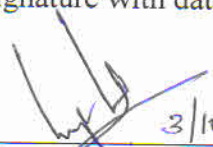


Title: Selection and Responsibilities of Independent Consultants


SOP Code: SOP04/v3

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Dr. Vikram Shetty, Chairperson, YEC-1	Signature with Date  3/10/19
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Notified by:


Registrar, Yenepoya deemed to be University	Signature with Date  3/10
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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 - 1 (YEC-1).
2. **Scope:** This SOP covers the procedures for selecting, appointing ICs (both empanelled and freelance) and getting their expert opinion during the ethical review process. It also defines the responsibilities of the IC.
3. **Definitions:**
 - 3.1. **Independent Consultant:** An independent consultant is a subject expert in a specific field who gives advice, comments and suggestions upon review of the study protocols. 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 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, YU 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 the IC panel members nominated by the Member-Secretary/member(s).
 - 4.3. **The Member-Secretary will:**
 - 4.3.1. Nominate the names of one or more IC(s) – 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. Declare CoI for the protocol whenever applicable
- 4.5.2. Follow the CoI policy of the YEC-1
- 4.5.3. Sign the Confidentiality agreement (Ann02/SOP3B/v3)
- 4.5.4. Maintain confidentiality of the protocol and related documents, the review process and the decision
- 4.5.5. Review the protocol in a timely manner

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. The 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 IC(s) for YEC-1, and get this notified by the Registrar, YU.
- 5.1.5. The Member-Secretary will update the panel of ICs as and when need arises.
- 5.1.6. Member-Secretary will issue appointment letter to IC(s) 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 the 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

5.3. 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 curriculum vitae of the IC (those outside roster) for YEC-1 records and future reference
 - 5.3.1.4. Declaration of conflict of interest (**Ann01/SOP3A/v3**)
 - 5.3.1.5. Confidentiality agreement form (**Ann02/SOP3B/v3**)
 - 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 IC(s)
- 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 document 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/v3*)
- 5.5.1.4. Confidentiality agreement (*Ann02/SOP3B/v3*)
- 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 IC(s) will read, understand and sign and date the Confidentiality and Conflict of Interest Agreement. (*Ann01/SOP3A/v3*)
- 5.5.1.8. The original copies of these agreements will be retained by the Secretariat and photocopies (or scanned copies) will be sent to IC(s).

5.6. IC Review process:

- 5.6.1. The Member-Secretary will provide a brief summary of the protocol
- 5.6.2. The Member-Secretary will also provide a list of specific questions/ issues 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 IC(s) (*Ann03/SOP04/v3*) to the IC(s).
- 5.6.4. The IC(s) may be provided with a copy of the current national/institutional Guidelines for Reviewers.
- 5.6.5. The IC(s) will be requested to 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/v3*).
- 5.6.6. The assessment report provided by the IC(s) becomes a permanent part of the study file.
- 5.6.7. The assessment report will be reviewed by Member-Secretary and the adequacy of review in relation to the queries asked by the YEC-1 is assessed.

5.6.8. If deemed necessary, 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. The comments and the recommendations of the ICs are considered in conjunction with the YEC-1 reviewers and decision is made accordingly (SOP7B/V3)

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 (SOP7B/V3)

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 IC(s) to attend YEC-1 meeting for providing additional information or clarifications that may be sought by YEC-1 members or Chairperson (Ann04/SOP04/v3).

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 from as and when required and at least every 3 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 by YEC-1.

- 5.9.3. YEC-1 will document the termination of services of the IC by providing a letter thanking the IC for the services rendered (Ann04/SOP04/v3).

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 meeting 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. Annexures

- 6.1. Ann01/SOP04/v3: Invitation to be an Independent consultant for the YEC-1
- 6.2. Ann02/SOP04/v3: Invitation to the review the protocol as IC
- 6.3. Ann03/SOP04/v3: Assessment Form for an Independent Consultant to YEC-1
- 6.4. Ann04/SOP04/v3: Thank you letter to the IC

Ann01/SOP04/v3

Invitation to be an Independent consultant for the YEC-1

From,

The Chairperson/ Member-Secretary, YEC-1

To,

Dear Sir/ Madam

YEC-1 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 YEC-1 about the protocol within 14 calendar days from the date of receipt
5. Fill and sign the assessment form and return the same to YEC-1 at the email id ethcom@yenepoya.edu.in
6. If you have any queries about the protocol or the specific questions sent to you by YEC-1, you are free to contact the Member Secretary/ Chairperson whose details are given below or email the same to ethcom@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 YEC-1 wants to further contact you regarding 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 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

completing the review process without sharing them with any third unconcerned 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

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

Signature of the Independent Consultant

Date:

Ann02/SOP04/v3: 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 YEC-1 secretariat (Ann02/SOP3B/v3)
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/v3)
3. Review the protocol provided to you and send the duly filled and signed “study assessment form” to the YEC-1 within 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 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 by the YEC-1.
7. Note that your tenure as an IC for the given protocol will terminate once the protocol is approved in the YEC-1 meeting.

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/v3

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 observation or comments (including on the Participant Information Sheet and Informed Consent Document):			
Remarks:			
Name of the independent consultant reviewing the protocol with signature and date:			

Signature of the Chairperson/Member-Secretary

Ann04/SOP04/v3

Appreciation letter to the Independent Consultant

Date:

To

Name and other details of the IC

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 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:

7. Flowchart:

