



YENEPOYA
[DEEMED TO BE UNIVERSITY]
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YENEPOYA ETHICS COMMITTEE 2
DHR registration No.: EC/NEW/INST/2020/1216
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Procedures for allowing guest /Observer to visit YEC2
YEC2/SOP05/v2
Effective Date:25.02.2023

Title: Procedures for allowing guest/Observer to visit YEC2

SOP Code: YEC2/SOP05/v2

Prepared by:

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Approved by:

Dr. Prasanna Keshava B Chairperson, YEC2	Signature with Date <i>Prasanna Keshava B / 25/02/23</i>
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Notified By:

Registrar, Yenepoya (Deemed to be university) Notification No: Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date <i>K. Somayajulu</i> 25/02/2023 Registrar YENEPOYA (Deemed to be University)
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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 2(YEC 2) and the Guest/Observer whenever he/she visits the YEC 2 Office/Secretariat or attends YEC 2 meeting.
- This SOP is needed to ensure adequate protection of confidentiality of information related to research studies

2. Scope:

This SOP covers the procedures for allowing a guest/observer to visit the YEC2 Office/Secretariat and/or observe a meeting in progress.

3. Glossary:

Guest(s)/observer(s) may include any individual (s) who visit the YEC2 as a

1. A student(s)/trainee(s),
2. Prospective member(s) of YEC2 who are yet to be inducted,
3. Member(s) of other ethics committees, secretarial staff of other ethics committees
4. Surveyor(s)
5. Member(s) of regulatory agencies
6. Representative(s) of patient group(s)
7. Representative(s) of special interest group(s)
8. Representative(s) of accrediting organization(s)
9. Representative(s) of YU who wish(es) to learn/understand/ review/assess the functioning of ethics committees
10. Representatives of participant group(s)
11. Principal Investigator invited to the YEC2 meeting
12. And should not have any interest – direct or indirect – in any of the active protocols currently at the YEC2, to be tabled in the agenda of that meeting.

4. Responsibility:

- **. The Chairperson will::**

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- Read the request received to visit the YEC2 office/ attend the YEC2 meeting
- Approve the request if found to be appropriate

The Member-Secretary will:

- Review the request of the individual to visit the YEC2 office/ meeting and decide whether the guest/observer intending to attend the YEC2 office/Secretariat or the YEC2 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.
- The Member-Secretary will inform the guest/observer to read, understand, agree and sign the agreement letter prior to visiting the YEC2 office or YEC2 meeting

Secretariat will:

- Inform the Member-Secretary when a request letter from the prospective visitor or guest is received
- Ensure that the confidentiality letter is duly signed with date by the guest/observer prior to visiting the YEC2 office or attending the YEC2 meeting.
- 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.
- Ensure that the study of the guest/observer is not tabled on the agenda of the meeting when the guest/observer will be attending.
- Ensure that the communications from the guest/observer and the related records are maintained and archived.

5. Detailed instructions:

Decision to allow the visitor/observer:

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- The guest/observer will enter the specified details stating clearly the purpose for the visit, in the given form (Ann01/SOP05/v2).
- On receiving a verbal or written request from a guest intending to visit the YEC 2 office or observe the YEC 2 meeting, the Member-Secretary will inform the Chairperson about the same
- The request is recorded in the YEC 2 file stating the reason for the visit.
- The Chairperson and Member-Secretary will decide whether the guest or the observer should be allowed to visit the YEC 2 Secretariat or attend the YEC 2 meeting based on the reasons quoted.
- Once it is decided to allow the guest/observer to visit the YEC 2 Secretariat or attend the YEC 2 meeting, the date and time of visit is informed to the guest via an email.

Signing the Confidentiality agreement form

- The Secretariat gives the confidentiality agreement form (Ann01/SOP05/v2) to the visitor/observer upon his arrival at the YEC 2 office on the scheduled date and time
- The guest/observer will read the form carefully prior to the visit to the YEC 2 Secretariat or before commencement of the YEC 2 meeting, whichever is applicable.
- If there are any doubts, questions, the guest/observer will seek clarifications from the Secretariat/Member-Secretary/member of YEC 2.
- 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 2, or one administrative staff of the YEC 2 Secretariat.
- The Chairperson/Member-Secretary will counter sign the confidentiality agreement form
- A photocopy of the duly signed and dated document will be provided to the guest/observer
- The guest/observer will acknowledge the receipt of the photocopy.

Filing of the confidentiality agreement forms

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- The Secretariat will file the original duly signed confidentiality agreement form in the YEC 2 file for confidentiality agreement forms for visitors of the YEC 2
- The file is maintained in the secure storage of the YEC 2

Attending the YEC2 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 YEC2 meeting and the same will be included in the minutes of the meetings

Visiting the YEC2 office:

- 1. The guest observers are permitted to visit the YEC2 office only when accompanied by the Secretariat/ Member-Secretary or other member of the YEC2
- 2. The guest observers are permitted to access any documents only after entering into the log book

Interacting with YEC2 members:

- The guest observers will speak to or interview the YEC2 members/Secretariat about the functioning of the YEC2 and will not enquire about any individual protocol/ decision of the YEC2.

