

**Selection and Responsibilities of Independent consultant**  
**YEC2/SOP04/v2**  
**Effective Date: 25.02.2023**

**Title: Selection and Responsibilities of Independent Consultant**

**SOP Code: YEC2/SOP04/v2**

**Prepared by:**

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**Approved by:**

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

Registrar, Yenepoya (Deemed to be university) Ref: No/YU/REG/ACA/YEC-2/SOP/2023 Date: 25.02.2023	Signature with Date <i>K. Somayaj</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 for selecting and engaging additional expertise of medical professionals as 'Independent Consultants (IC) to the Yenepoya Ethics Committee 2(YEC2).

## **2. Scope**

This SOP covers the procedures for selecting, appointing ICs and getting their expert opinion during the ethical review process. It also defines the responsibilities of the IC.

## **3. Definitions:**

3.1. The YEC2 may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the EC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision making power. (From ICMR Guidelines page No :31) Point no: 4.3.11.

3.2. The comments of an independent consultant (if applicable) could be presented by the Member Secretary or subject experts could be invited to offer their views, but they should not participate in the decision-making process. However, her/his opinion must be recorded.(From ICMR Guidelines page No :42 ) Point no: 4.9.13

## **4. Responsibility**

### **4.1 . The Registrar, Yenepoya (Deemed to be University) will:**

- 4.1. Notify the panel of ICs recommended by the Chairperson

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**4.2. The Chairperson YEC2 will :**

- Approve the names of the IC panel members nominated by the Member-Secretary/member(s).

**4.3. The Member-Secretary will:**

- Nominate the names of one or more IC(s) – based on inputs from the members – so as to constitute a panel of ICs
- Get the panel of IC notified by the office of the Registrar, YU
- Involve appropriate IC for review & decision-making on a given protocol
- Invite the IC if required to attend the YEC2 meeting

**4.4. The Secretariat will:**

- Complete the administrative formalities regarding selection, confidentiality agreement and maintenance of roster of ICs

**4.5. The Independent Consultant will**

- Declare CoI for the protocol whenever applicable
- Follow the CoI policy of the YEC2 (YEC2/Ann02/SOP04/v2)
- Sign the Confidentiality agreement YEC2/Ann01/SOP04/v2
- Maintain confidentiality of the protocol and related documents, the review process and the decision
- Review the protocol in a timely manner

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**4. 6.Detailed instructions**

**4.6.1.Recommendation of names of ICs and making a roster of ICs for YEC 2**

- Chairperson/Member Secretary/member(s) will nominate the names of ICs from different specialties of Medicine, Dentistry/Ayurveda/Physiotherapy/Nursing/Allied health science from Yenepoya (Deemed to be University).or external members.
- Member-Secretary in consultation with Chairperson will constitute a panel of IC(s) for YEC 2, with approval of the Vice-Chancellor, Yenepoya (Deemed to be University).
- Member-Secretary will issue an appointment letter to the IC(s) after confirming their willingness through telephonic/electronic communication.
- After receiving written approval from ICs, a list of specialty-wise ICs will be maintained by the Secretariat in the YEC 2 records. The details of each IC (Name, designation, affiliation, contact details and updated curriculum vitae) will be maintained in the YEC 2 records.
- Independent consultants, not included in the panel, can also be inducted on a case-by-case basis, when required

**4.7. Consulting an IC during ethical review process**

- A YEC 2 member/Member-Secretary/Chairperson may suggest that additional opinion be sought from one or more IC(s) and may suggest the name of a particular IC(s) from the roster of ICs maintained by YEC 2 Secretariat or from outside the roster (if felt necessary by the YEC 2) - if during the review process of any given research study it is felt that the study involves procedures or information that requires additional expertise of the IC.
- The Member-Secretary in consultation with Chairperson (or at YEC 2 meeting; as deemed necessary) will decide, identify and select the IC(s) outside the roster to be invited based on area of expertise, independence and availability.
- Member-Secretary on behalf of YEC 2 will invite IC(s) in writing to assist in the

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review of the research study and provide his/her independent opinion in writing, via electronic communication, in addition to the comments of the in-house reviewers. This may be done after seeking concurrence and confirming availability of the IC through telephonic/electronic communication

**4.8. Communication with ICs**

- The Secretariat may request a copy of the updated curriculum vitae of the IC (those outside roster) for YEC 2 records and future reference.
- The Member Secretary will request IC to declare conflict of interest, if any, in writing and sign confidentiality and conflict of interest agreements.
- The Secretariat will forward copies of the confidentiality agreement (YEC2/Ann01/SOP04/V2 and conflict of interest agreement (YEC2/Ann02/SOP04/V2), to the IC(s), for careful reading, understanding and signing.
- The Member Secretary will provide explanations/clarifications (telephonically or in writing) to the IC(s) if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/Legal expert/YEC 2 members.
- Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement.
- The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.
- The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to IC(s).

