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

6. Reference to other SOPs:

- 6.1. SOP3A/v3: Handling Conflict of Interest
- 6.2. SOP3B/v3: Maintenance of confidentiality
- 6.3. SOP04/v3: Selection and responsibilities of Independent Consultant
- 6.4. SOP7A/v3: Full review of protocols
- 6.5. SOP08/v3: Preparation of agenda, meeting proceedings and recording of the minutes of meeting
- 6.6. SOP18/v3: Maintenance, archival, retrieval and disposal of YEC-1 files
- 6.7. SOP20/v3: Preparing for audit and Inspection of YEC-1

7. Annexures:

- 7.1. Ann01/SOP05/v3: Request letter to be a YEC-1 Guest/Observer
- 7.2. Ann02/SOP05/v3: Responsibilities of the Guest/ Observer

Ann01/SOP05/v3

Request letter to be YEC-1 Guest/Observer

To
The Member-Secretary/Chairperson
Yenepoya Ethics Committee – 1 (YEC-1)
Yenepoya deemed to be University

Sir/Madam,

I request you to permit me to

1. Visit the YEC-1 office

2. Attend the YEC-1 meeting
3. Interview YEC-1 Member/Secretariat

Following are my details:

Name:

Designation:

Institution:

Address:

Phone number:

Email address:

Desired date and time of visit:

Purpose of visit: (Provide specific details)

1. As an Inspector/ Assessor/Auditor:
2. As a trainee/student observer:
3. As a patient representative/special interest group:
4. As a prospective YEC-1 member/ Other EC member:
5. As a Principal Investigator:
6. Any other:

I do hereby solemnly affirm that I have no active, on-going or pending protocols in YEC-1 – either as PI, or Co-PI or research team member.

I understand that YEC-1 reserves the right to not grant me permission to attend the meeting, and that such decision will be binding. I will sign Confidentiality agreement form and abide by the same. I have read and understood the responsibilities of the Guest/ observer (Ann02/SOP05/v3) and will abide by the same.

Thanking you,

Yours sincerely,

Signature with Name and date

For office use only: Verified that the guest/observer has no protocols tabled on the agenda for this YEC-1 meeting

Date:

YEC-1 Secretariat

Ann02/SOP05/v3

Responsibilities of the Guest/Observer

Attending the YEC-1 meeting

The guest observers are permitted to sit through the deliberation of the protocol, but will not take part in the decision making or voting

The guest observers who are attending the meeting for a specific protocol (participant representatives, ICs, PIs) will attend the meeting only during the discussion of the concerned protocol

The guest/observer will sign the attendance sheet for the YEC-1 meeting and the same will be included in the minutes of the meetings.

Visiting the YEC-1 office:

The guest observers are permitted to visit the YEC-1 office only when accompanied by the Secretariat/ Member-Secretary or other member of the YEC-1

The guest observers are permitted to access any documents only after entering into the log book

Interacting with YEC-1 members:

The guest observers will speak to or interview the YEC-1 members/Secretariat about the functioning of the YEC-1 and will not enquire about any individual protocol/ decision of the YEC-1

8. Flowchart:

