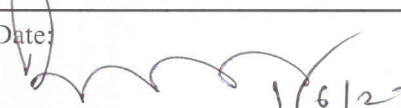


**Title: Selection and responsibilities of Independent Consultants of YEC-1**

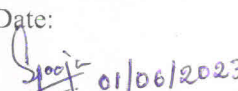
**SOP Code: SOP04/v4**

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


**Prepared by:**

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

Dr. Pooja Harish S Member, YEC-1 SOP Subcommittee	Signature & Date:  01/06/2023
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**Approved by:**

Dr. Vikram Shetty, Chairperson, YEC-1	Signature & Date:  6/4/23
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**Notified by:**

Registrar, Yenepoya (deemed to be University)	Signature & Date:  7/6/23
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**Details of superseded SOP04**

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 SOP04/v4**

Name of the SOP subcommittee convenor	Version	Effective date	Describe the main change(s)
Dr. Uma Kulkarni	v4	01-07-2023	<ol style="list-style-type: none"> <li>1. Glossary section added in the SOP</li> <li>2. Definition strengthened with types of ICs</li> <li>3. Deficiencies rectified</li> <li>4. Typographical errors rectified</li> </ol>

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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/scientific professionals as 'Independent Consultants' (IC) to the Yenepoya Ethics Committee - 1 (YEC-1).
2. **Scope:** This SOP covers the procedures for selecting and appointing ICs (both empanelled and freelance) and getting their expert opinion during the ethical review process or in the post approval process. It also defines the roles and responsibilities of the IC.
3. **Definitions:**
  - 3.1. **Independent Consultant:** An independent consultant is a subject expert in a specific field who, upon review of the study protocols, gives scientific advice, comments and suggestions, or answers specific queries raised by YEC-1. He/she has no affiliation to the investigators proposing the research protocols. He/she cannot participate in the ethical deliberations or the decision-making process of the YEC-1.
  - 3.2. **Empanelled IC:** An IC who has agreed to be on the panel of ICs for the tenure of the YEC-1 and whose name has been included after signing the agreement.
  - 3.3. **Freelance IC:** An IC who has been consulted to review a protocol and who is not on the panel of ICs for YEC-1.
4. **Responsibility:**
  - 4.1. **The Registrar, Yenepoya Deemed to be University will:**
    - 4.1.1. Notify the panel of ICs recommended by the Chairperson
  - 4.2. **The Chairperson will:**
    - 4.2.1. Approve the names of IC panel members nominated by Member-Secretary/members.
  - 4.3. **The Member-Secretary will:**
    - 4.3.1. Nominate the names of one or more ICs – based on inputs from the members – so as to constitute a panel of ICs
    - 4.3.2. Get the panel of IC notified by the office of the Registrar, YU
    - 4.3.3. Involve appropriate IC for review & decision-making on a given protocol
    - 4.3.4. Invite the IC, if required, to attend the YEC-1 meeting
  - 4.4. **The Secretariat will:**
    - 4.4.1. Complete the administrative formalities regarding selection, confidentiality agreement and maintenance of roster of ICs.
  - 4.5. **The Independent Consultant will:**
    - 4.5.1. Follow the CoI policy of the YEC-1 (SOP3A/v4) and sign the declaration of CoI (Ann01/SOP3A/v4)
    - 4.5.2. Sign the confidentiality agreement (Ann02/SOP3B/v4)

- 4.5.3. Review the protocol in a timely manner
- 4.5.4. Declare CoI for the protocol whenever applicable
- 4.5.5. Maintain confidentiality of the protocol and related documents

**5. Detailed instructions:**

**5.1. Formation of a panel of ICs:**

- 5.1.1. The Chairperson/Member-Secretary/member(s) with the suggestions of the YEC-1 members will nominate ICs from different specialties of health care.
- 5.1.2. ICs will be nominated based on the areas of expertise, independence and availability.
- 5.1.3. The Member-Secretary will communicate with the nominated members to confirm their agreement to be empanelled into the YEC-1 as IC.
- 5.1.4. The Member-Secretary in consultation with the Chairperson will constitute the panel of ICs for YEC-1, and get this notified by the Registrar, YU.
- 5.1.5. The panel of ICs will be valid for the tenure of the YEC-1. The Member-Secretary will update the panel of ICs, as and when the need arises.
- 5.1.6. The Member-Secretary will issue an appointment letter to ICs after confirming their willingness through telephonic/electronic communication.
- 5.1.7. The list of specialty-wise ICs on the panel will be maintained by the Secretariat in the YEC-1 records.
- 5.1.8. The details of each IC (Name, designation, affiliation, contact details and updated curriculum vitae) will be maintained in the YEC-1 records.

**5.2. Independent consultants (freelance)**

- 5.2.1. If need arises, an IC who is not on the panel may be suggested by YEC-1 members
- 5.2.2. The freelance IC may be approached to review a protocol whether or not he/she is going to be included in the panel
- 5.2.3. The freelance IC's consultancy will automatically terminate with the approval of the protocol. It may be re-initiated, as and when needed, for any post-approval processes related to a protocol where the expertise was initially sought..
- 5.2.4. All other terms and conditions, applicable to empanelled ICs will be applicable to freelance ICs.

**5.3. Building a file for the ICs.:**

- 5.3.1. The Secretariat will file the following documents in the IC file:
  - 5.3.1.1. The list of ICs who have agreed to be on the panel of ICs for YEC-1

- 5.3.1.2. Request letter from the YEC-1 and willingness of the IC to review the protocol/ be on the panel of ICs for YEC-1
- 5.3.1.3. A copy of the updated CV of the IC for records and future reference
- 5.3.1.4. Declaration of conflict of interest (Ann01/SOP3A/v4)
- 5.3.1.5. Confidentiality agreement form (Ann02/SOP04/v4)
- 5.3.1.6. Details of IC consultation, protocol details and remuneration

**5.4. Selecting an IC for a given protocol:**

- 5.4.1. A YEC-1 member/Member-Secretary/Chairperson may suggest that additional opinion be sought from one or more ICs.
- 5.4.2. The IC will be selected based on the nature of the protocol and the expertise needed
- 5.4.3. The IC will be selected from the panel of ICs, if the expertise is available.
- 5.4.4. If the expertise is not available in the panel of ICs, another IC may be nominated as a freelance IC based on area of expertise, independence and availability.

**5.5. Requesting an IC for ethical review process:**

- 5.5.1. The Member-Secretary will request the IC to review a given protocol/ protocol related documents and will communicate the following:
  - 5.5.1.1. Willingness to review the given protocol
  - 5.5.1.2. Ability to review the protocol within the stipulated time
  - 5.5.1.3. Declaration of conflict of interest for the protocol (Ann01/SOP3A/v4)
  - 5.5.1.4. Confidentiality agreement (Ann02/SOP3B/v4)
  - 5.5.1.5. Willingness for the recommendation and comments to be minuted and taken into consideration during the decision making process for the protocol.
  - 5.5.1.6. Availability to attend the YEC-1 meeting, in case required
  - 5.5.1.7. The ICs will read, understand and sign and date the confidentiality (Ann02/SOP3B/v4) and conflict of interest agreement. (Ann01/SOP3A/v4)
  - 5.5.1.8. The original copies of these agreements will be retained by the Secretariat and photocopies (or scanned copies) will be provided to ICs.

**5.6. IC Review process:**

- 5.6.1. The Member-Secretary will provide a brief summary of the protocol, if a

summary is not included in the redacted protocol.

- 5.6.2. The Member-Secretary will also provide a list of specific questions/issues (if any) that need to be reviewed by the IC.
- 5.6.3. The Secretariat will provide the protocol documents after redacting the identifiable information and confidential information along with the study assessment form for ICs (Ann03/SOP04/v4) to the ICs.
- 5.6.4. ICs may be provided with a copy of guidelines for review.
- 5.6.5. ICs will review, fill and return the assessment form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date (Ann03/SOP04/v4).
- 5.6.6. Assessment report provided by the ICs will be a permanent part of the study file.
- 5.6.7. The assessment report will be reviewed by the Member-Secretary and the adequacy of review in relation to the queries asked by the YEC-1 is assessed.
- 5.6.8. The Member-Secretary may seek additional information or clarification.
- 5.7. **Decision-making:**
  - 5.7.1. **In case of expedited review protocols:**
    - 5.7.1.1. Comments and recommendations of the ICs are considered in conjunction with the YEC-1 reviewers and a decision is made accordingly (SOP09/v4).
    - 5.7.1.2. The comments and recommendations are recorded in the file.
  - 5.7.2. **In case of full review protocols:**
    - 5.7.2.1. The comments and recommendations of the ICs are considered in conjunction with the YEC-1 reviewers and taken for discussion in the YEC-1 meeting and the decision is made accordingly (SOP08/v4)
    - 5.7.2.2. The comments and recommendations are recorded in the file and in the minutes of the meetings.
    - 5.7.2.3. If deemed necessary, the Member-Secretary in consultation with the Chairperson may invite the ICs to attend YEC-1 meeting for providing additional information or clarifications that may be sought by YEC-1 members or Chairperson.
    - 5.7.2.4. However, the IC will not participate in the ethical deliberations or the decision making process on the research study.
- 5.8. **Reimbursement for the IC:**
  - 5.8.1. The IC may be reimbursed for the time spent in review, the documents

referred to in the library/internet or any other incidental expenses, expenses on travel, etc as per YU norms to match the current practice.

5.8.2. The reimbursement details are filed in the budget related file.

**5.9. Tenure of Service of IC:**

- 5.9.1. A roster of ICs maintained at the YEC-1 secretariat will be updated as and when required and at least every 5 years
- 5.9.2. For a freelancing IC appointed for a particular study, the services of IC get automatically terminated once the final decision regarding the study is taken.
- 5.9.3. YEC-1 will document the termination of services of the IC by providing a letter of appreciation, thanking the IC for the services rendered (Ann04/SOP04/v4 for empanelled ICs and Ann05/SOP04/v4 for freelance ICs).

**5.10. Responsibilities of IC:**

- 5.10.1. If the IC agrees to review a research proposal, he/she will comply with YEC-1 requirements of signing confidentiality and conflict of interest agreements.
- 5.10.2. 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.
- 5.10.3. The IC may attend YEC-1 meetings for providing additional information or clarifications, only if invited by Member Secretary/Chairperson. However, the IC will not participate in the ethical deliberations and the decision making process on the research study.
- 5.10.4. The IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

**6. References:**

- 6.1. SOP3A/v4
- 6.2. SOP3B/v4

**7. Annexures:**

- 7.1. Ann01/SOP04/v4: Invitation to be an Independent consultant for YEC-1
- 7.2. Ann02/SOP04/v4: Invitation to the review the protocol as IC
- 7.3. Ann03/SOP04/v4: Assessment Form for an Independent Consultant
- 7.4. Ann04/SOP04/v4: Letter of appreciation to an empanelled IC
- 7.5. Ann05/SOP04/v4: Letter of appreciation to a freelance IC

**Ann01/SOP04/v4**

**Invitation to be an Independent consultant for the YEC-1**

To,

Dear Sir/ Madam

YEC-1 requests you to be an Independent Consultant for 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, before starting any review process.
2. Sign the conflict of interest form sent along with the protocol before starting the review process
3. The protocol will be sent 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 YEC-1 about the protocol within 14 calendar days from the date of receipt, or the date specified by the Member-Secretary.
5. Fill and sign the assessment form and return the same to YEC-1 at [ethcom@yenepoya.edu.in](mailto:ethcom@yenepoya.edu.in)
6. If you have any queries about the protocol or the specific questions sent to you, please contact the Member Secretary/Chairperson by email.
7. Your comments and recommendations on the protocol will be discussed in the YEC-1 meeting, during the scientific deliberations and will be included in the minutes of the meeting anonymously.
8. If YEC-1 wants to further contact you seeking clarification on the protocol, it will do so by email.
9. If deemed necessary, YEC-1 may invite you to attend the YEC-1 meeting during the scientific deliberation on the protocol. You will be required to provide your opinion, however you will not participate in the ethical discussion and decision making process.
10. Please delete all the documents sent to you, after the review process, without sharing with anybody.
11. 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 contract will end when a decision on the protocol is made. It may be reactivated, if required, during the post-approval processes on that protocol.
12. If you agree to be on the panel of ICs, your term will be for the entire tenure of the YEC-1. You will be eligible for re-appointment, if mutually agreed upon.
13. Please provide us your updated CV for the purpose of records
14. 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)

**Signature of the Member-Secretary**

**Date:**



**PART B: Statement of agreement**

I agree to be on the panel of Independent Consultants for YEC-1  
 I agree to be an Independent Consultant (freelance) but not be on the panel  
 I do not agree to be an Independent Consultant for YEC-1  
 Signature, name and date:

**Ann02/SOP04/v4: Invitation to review the protocol as Independent Consultant**

To

Name of the IC

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 YEC-1 secretariat.
2. Read, understand and sign the conflict of interest form provided by the YEC-1 secretariat and declare conflict of interest, whenever applicable during the review process  
(Ann01/SOP3A/v4)
3. Review the protocol provided to you and send the duly filled and signed “study assessment form” within 14 calendar days from the date of receipt, or on the date stipulated by Member-Secretary..
4. Maintain the confidentiality of the protocol document received.
5. Be available to provide additional clarification/comments when the YEC-1 requests.
6. Be available to attend the YEC-1 meeting 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.
7. Note that, if you are not an empanelled IC, your contract as an IC for YEC-1 will terminate once the protocol is approved. If required, the contract will be reactivated during any post-approval process.

**Details of the protocols:**

1	Protocol No.	
2	Title of the study:	
3	Date of YEC-1 meeting in which tabled for discussion	
4	Due date for sending the assessment form:	

**Signature of the Member-Secretary:**

**Date:**

**Ann03/SOP04/v4**  
**Assessment Form for an Independent Consultant to**  
**YEC-1**

YEC-1 protocol number:			
Protocol Title:			
IC responses:			
S. No.	YEC-1 Query	IC response	Justification/ Remarks/Reference
Any other comments on the scientific aspects: Assessment of risk-benefit ratio: Favourable/Not favourable Comments on the scientific aspects mentioned in the Informed Consent Document:			
Name of the independent consultant reviewing the protocol with signature and date:			

Signature of the Chairperson/Member-Secretary

Date:

**Ann04/SOP04/v4**  
**Appreciation letter to the Independent Consultant (empanelled)**

To

Dear Sir or Madam,

Yenepoya Ethics Committee – 1 acknowledges and appreciates your role as independent consultant and assisting the YEC-1, in carrying out the ethical review of protocol no. “\_\_\_\_”, titled “\_\_\_\_\_”. The matter was discussed in the recently concluded YEC-1 meeting and an appropriate decision was taken. Your contribution to the review process of the protocol was invaluable and YEC-1 expresses its sincere gratitude to you, for your help and assistance. We look forward to continued support from you, as and when needed.

Signature of the Member-Secretary

Date:

**Ann05/SOP04/v4**  
**Appreciation letter to the Independent Consultant (empanelled)**

To

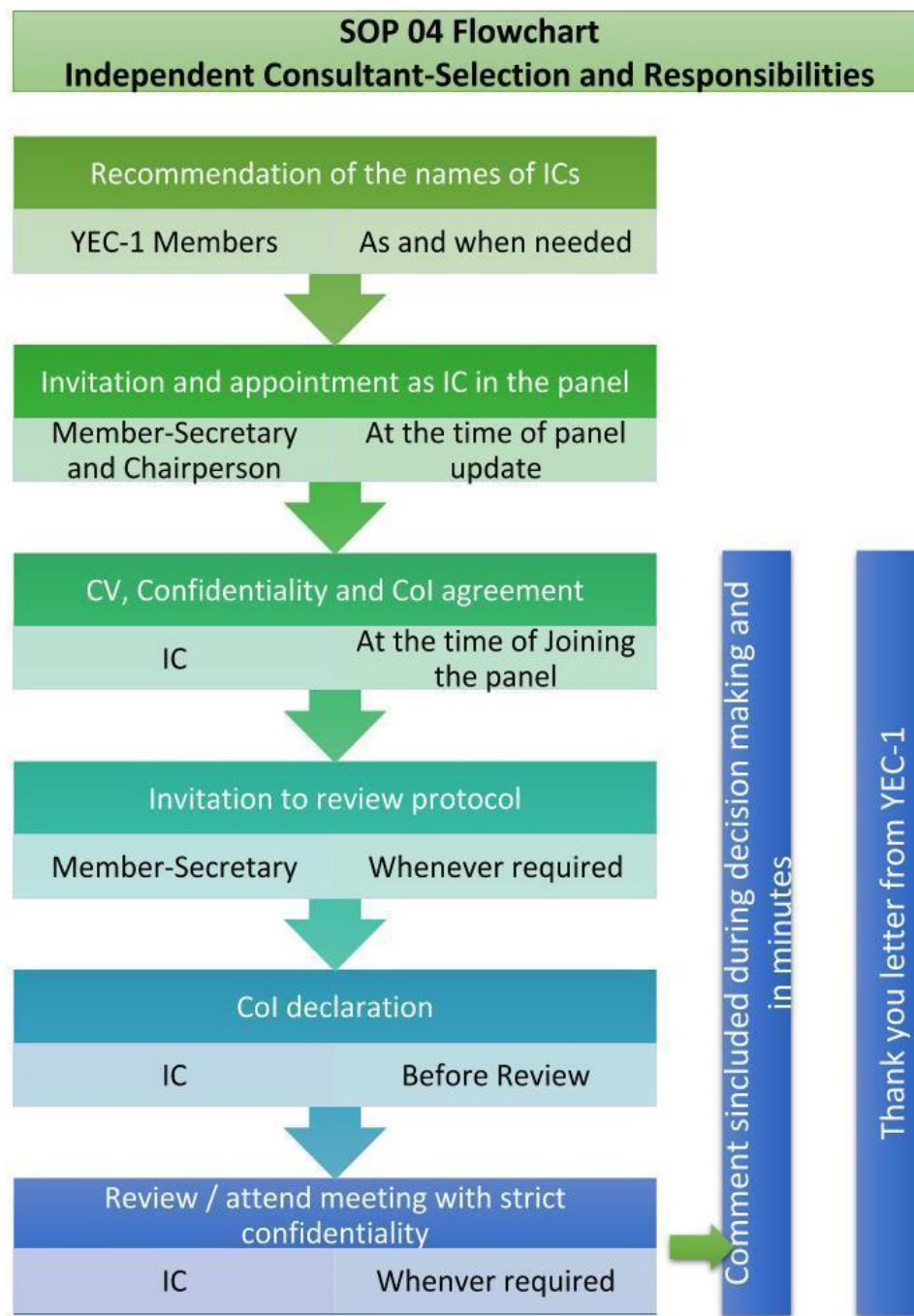
Dear Sir or Madam,

Yenepoya Ethics Committee – 1 acknowledges and appreciates your role as independent consultant and assisting the YEC-1, in carrying out the ethical review of protocol no. “\_\_\_\_”, titled “\_\_\_\_\_”. The matter was discussed in the recently concluded YEC-1 meeting and an appropriate decision was taken. Your contribution to the review process of the protocol was invaluable and YEC-1 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:

8. **Flowchart:**



9. **Glossary:**

CoI: Conflict of Interest  
 IC: Independent Consultant  
 SOP: Standard Operating Procedure