

**Title: Maintenance of confidentiality**

**SOP Code: SOP3B/v1**

**Effective Date: 20/02/2025**

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**1. Purpose:** The purpose of this SOP is to describe the process of maintaining confidentiality of documents and information pertaining to the functioning of YEC-3.

**2. Scope:** This SOP covers the policy related to the maintenance of confidentiality of documents and information and is applicable to all YEC-3 members, YEC-3 secretariat, independent consultants, and guest/observer/invitee to the YEC-3.

### **3. Definition**

**3.1. Confidentiality:** Confidentiality, for the purpose of this SOP, is defined as the state of securely keeping information gathered from research-related documents and data without sharing or disclosing it to unconcerned and unauthorized third parties.

### **4. Responsibility:**

#### **4.1. The Chairperson will:**

- 4.1.1. Ensure that the confidentiality of the YEC-3 functioning and its related data is maintained at all times.
- 4.1.2. Ensure that the YEC-3 documents are accessed only by authorized persons under strict confidentiality agreement at all times.
- 4.1.3. Reinforce that the YEC-3 members and any other person visiting the YEC-3 office or attending the YEC-3 meeting should adhere to the confidentiality agreement pertaining to all the business activities of the YEC-3.
- 4.1.4. Ensure that no identifying data pertaining to the protocols or YEC-3 members is divulged during the conduct of research or YEC-3 functioning.

#### **4.2. The Member-Secretary will:**

- 4.2.1. Prepare the core minutes of the meeting for the purpose of sharing with the Registrar, YU, and the authorized persons (auditors/inspectors) without divulging names and other sensitive data.
- 4.2.2. Ensure that appropriately redacted versions of the protocol and protocol-related documents are prepared for sending to Independent Consultants for review.
- 4.2.3. Ensure that appropriately redacted versions of protocol or related documents are used for academic purposes during research ethics training programs.

#### **4.3. The Secretariat will:**

- 4.3.1. Send confidentiality agreement forms to members, ICs, guest/observer/invitees.
- 4.3.2. File the confidentiality agreement forms in the respective members' files.
- 4.3.3. Prepare appropriately redacted versions of protocols and protocol-related documents for IC review and case study.

#### **4.4. YEC-3 Members will:**

- 4.4.1. Understand the definition and need for confidentiality.
- 4.4.2. Adhere to the confidentiality of documents sent to them for review.
- 4.4.3. Adhere to the confidentiality of information on the review, decision-making in the YEC-3 meetings, and all other activities of the YEC-3 functioning.
- 4.4.4. Adhere to the confidentiality of post-approval activities of the protocols.

**4.5. The Independent Consultant will:**

- 4.5.1. Understand the definition and need for confidentiality.
- 4.5.2. Adhere to the confidentiality of documents sent to them for review.
- 4.5.3. Adhere to the confidentiality of information on review and decision-making.

**4.6. The guest/observer/invitee will:**

- 4.6.1. Understand the definition and need for confidentiality.
- 4.6.2. Adhere to the confidentiality of documents accessed by them.
- 4.6.3. Adhere to the confidentiality of information on the review and decision-making.

**5. Detailed Instructions:**

**5.1. YEC-3 Members:**

- 5.1.1. **At the time joining YEC-3:** YEC-3 members (including the Chairperson and Member-Secretary) and staff of YEC-3 secretariat shall sign a declaration – at the time of joining the service of the ethics committee – that they will maintain confidentiality of the research-related documents and other information for their entire tenure and beyond (if necessary).
- 5.1.2. **At the time of review:** Maintain confidentiality of the documents and the assessment forms sent to them at the time of review
- 5.1.3. **YEC-3 meetings:** Maintain confidentiality of the agenda, proceedings and the minutes of the YEC-3 meeting. The members will not divulge any details of the protocols discussed, the proceedings and decisions on the protocols to anyone outside the YEC-3 by any means.
- 5.1.4. **In the post-approval activities:** Maintain confidentiality of protocol related post-approval activities like site monitoring/audits/deviations/ violations/continuing review (SOP16/v1; SOP11/v1; SOP19/v1)
- 5.1.5. **Annually and/or at the time of resigning/finishing the tenure in YEC-3:** The YEC-3 members will delete all the soft copies of the protocols or protocol-related documents and review forms from the computer or accessories/mobiles/emails

without sharing them with any unconcerned third person/party annually and/or at the end of the tenure/at the time of resignation. (SOP18/v1)

**5.2. Independent consultants:**

- 5.2.1. **At the time of joining YEC-3:** All ICs shall sign a declaration – at the time of joining the service of ethics committee – that they will maintain confidentiality of the documents and other information for their entire tenure as ICs and beyond.
- 5.2.2. **At the time of review:** Maintain confidentiality of the documents and the assessment forms sent to them at the time of review
- 5.2.3. **During YEC-3 meetings:** Maintain confidentiality of the agenda, proceedings and the minutes of the YEC-3 meeting, if invited to attend the meeting.