Ensuring confidentiality

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

Annexures:

1. Ann01/SOP05/v2: Request letter to be a YEC2 Guest/Observer
2. Ann02/SOP05/v2: Responsibilities of the Guest/ Observer

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Ann01/SOP05/v2

Request letter to visit YEC 2 or attend YEC 2 meeting

To The Member-Secretary/Chairperson

Yenepoya Ethics Committee 2 (YEC2)

Yenepoya deemed to be University

Sir/Madam,

I request you to permit me to

1. Visit the YEC2 office
2. Attend the YEC2 meeting
3. Interview YEC2 Member/Secretariat

Sir/Madam,

I request you to permit me to visit the YEC 2 office/YEC 2 meeting. The 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

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Confidentiality Agreement Form For Guest / Observer Attendees to YEC 2 Secretariat/ YEC 2 Meetings

Confidentiality agreement

I have read carefully and understood the terms of confidentiality agreement provided by the YEC 2 Secretariat for visiting the YEC 2 Secretariat/office on (date)_____at (time) /attending YEC 2 meeting on (date) _____ at (time) _____ at (venue)_____

I understand that I am being allowed to visit YEC 2 office/attend YEC 2 meeting only as a guest/observer. I may become aware of some confidential information during my visit to YEC 2 / during the course of the YEC 2 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 2 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:

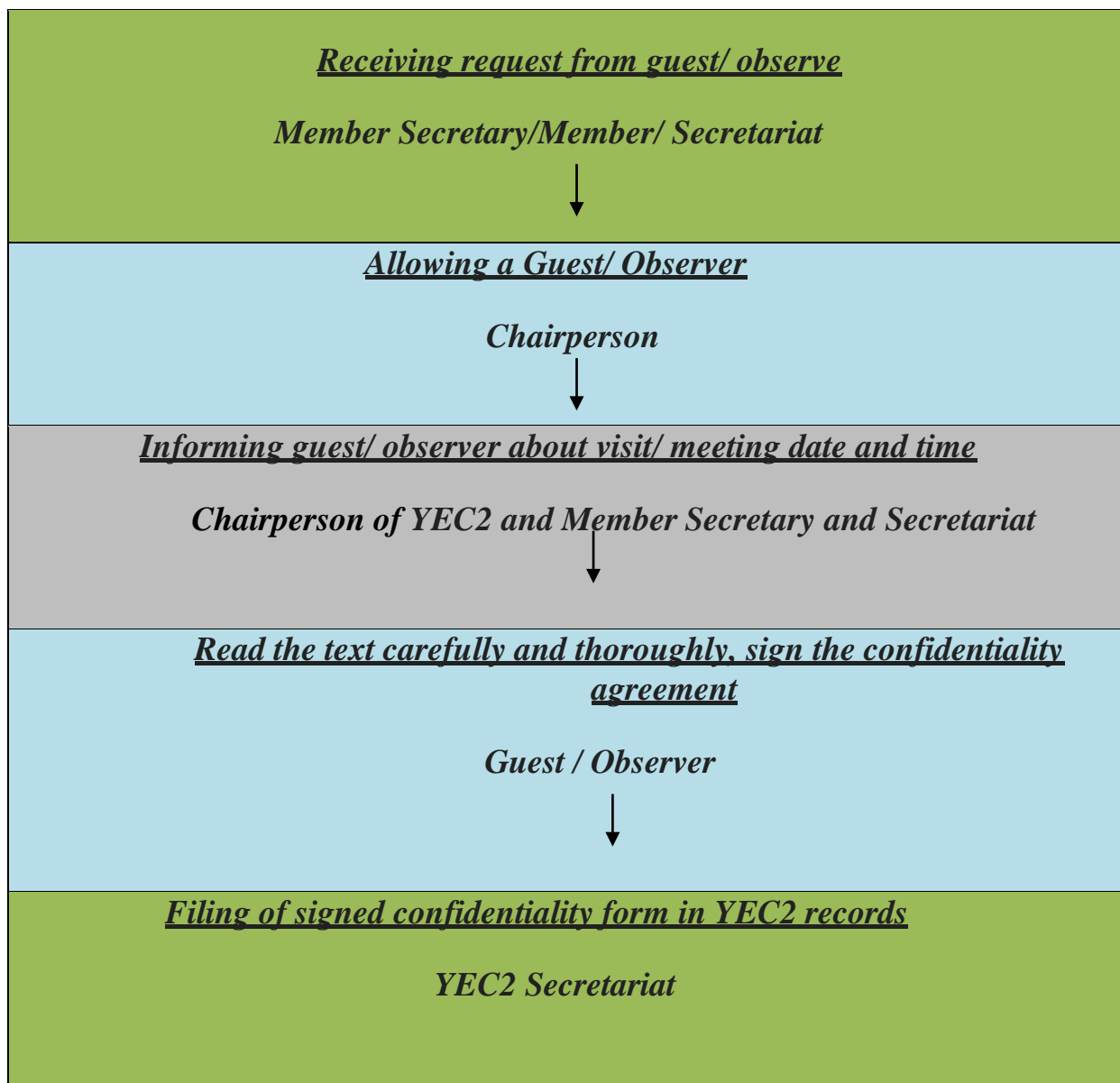
Acknowledgment:

I, _____(name) acknowledge that I have received a copy of the agreement signed by the Chairperson YEC 2 and me.

Signature of guest with date

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6. **Flow chart**



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7. References

Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from:

http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf