


**Title: Maintenance of confidentiality**

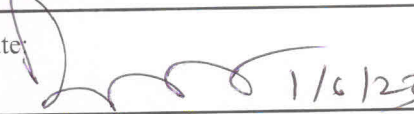
**SOP Code: SOP3B/v4**

**Effective Date: 01/07/2023**

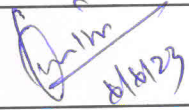
**Prepared by:**

Dr. Uma Kulkarni Convenor, YEC-1 SOP Subcommittee	Signature & Date:  1/6/2023
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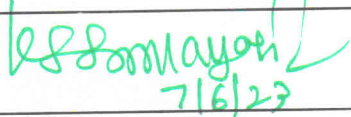
**Reviewed by:**

Dr. Ravi Vaswani Member, YEC-1 SOP Subcommittee	Signature & Date:  1/6/23
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**Approved by:**

Dr. Vikram Shetty, Chairperson, YEC-1	Signature & Date:  1/6/23
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**Notified by:**

Registrar, Yenepoya (deemed to be University)	Signature & Date:  7/6/23
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**Details of superseded SOP3B**

Name of the subcommittee convenor	Version	Effective date (dd-mm-yyyy)	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 and NABH assessment

**Details of current SOP3B/v4**

Name of the SOP subcommittee convenor	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	Glossary section added in the SOP

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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-1.
2. **Scope:** This SOP covers the policy related to the maintenance of confidentiality of documents and information and is applicable to all YEC-1 members, YEC-1 secretariat, independent consultants and guest/observer/invitee to the YEC-1.
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 with uninterested and unauthorized third parties
4. **Responsibility:**
  - 4.1. **The Chairperson will:**
    - 4.1.1. Ensure that the confidentiality of the YEC-1 functioning and its related data is maintained at all times.
    - 4.1.2. Ensure that the YEC-1 documents are accessed only by authorized persons under strict confidentiality agreement at all times.
    - 4.1.3. Reinforce that the YEC-1 members and any other person visiting the YEC-1 office or attending the YEC-1 meeting should adhere to the confidentiality agreement pertaining to all the business activities of the YEC-1.
    - 4.1.4. Ensure that no identifying data pertaining to the protocols or YEC-1 members is divulged during the conduct of research or YEC-1 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 version 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-1 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-1 meetings and all other activities of the YEC-1 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-1 Members:**
- 5.1.1. **At the time joining YEC-1:** YEC-1 members (including the Chairperson and Member-Secretary) and staff of YEC-1 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-1 meetings:** Maintain confidentiality of the agenda, proceedings and the minutes of the YEC-1 meeting. The members will not divulge any details of the protocols discussed, the proceedings and decisions on the protocols to anyone outside the YEC-1 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/v4; SOP11/v4; SOP19/v4)
- 5.1.5. **Annually and/or at the time of resigning/finishing the tenure in YEC-1:** The YEC-1 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/v4)
- 5.2. **Independent consultants:**
- 5.2.1. **At the time of joining YEC-1:** 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-1 meetings:** Maintain confidentiality of the agenda, proceedings and the

minutes of the YEC-1 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-1 office and/or attend the YEC-1 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/4)

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-1 Secretariat will scan a copy and give it to the concerned individual. The original will be kept in the 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-1 members, ICs or guest/observer/invitees in the respective files

5.6. **Maintenance of confidentiality at the YEC-1 office:**

5.6.1. Access to the archival room, computer, hard disc and YEC-1 documents will be restricted only to authorized personnel as given in SOP20/v4.

5.6.2. The resubmissions including the queries raised by the reviewers will be anonymized and sent to the investigators (SOP9A/v4)

5.6.3. The protocol or related documents sent to the ICs will be redacted so that the researcher will not be identified (SOP20/v4).

5.6.4. Protocols used for academic purposes during research ethics training will be redacted so that the researcher or /institution will not be identified.

