




**Title: Maintenance of confidentiality**

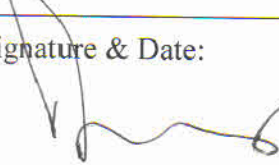
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**Effective Date: 03/10/2019**

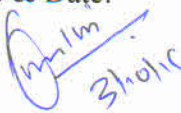
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**Notified by:**

Registrar, Yenepoya deemed to be University	Signature & Date:  3/10
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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 Yenepona Ethics Committee – 1 (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/observers to the YEC-1.
3. **Definition**
  - 3.1. **Confidentiality:** Confidentiality, for the purpose of this SOP, is defined as the state of keeping the information from research related documents and data without sharing or disclosing with unconcerned third parties
4. **Responsibility:**
  - 4.1. **The Chairperson will:**
    - 4.1.1. Ensure that the confidentiality of the YEC-1 functioning 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 the review, discussion and decision on protocols
    - 4.1.4. Ensure that no identifying data pertaining to the protocols or YEC-1 members is divulged during the conduct of research on 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 an appropriately redacted version of the protocol and protocol-related documents is prepared for sending to the Independent Consultant 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 the confidentiality agreement forms to the new members, ICs, guest observers.
- 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
- 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 the review, decision making in the YEC-1 meetings

**4.6. The guest/observer 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, decision making in the YEC-1 meetings.

**5. Detailed Instructions:**

**5.1. YEC-1 Members:**

- 5.1.1. **At the time joining YEC-1:** All YEC-1 members (including the Chairperson and Member-Secretary), ICs and the staff of the 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

documents and other information for their entire tenure as ethics committee members and beyond.

- 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 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/v3; SOP11/v3; SOP19/v3)
- 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/v3)

**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 the 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:**

- 5.3.1. **At the time of being permitted as a guest/observer:** 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 given in Ann01/SOP3A/v3
- 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 like site monitoring
  - 5.4.2.6. Any other documents/data/information that needs maintenance of confidentiality

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

- 5.5.1. YEC-1 Member-Secretary and the Secretariat will file the Confidentiality Agreement forms signed by the YEC-1 members, ICs or guest observers in the respective files
- 5.5.2. The confidentiality agreement will be countersigned by the Chairperson
- 5.5.3. The YEC-1 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 observers' file.

**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/v3.
- 5.6.2. The resubmissions including the queries raised by the reviewers will be anonymized and sent to the investigators (SOP9A/v3)
- 5.6.3. The protocol or related documents sent to the ICs will be redacted so that the researcher will be not be identified (SOP20/v3).

- 5.6.4. The protocol or related documents used for academic purposes during research ethics training program will be redacted so that the researcher or the institution will be not be identified
- 5.6.5. The detailed minutes of the meeting will be filed in the YEC-1 office, but only the 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/v3)
- 5.6.6. The core minutes of the meetings will *not* include
  - 5.6.6.1. The detailed discussion
  - 5.6.6.2. The 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
- 5.6.7. No identifying data pertaining to the protocols/ researchers or YEC-1 members will be divulged during the conduct of research on YEC-1 functioning

**5.7. Annexures:**

- 5.7.1. **Ann01/SOP3B/v3:** Confidentiality Agreement Form for YEC-1 member
- 5.7.2. **Ann02/SOP3B/v3:** Confidentiality Agreement Form for Independent Consultant
- 5.7.3. **Ann03/SOP3B/v3:** Confidentiality Agreement Form for Guest Observer
- 5.7.4. **Ann04/SOP3B/v3:** Confidentiality Agreement Form for Staff of the Secretariat

**Ann01/SOP3B/v3**

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

I, Dr/Mr/Ms \_\_\_\_\_ (*Member's name, his/her position on YEC-1 and affiliation*) herein referred to as the “undersigned” have been appointed as a member of Yenepeya Ethics Committee - 1 (YEC-1).

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

1. All the data and information (and any copies and notes thereof) that I read, hear or discuss, shall remain the sole property of YEC-1
2. All the data and information that is shared with me, as a YEC-1 member, in the course of the functioning of the YEC-1, will remain in my trust or confidence
3. I shall use the documents/information shared with me, only for the express purpose of smooth functioning of the YEC-1
4. I shall not share the documents or the information from within them, 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 archives of YEC-1.
6. I shall delete all the documents from my email/computer/mobile/electronic storage/cloud/prints after the decision on the protocol is completed.
7. I shall ensure that all e-documents are deleted annually/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 archives



- e. Research files and data accessed during the post-approval activities like site monitoring/ audits/ deviations/ violations/ continuing review:
  - f. Any other, if applicable
9. This agreement is binding on me beyond the boardroom meetings as well as beyond my tenure as a YEC-1 member, for a reasonable time, considering that research studies often remain active for years.

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 the ethics committee and/or liable to legal actions from the 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/v3**

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

I, Dr/Mr/Ms \_\_\_\_\_ (*Member’s name and affiliation*) herein referred to as the “undersigned” has been appointed as a, Independent Consultant (IC) of Yenepoya Ethics Committee - 1 (YEC-1) and 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 an IC to YEC-1
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 decision on the protocol is completed.
6. This agreement encompasses any information deemed confidential, provided to me in conjunction with my duties as an IC of YEC-1 and may include:
  - a. The protocol/protocol-related documents sent to me for review by email:
  - b. 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
  - c. The protocol/protocol-related documents/ YEC-1 files accessed from the archival room, if applicable:
  - d. Any other, if applicable

I, Dr/Mr/Ms \_\_\_\_\_ (IC name) have read and accept the aforementioned conditions as explained in this agreement. I am liable to be removed from the ethics committee and/or liable to legal actions from the 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/v3**

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

I, Dr/Mr/Ms \_\_\_\_\_ (*Guest's name and affiliation*) herein referred to as the “undersigned” have been 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 indicated purposes
4. I shall not share the documents with the PI or sponsor or any third unconcerned person/party
5. If shared with me, I shall delete all the documents from my email/computer/mobile/ electronic storage/cloud/prints after the purpose of the visit is completed.
6. This agreement encompasses any information deemed confidential, provided to me in conjunction with my visit to YEC-1 and may include:
  - a. The protocol/protocol-related documents:
  - b. 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
  - c. The protocol/protocol-related documents/ YEC-1 files accessed from the archival room, if applicable:
  - d. 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

e. 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 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

**Ann04/SOP3B/v3:**

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

I, \_\_\_\_\_ (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, \_\_\_\_\_ (Staff name & designation) have read

and accept the conditions as explained in this agreement.

Signature Date

Chairperson's signature Date

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