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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 unconcerned 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 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-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 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-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
- 5.6.7. No identifying data pertaining to the protocols/ researchers or YEC-1 members will be divulged during the conduct of research on YEC-1 functioning

6. Annexures:

- 6.1.1. **Ann01/SOP3B/v4:** Confidentiality Agreement Form for YEC-1 member
- 6.1.2. **Ann02/SOP3B/v4:** Confidentiality Agreement Form for Independent Consultant
- 6.1.3. **Ann03/SOP3B/v4:** Confidentiality Agreement Form for Guest/Observer/Invitee
- 6.1.4. **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 _____ (Name and affiliation) have been permitted to attend the meeting of Yenepoya Ethics Committee - 1 (YEC-1) and access the protocol-related documents. 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 _____ (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 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, Mr/Ms _____ (*staff's name and designation*)
have been appointed as a staff of Yenepoya Ethics Committee - 1 (YEC-1) Secretariat. 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 take all possible efforts to keep confidential, all YEC-1 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-1 Secretariat and may include:
 - a. The protocol/ protocol-related documents
 - b. The agenda and minutes of the meeting
 - 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, 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

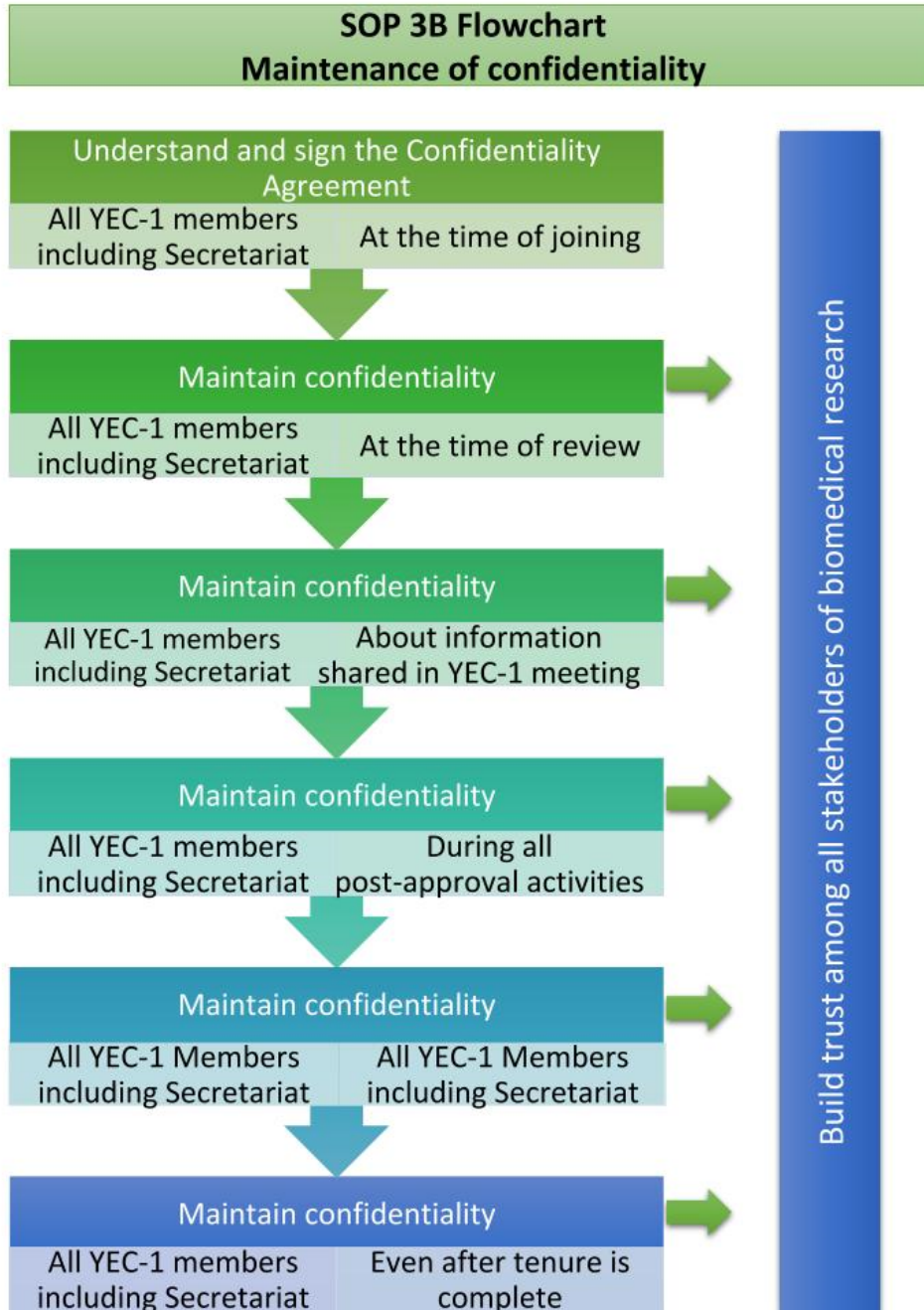
[The original (signed and dated Agreement) will be kept on file in the custody of the Secretariat YEC-1. A copy will be given to the Undersigned.]

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