5.6.5. The detailed minutes of the meeting will be filed in the YEC-1 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/v4)

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-1 members who raised the issues during discussion

- 5.6.6.3. The names of the YEC-1 members who dissented during voting.
- 5.6.6.4. The names and affiliations of the investigators
- 5.6.6.5. No identifying data pertaining to protocols/researchers or YEC-1 members will be divulged during the conduct of research on YEC-1 functioning

6. **Annexures:**

- 6.1. **Ann01/SOP3B/v4:** Confidentiality Agreement Form for YEC-1 member
- 6.2. **Ann02/SOP3B/v4:** Confidentiality Agreement Form for Independent Consultant
- 6.3. **Ann03/SOP3B/v4:** Confidentiality Agreement Form for Guest/Observer/Invitee
- 6.4. **Ann04/SOP3B/v4:** Confidentiality Agreement Form for Staff of the Secretariat

**Ann01/SOP3B/v4**

**Confidentiality Agreement Form for YEC-1 member**

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

1. All confidential information (and copies/notes thereof) shall remain the sole property of YEC-1
2. All the confidential information is shared with me in trust or confidence as a YEC-1 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-1 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-1, whichever is earlier.
8. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of YEC-1 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-1 meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the YEC-1 meeting:
  - d. The protocol/ protocol-related documents/ YEC-1 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 \_\_\_\_\_ (Member name, YEC-1 designation) have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from YEC-1 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-1. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-1 Chairperson and me  
Signature \_\_\_\_\_ Date: \_\_\_\_\_

**Ann02/SOP3B/v4**

**Confidentiality Agreement Form for YEC-1 Independent Consultant**

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

1. All confidential information (and copies/notes thereof) shall remain the sole property of YEC-1
2. All the confidential information is shared with me in trust or confidence as a YEC-1 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-1 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-1, whichever is earlier.
8. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as a member of YEC-1 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-1 meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the YEC-1 meeting:
  - d. The protocol/ protocol-related documents/ YEC-1 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-1 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-1. A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-1 Chairperson and me  
Signature \_\_\_\_\_ Date \_\_\_\_\_



**Ann03/SOP3B/v4**

**Confidentiality Agreement Form for YEC-1 Guest/Observer/Invitee**

I, Dr/Mr/Ms \_\_\_\_\_ (*Member's name and affiliation*) herein referred to as the "undersigned" has been appointed permitted to visit the YEC-1 office/ attend a YEC-1 meeting as a Guest observer.

I understand the Confidentiality policy of the YEC-1 and I agree that

1. All the confidential information (and any copies and notes thereof) shall remain the sole property of YEC-1
2. All the confidential information is shared with me in trust or confidence as a guest observer to YEC-1 office/meeting
3. I shall use the documents/ information shared with only for the contemplated purposes
4. I shall not share the documents with the PI or sponsor or any third unconcerned person/party
5. I shall delete all the documents from my email/computer/ mobile/ electronic storage/cloud/prints after the purpose of the visit is completed, if shared with me.
6. This agreement encompasses any information deemed confidential, provided to me in conjunction with my visit to YEC-1 and may include:
  1. The protocol/ protocol-related documents:
  2. Proceedings of the YEC-1 meetings including any information pertaining to the discussions, opinions, decisions, voting or any other component of the YEC-1 meeting, when applicable
  3. The protocol/ protocol-related documents/ YEC-1 files accessed from the archival room, if applicable:
  4. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review, if accessed by me/shared with me
  5. Any other, if applicable

I, Dr/Mr/Ms \_\_\_\_\_ (Guest observer name) have read and accept the aforementioned conditions as explained in this agreement. I am liable to legal actions from the Yenepoya deemed to be University, if confidentiality is will fully breached by me.

Signature

Date

Chairperson's Signature

Date

*[The original will be kept on file in the custody of Secretariat YEC-1, with a copy to the Undersigned]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-1 Chairperson and me

Signature

Date



**Ann04/SOP3B/v4:**

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

I, \_\_\_\_\_, Secretarial Staff, YEC-1 (Staff name & designation) herein referred to as the “undersigned”, have been appointed as a staff of the YEC-1 Secretariat. This agreement encompasses any information deemed confidential provided to the undersigned in conjunction with the duties as a staff of the YEC-1. All confidential information (and any copies and notes thereof) shall remain the sole property of the YEC-1.