**4.9. Review of research study proposal**

- The Secretariat will provide study protocol documents along with the Study Assessment Form for IC(s) (YEC2/Ann03/SOP04/v2 to the IC(s). The IC(s) may be

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provided with a copy of 'Guidelines for Reviewers'.

- The IC(s) will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date.
- The assessment report provided by the IC(s) becomes a permanent part of the study file.
- The assessment report will be reviewed by Member Secretary in YEC 2's next meeting when the concerned study is being discussed.
- If deemed necessary, the Chairperson or Member-secretary may seek additional information or clarifications from the IC in writing. Additional information provided by the IC will be considered as a part of the Assessment Report.
- If deemed necessary, the Chairperson or Member-secretary may invite the IC(s) to attend YEC 2 meeting for providing additional information or clarifications that may be sought by YEC 2 members or Chairperson. However, the IC will not participate in the decision making process on the research study.
- The IC may be reimbursed for expenses on travel, time spent, documents referred to in library/internet or any other incidental expenses, etc as per Yenepoya (Deemed to be University) norms existing from time to time.

#### **4.10. Tenure of Services of IC**

- The roster of ICs maintained at the YEC 2 secretariat will be updated every 3 years or as required, from time to time.
- For IC appointed for a particular study, the services of IC get automatically terminated once the final decision regarding the study is taken by YEC 2. YEC 2 will document the termination of services of the IC by providing a letter thanking the IC for the services rendered.

#### **4.11. Responsibilities of IC**

- If the IC agrees to review a research proposal, he/she will comply with YEC 2



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requirements of signing confidentiality and conflict of interest agreements.

- The IC will review the research study and complete the reviewer's assessment form (duly signed and dated) within a stipulated period or by a stipulated date.
- The IC may attend YEC 2 meeting for providing additional information or clarifications, only if invited by Member Secretary/Chairperson. However, the IC will not participate in the decision making process on the research study.
- The IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

**5. Annexures**

5.1 YEC2/Ann01/SOP04/v2: Confidentiality Agreement for an Independent Consultant

5.2 YEC2/Ann02/SOP04/v2: Conflict of Interest Agreement for an Independent consultant

5.3 YEC2/Ann03/SOP04/v2: Invitation to review the protocol as Independent Consultant

5.4. YEC2/Ann04/SOP04/v2: Appreciation letter to the Independent Consultant

5.5. YEC2/Ann05/SOP04/v2: Invitation to be an Independent consultant for the YEC2

**YEC2/Ann01 /SOP04/V2**

**Confidentiality Agreement Form for Independent Consultant**

I, \_\_\_\_\_ (Name and Designation) as a non-member of Yenepoya Ethics Committee (YEC 2) understand that the copy/copies given to me by YEC 2 is/are confidential. I shall use the information only for



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the indicated purpose as described by YEC 2 and shall not duplicate, give or distribute these documents to any person(s) without prior permission from YEC 2 in writing. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Date:

Signature of the IC

Place:

Signature of Chairperson, YEC 2

**YEC2/Ann02/SOP04/V2**

**Conflict of Interest Agreement Form for Independent Consultant**

1. I understand that it is the policy of Yenepoya Ethics Committee (YEC 2) that no independent consultant reviewer, may participate in the review, comment or approve of any activity in which he/she has a conflict of interest except to provide information as requested by YEC 2.
2. I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the YEC 2 to me.
3. In the event that I develop any conflict of interest in relation to the particular proposal during the review process, I will declare it to YEC 2 and refrain from reviewing it.

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I, \_\_\_\_\_ (Name and designation) have read and accept the aforementioned terms and conditions as explained in this agreement.

Date:

Signature of the IC

Place:

Signature of Chairperson, YEC 2

I acknowledge that I have received a copy of this Agreement signed by YEC 2 Chairperson and me.

Date:

Signature of the IC

*Please note: We thank you for accepting to be an independent consultant for Yenepoya Ethics Committee 2, as per the rules/regulations/norms. The original signed and dated agreement will be kept on file in the custody of the YEC 2 Secretariat. A copy will be given to you for your records.*

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**YEC2/Ann03/SOP04/V2**

**Invitation to review the protocol as Independent Consultant**

To

Name of the Reviewer:

Dear Sir/Madam,

You have been assigned to review the given protocol as an Independent Consultant You are requested to:

1. Read, understand and sign the confidentiality agreement provided by the YEC2secretariat (Ann02/SOP3B/v3)
2. Read, understand and sign the conflict of interest form provided by the YEC2secretariat and declare conflict of interest, whenever applicable during the review process (Ann01/SOP3A/v3)
3. Review the protocol provided to you and send the duly filled and signed “study assessment form” to the YEC2within at least 7 calendar days from the date of receipt.
4. Maintain the confidentiality of the protocol document received.
5. Be available to provide additional clarification/comments when the YEC2 requests.
6. Be available to attend the YEC2meeting in case your services are required. However, you will not take part in the decision making of the protocol. Your travel and other expenses will be reimbursed by the YEC2.
7. Note that your tenure as an IC for the given protocol will terminate once the protocol is approved in the YEC2 meeting

**Study Assessment Form for an Independent Consultant to YEC 2**

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YEC 2 protocol number:	
Protocol Title:	
Comments on the protocol:	
Comments on the Participant Information Sheet and Informed Consent Document:	
Remarks:	<input type="checkbox"/> Recommend approval <input type="checkbox"/> Recommend approval after incorporation of changes (please specify)  <input type="checkbox"/> Recommend disapproval (please state reasons)
Name of the independent consultant reviewing the protocol with signature and date:	

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**YEC2/Ann04/SOP04/v2**

**Appreciation letter to the Independent Consultant**

Date:

To Name and other details of the IC

Dear Sir or Madam,

Yenepoya Ethics Committee 2 acknowledges and appreciates your role as independent consultant and assisting the YEC2, in carrying out the ethical review of protocol no. “\_\_\_”, titled “\_\_\_\_\_”. The matter was discussed in the recently concluded YEC2 meeting and appropriate decision was taken. Your contribution to the review process of the protocol was invaluable and YEC2 expresses its sincere gratitude to you, for your help and assistance. Your services as IC end with this letter, however, we look forward to continued support from you, as and when we ask for it.

Signature of the Member-Secretary Date:

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**YEC2/Ann05/SOP04/v2**

**Invitation to be an Independent consultant for the YEC2**

From,

The Chairperson/ Member-Secretary, YEC2

To,

Dear Sir/ Madam

YEC2 requests you to be an Independent Consultant for certain protocols for which your expertise and qualification would be required during the review process. If you agree to be an Independent Consultant, you would be required to agree to the following terms:

1. Sign the Confidentiality agreement form sent to you which is essential before starting any review process
2. Sign the Conflict of Interest form sent to you along with the protocol before starting the review process
3. The research protocol will be sent to you by email after redacting the identifiers of the researcher and the institution
4. Review the research protocol and respond to the queries raised by the YEC2 about the protocol within 14 calendar days from the date of receipt
5. Fill and sign the assessment form and return the same to YEC2 at the email id [yec2@yenepoya.edu.in](mailto:yec2@yenepoya.edu.in)
6. If you have any queries about the protocol or the specific questions sent to you by YEC2, you are free to contact the Member Secretary/ Chairperson whose details are given below or email the same to [yec2@yenepoya.edu.in](mailto:yec2@yenepoya.edu.in)
7. Your comments and recommendations on the protocol will be referred to during the decision making on the protocol and will be included in the minutes of the meeting anonymously.
8. If YEC2 wants to further contact you regarding the protocol, it will do so by email.

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9. If deemed necessary, YEC2 may invite you to attend the YEC2 meeting during the deliberation and decision making on the protocol. You will be required to provide your opinion, however you will not participate in the voting and decision making process.
  10. You are requested to delete all the protocol and related documents sent to you after Yenepoya ethics committee 2 completing the review process without sharing them with any third uninterested party.
  11. You are entitled to an honorarium and reimbursement of the expenses by the Yenepoya deemed to be University for the protocol that you review. (PAN card and Bank Account details will be required)
  12. If you agree to review the protocols but do not agree to be on the panel of ICs, you will be consulted on a case to case basis as a Freelance IC and your term will end when the decision on the protocol is made
  13. If you agree to be on the panel of ICs, your term will be for a period of 3 years.
  14. If you agree to be on the panel of ICs, you will be required to provide us your updated CV for the purpose of records

Signature of the Member-Secretary Date:

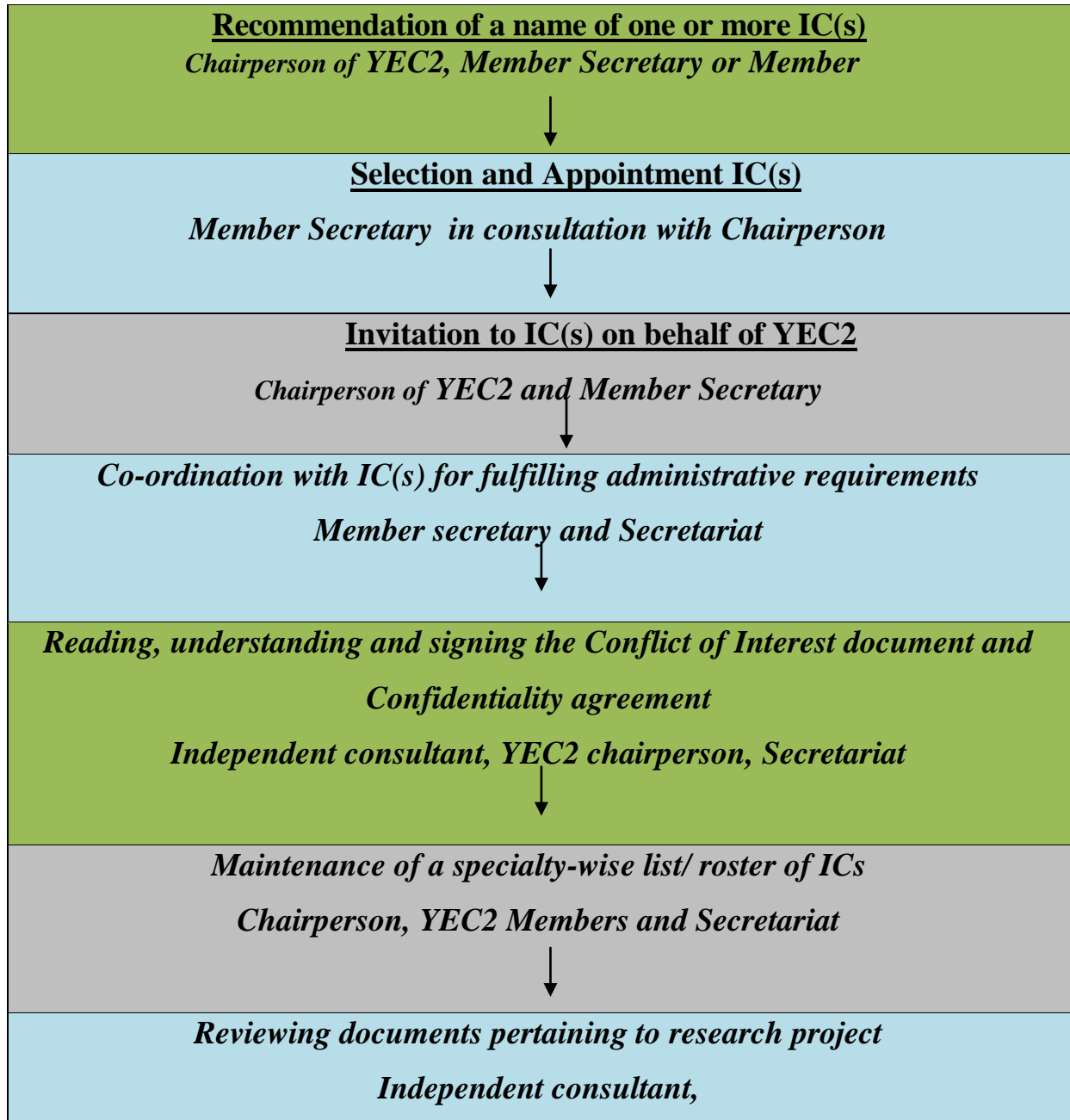
**PART B: Statement of agreement**

<p>I agree to be on the panel of Independent Consultants for YEC2</p> <p>I agree to be an Independent Consultant (Freelance) but not be on the panel</p> <p>I do not agree to be an Independent Signature of the Independent Consultant Date:</p>
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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 6 th October 2019) available from: [http://www.icmr.nic.in/guidelines/ICMR\\_Ethical\\_Guidelines\\_2017.pdf](http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf)*