**5.3. Guest/observer/invitee:**

- 5.3.1. **At the time of being permitted as a guest/observer/invitee:** Any individual who is permitted by the Chairperson to visit the YEC-3 office and/or attend the YEC-3 meeting shall sign a declaration that they will maintain confidentiality of the documents and other information during their visit and beyond.

**5.4. Confidentiality form:**

- 5.4.1. The Confidentiality form will be prepared as per the format (Ann01/SOP3A/v1)
- 5.4.2. The confidentiality form will encompass the following elements
  - 5.4.2.1. Documents sent by email for review
  - 5.4.2.2. Documents/ files accessed from the archival room
  - 5.4.2.3. Agenda and minutes of the meeting sent by email
  - 5.4.2.4. Proceedings of the minutes
  - 5.4.2.5. Research files and data accessed during the post-approval activities
  - 5.4.2.6. Any other documents/data/information that needs to be confidential

**5.5. Recording of the confidentiality agreement:**

- 5.5.1. The confidentiality agreement will be countersigned by the Chairperson
- 5.5.2. The YEC-3 Secretariat will scan a copy of the Confidentiality form and give it to the concerned individual and the original will be kept in the respective member's file/ IC file/ guest/observer/invitee's file.
- 5.5.3. The Secretariat will file the Confidentiality Agreement forms signed by the YEC-3 members, ICs or guest/observer/invitees in the respective files

**5.6. Maintenance of confidentiality at the YEC-3 office:**

- 5.6.1. Access to the archival room, computer, hard disc and YEC-3 documents will be restricted only to authorized personnel as given in SOP20/v1.

- 5.6.2. The resubmissions including the queries raised by the reviewers will be anonymized and sent to the investigators (SOP9A/v1)
- 5.6.3. The protocol or related documents sent to the ICs will be redacted so that the researcher will not be identified (SOP20/v1).
- 5.6.4. Protocols used for academic purposes during research ethics trainings will be redacted so that the researcher or /institution will be not be identified
- 5.6.5. The detailed minutes of the meeting will be filed in the YEC-3 office. Only core minutes of the meetings will be forwarded to the Registrar or any other authority (auditors/accreditors/inspectors) to which it needs to be sent. (SOP08/v1)
- 5.6.6. The core minutes of the meetings will **not** include
  - 5.6.6.1. The detailed discussion
  - 5.6.6.2. Names of the YEC-3 members who raised the issues during discussion
  - 5.6.6.3. The names of the YEC-3 members who dissented during voting.
  - 5.6.6.4. The names and affiliations of the investigators
- 5.6.7. No identifying data pertaining to the protocols/ researchers or YEC-3 members will be divulged during the conduct of research on YEC-3 functioning

## 6. Annexures:

- 6.1.1. **Ann01/SOP3B/v1:** Confidentiality Agreement Form for YEC-3 member
- 6.1.2. **Ann02/SOP3B/v1:** Confidentiality Agreement Form for Independent Consultant
- 6.1.3. **Ann03/SOP3B/v1:** Confidentiality Agreement Form for Guest/Observer/Invitee
- 6.1.4. **Ann04/SOP3B/v1:** Confidentiality Agreement Form for Staff of the Secretariat

### **Ann01/SOP3B/v1**

#### **Confidentiality Agreement Form for YEC-3 member**

I, Dr/Mr/Ms \_\_\_\_\_ (*Member's name, his/her position on YEC-3 and affiliation*) have been appointed as a member of Yenepoya Ethics Committee - 1 (YEC-3). I have read and understand the confidentiality policy of the YEC-3. I agree that:

1. All confidential information (and copies/notes thereof) shall remain the sole property of YEC-3
2. All the confidential information is shared with me in trust or confidence as a YEC-3 member
3. I shall use the documents/ information shared with me, only for the authorized purposes
4. I shall not share any documents with the PI or sponsor or any third unconcerned person/party
5. I shall not photocopy/ photograph any of the documents accessed by me from the archival
6. I shall delete all the YEC-3 documents from my email/computer/ mobile/ electronic storage/cloud/prints after the research study is completed.
7. I shall ensure that all soft copies are deleted annually or at the end of my term in YEC-3, whichever is earlier.

8. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of YEC-3 and may include:
- The protocol/ protocol-related documents sent to me for review by email:
  - The agenda and minutes of the meeting sent to me by email
  - Proceedings of the YEC-3 meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the YEC-3 meeting:
  - The protocol/ protocol-related documents/ YEC-3 files accessed from the archival room:
  - Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review:
  - Any other, if applicable

I, Dr/Mr/Ms \_\_\_\_\_ (Member name, YEC-3 designation)

have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from YEC-3 and/or liable to legal actions from Yenepoya deemed to be University, if confidentiality is willfully breached by me.

Signature

Date

Chairperson's Signature

Date

*[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat YEC-3. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-3 Chairperson and me

Signature

Date:

### Ann02/SOP3B/v1

### Confidentiality Agreement Form for YEC-3 Independent Consultant

I, Dr/Mr/Ms \_\_\_\_\_ (IC's name and affiliation) have been appointed as an Independent Consultant of Yenepoya Ethics Committee - 1 (YEC-3). I have read and understand the confidentiality policy of the YEC-3. I agree that:

- All confidential information (and copies/notes thereof) shall remain the sole property of YEC-3
- All the confidential information is shared with me in trust or confidence as a YEC-3 member
- I shall use the documents/ information shared with me, only for the authorized purposes
- I shall not share any documents with the PI or sponsor or any third unconcerned person/party
- I shall not photocopy/ photograph any of the documents accessed by me from the archival
- I shall delete all the YEC-3 documents from my email/computer/ mobile/ electronic storage/cloud/prints after the research study is completed.
- I shall ensure that all soft copies are deleted annually or at the end of my term in YEC-3, whichever is earlier.
- This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of YEC-3 and may include:
  - The protocol/ protocol-related documents sent to me for review by email:
  - The agenda and minutes of the meeting sent to me by email
  - Proceedings of the YEC-3 meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the YEC-3 meeting:
  - The protocol/ protocol-related documents/ YEC-3 files accessed from the archival room:

- e. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review:
- f. Any other, if applicable

I, Dr/Mr/Ms \_\_\_\_\_ (IC's name, affiliation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from YEC-3 and/or liable to legal actions from Yenepoya deemed to be University, if confidentiality is willfully breached by me.

Signature

Date

Chairperson's Signature

Date

*[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat YEC-3. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-3 Chairperson and me

Signature

Date

### Ann03/SOP3B/v1

### Confidentiality Agreement Form for YEC-3 Guest/Observer/Invitee

I, Dr/Mr/Ms \_\_\_\_\_ (Name and affiliation) have been permitted to attend the meeting of Yenepoya Ethics Committee - 1 (YEC-3) and access the protocol-related documents. I have read and understand the confidentiality policy of the YEC-3. I agree that:

1. All confidential information (and copies/notes thereof) shall remain the sole property of YEC-3
2. All the confidential information is shared with me in trust or confidence as a YEC-3 member
3. I shall use the documents/ information shared with me, only for the authorized purposes
4. I shall not share any documents with the PI or sponsor or any third unconcerned person/party
5. I shall not photocopy/ photograph any of the documents accessed by me from the archival
6. I shall delete all the YEC-3 documents from my email/computer/ mobile/ electronic storage/cloud/prints after the research study is completed.
7. I shall ensure that all soft copies are deleted annually or at the end of my term in YEC-3, whichever is earlier.
8. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of YEC-3 and may include:
  - a. The protocol/ protocol-related documents sent to me for review by email:
  - b. The agenda and minutes of the meeting sent to me by email
  - c. Proceedings of the YEC-3 meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the YEC-3 meeting:
  - d. The protocol/ protocol-related documents/ YEC-3 files accessed from the archival room:
  - e. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review:
  - f. Any other, if applicable

I, Dr/Mr/Ms \_\_\_\_\_ (Name, affiliation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from YEC-3 and/or liable to legal actions from Yenepoya deemed to be University, if confidentiality is willfully breached by me.

Signature

Date

Chairperson's Signature

Date

*[The original will be kept on file in the custody of Secretariat YEC-3, with a copy to the Undersigned]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-3 Chairperson and me

Signature

Date

**Ann04/SOP3B/v1:**

**Confidentiality Agreement Form for Staff of the Secretariat**

I, Mr/Ms \_\_\_\_\_ (*staff's name and designation*) have been appointed as a staff of Yenepoya Ethics Committee - 1 (YEC-3) Secretariat. I have read and understand the confidentiality policy of the YEC-3. I agree that:

1. All confidential information (and copies/notes thereof) shall remain the sole property of YEC-3
2. All the confidential information is shared with me in trust or confidence as a YEC-3 member
3. I shall use the documents/ information shared with me, only for the authorized purposes
4. I shall not share any documents with the PI or sponsor or any third unconcerned person/party
5. I shall not photocopy/ photograph any of the documents accessed by me from the archival
6. I shall take all possible efforts to keep confidential, all YEC-3 data in my email, computer, mobile, electronic storage, cloud or prints .
7. This agreement encompasses any information deemed confidential, accessed by me in conjunction with my duties as a staff of YEC-3 Secretariat and may include:
  - a. The protocol/ protocol-related documents
  - b. The agenda and minutes of the meeting
  - c. Proceedings of the YEC-3 meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the YEC-3 meeting:
  - d. The protocol/ protocol-related documents/ YEC-3 files accessed from the archival room:
  - e. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review:
  - f. Any other, if applicable

I, Mr/Ms \_\_\_\_\_ (staff name, designation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from service and/or liable to legal actions from Yenepoya deemed to be University, if confidentiality is willfully breached by me.

Signature

Date

Chairperson's Signature

Date

*[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat YEC-3. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-3 Chairperson and me

Signature

Date



7. **Glossary:**

IC: Independent Consultant

SOP: Standard Operating Procedure