The undersigned hereby agrees not to disclose or utilize, directly or indirectly all confidential information known to him/her during the tenure of his/her service and beyond if necessary.

I, \_\_\_\_\_, Secretarial Staff, YEC-1 (Staff name & designation) have read and accept the conditions as explained in this agreement.

Signature \_\_\_\_\_ Date \_\_\_\_\_

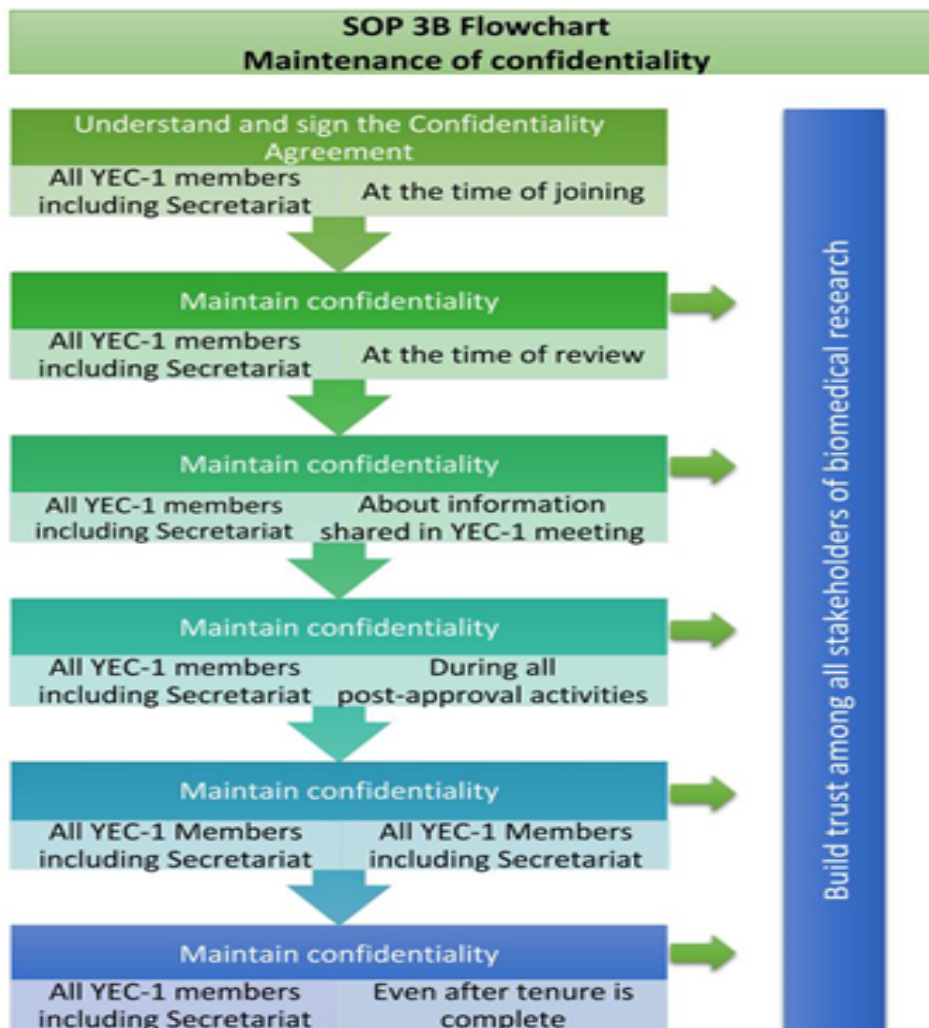
Chairperson’s signature \_\_\_\_\_ Date \_\_\_\_\_

*[Original (signed/ dated agreement) will be kept on file in the custody of YEC-1. A copy will be given to the undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the YEC-1 Chairperson and me

Signature \_\_\_\_\_ Date \_\_\_\_\_

7. **Flowchart:**



8. **Glossary:**

IC: Independent Consultant  
 SOP: Standard Operating Procedure