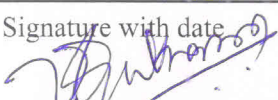


Title: Procedures for allowing Guest/Observer to visit Yenepoya Ethics Committee - 1 or attend meeting

SOP Code: SOP05/v4

Effective date: 01/07/2023

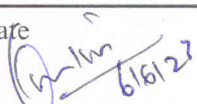
Prepared by:

Dr. Uma Kulkarni Members, YEC-1 SOP Subcommittee	Signature with date  1/6/2023
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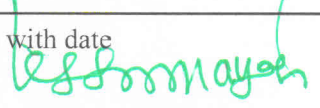
Reviewed by:

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature with date  1/6/23
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Approved by:

Dr. Vikram Shetty, Chairperson, YEC-1	Signature with date  6/6/23
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Notified by:

Registrar, Yenepoya (deemed to be University)	Signature with date  7/6/23
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Details of superseded SOP05

Subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Vina Vaswani	v1.4	10-08-2015	Major revision
Dr. Ravi Vaswani	v2	01-08-2016	Major revision following FERCAP assessment (2016)
Dr. Uma Kulkarni	v3	03-10-2019	Major revision following introduction of NDCTR-19, FERCAP & NABH assessment

Details of current SOPv4

SOP subcommittee convenor name	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01/07/2023	<ol style="list-style-type: none"> Glossary section added in the SOP Section on declaring Conflict of interest added Provision of certificate of attendance if required

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1. Purpose:

- 1.1. The purpose of this Standard Operating Procedure (SOP) is to describe procedures to be followed by Yenepona Ethics Committee – 1 (YEC-1) and the Guest/Observer whenever he/she visits the YEC-1 Office/Secretariat or attends YEC-1 meetings.
- 1.2. This SOP is needed to ensure adequate protection of confidentiality of information related to research studies, yet allow for training, 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. Definition:

- 3.1. Guest(s)/observer(s) may include any individual (s) who visit the YEC-1 as any one of the following 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:
 - 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. Auditor(s), 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 wishing to learn/understand/ review/assess the functioning of ethics committees
 - 3.1.10. Representatives of participant group(s)
 - 3.1.11. Principal Investigator or research team member invited to the YEC-1 meeting
 - 3.1.12. Researchers conducting research involving EC work

4. Responsibility:

4.1. The Chairperson will:

- 4.1.1. Approve the request received to visit the YEC-1 office/ attend the YEC-1 meeting 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 or not, and seek approval from the Chairperson.

- 4.2.2. Inform the guest/observer to read, understand, agree and sign the agreement letter prior to visiting the YEC-1 office or YEC-1 meeting
- 4.2.3. Provide a certificate of attendance for trainees, if required.

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 guest/observer is not attending the meeting when the study of the guest/observer is tabled on the agenda of the meeting (unless the PI/research team member has been invited to the meeting by YEC-1)
- 4.3.5. Ensure that the communications from the guest/observer and the related records are maintained and archived.
- 4.3.6. Prepare and communicate the certificate of attendance, when required for trainees/interns

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/v4*)
- 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.
- 5.1.6. 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.

5.2. Signing the Confidentiality agreement form

- 5.2.1. The Secretariat will give the confidentiality agreement form (*Ann03/SOP3B/v4*) to the visitor/observer upon 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. Declaring Conflict of interest:

- 5.4.1. The Guest observer will declare CoI, if any before accessing a protocol document
- 5.4.2. The guest observer will sign and submit the CoI form to YEC-1 (*Ann01/SOP3A/v4*)

5.5. Attending the YEC-1 meeting

- 5.5.1. The guest observers are permitted to sit through the meeting and deliberation of the protocols, but will not take part in the decision making or voting
- 5.5.2. 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
- 5.5.3. 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.

5.6. Visiting the YEC-1 office:

- 5.6.1. 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 and after entering the log book
- 5.6.2. The guest observers are permitted to access any documents only after entering into the log book

5.7. Interacting with YEC-1 members:

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

5.8. Ensuring confidentiality:

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

6. Reference to other SOPs:

- 6.1. [SOP3A/v4: Handling Conflict of Interest](#)
- 6.2. [SOP3B/v4: Maintenance of confidentiality](#)
- 6.3. [SOP04/v4: Selection and responsibilities of Independent Consultant](#)
- 6.4. SOP7A/v4: Full review of protocols
- 6.5. SOP08/v4: Preparation of agenda, meeting proceedings and recording of the minutes of meeting
- 6.6. SOP18/v4: Maintenance, archival, retrieval and disposal of YEC-1 files
- 6.7. SOP20/v4: Preparing for audit and Inspection of YEC-1

7. Annexures:

- 7.1. Ann01/SOP05/v4: Request letter to be a YEC-1 Guest/Observer

Ann01/SOP05/v4

Request letter to be YEC-1 Guest/Observer

Date:

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: _____
Date and time of proposed 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. Any other:

I solemnly affirm that I have no on-going or pending protocols in YEC-1, either as PI, or research team member (unless a PI or research team member has been invited to the meeting by YEC-1).

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 the confidentiality agreement form and abide by the same. I have read and understood the responsibilities of guest/observer (as below) and will abide by the same.

Responsibilities of the Guest/Observer

Attending the YEC-1 meeting: Guest/ observers are permitted to sit through the deliberation of the protocol, but will not take part in the decision making or voting. 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 meeting and the same will be included in the minutes of the meetings.

Visiting the YEC-1 office: Guest/ observers are permitted to visit the YEC-1 office only in the presence of the Secretariat/ Member-Secretary or other member of the YEC-1 after signing the log book. 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

Thanking you,

Yours sincerely,

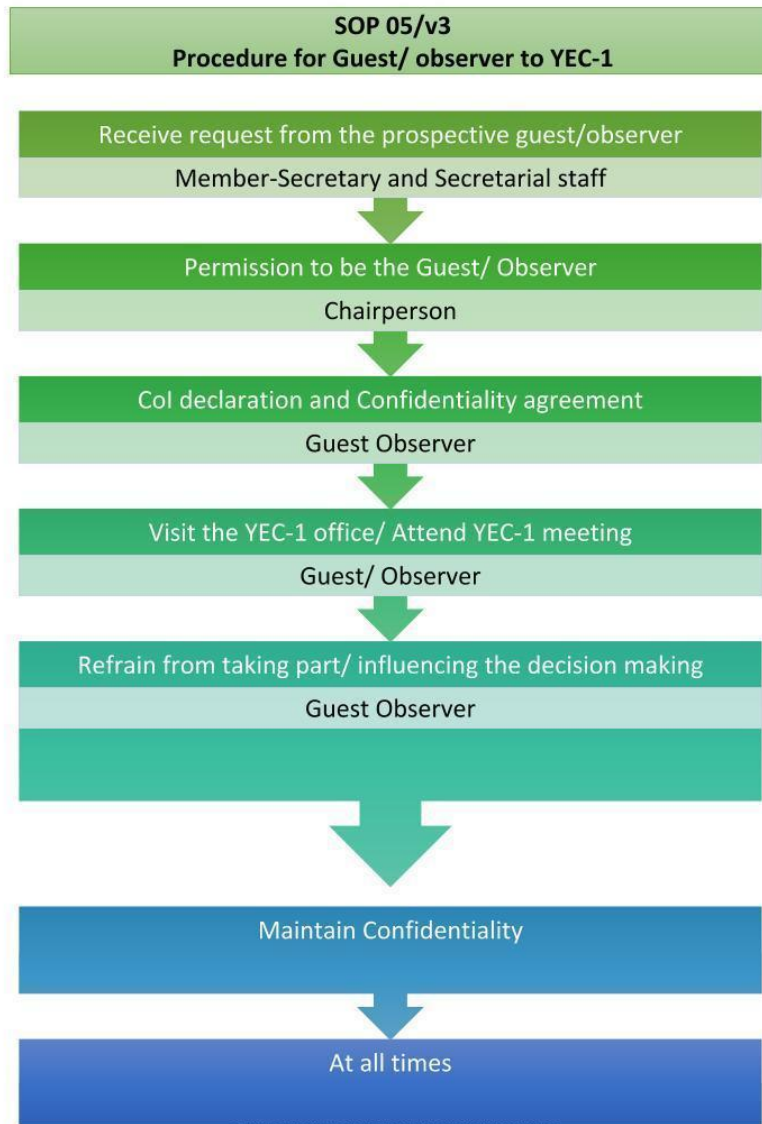
Signature with Name

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

8. Flowchart:



9. Glossary:

EC: Ethics Committee

IC: Independent Consultant

CoI: Conflict of Interest

SOP: Standard Operating Procedure