

Title: Selection and Responsibilities of Independent Consultants

SOP Code: SOP04/v2

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Table of Contents:

No.	Contents	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Detailed Instructions	3
5	Glossary	6
6	Annexures	7
7	Flowchart	10

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 University Ethics Committee (YUEC).

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. Responsibility

It is the responsibility of the Chairperson/Member Secretary/YUEC member(s) to nominate the name of one or more IC(s). The Chairperson is responsible for endorsing the choice of IC nominated by the Member Secretary/member(s). The administrative procedures regarding selection, confidentiality agreement and maintenance of roster of ICs will be carried out by YUEC Secretariat.

4. Detailed instructions

4.1 Recommendation of names of ICs and making a roster of ICs for YUEC

4.1.1 Chairperson/Member Secretary/member(s) will nominate the names of ICs from different specialties of medicine.

4.1.2 Member-Secretary in consultation with Chairperson will constitute a panel of IC(s) for YUEC, with approval of the Vice-Chancellor, Yenepoya University.

4.1.3 Member-Secretary will issue an appointment letter to the IC(s) after confirming their willingness through telephonic/electronic communication.

4.1.4 After receiving written approval from ICs, a list of specialty-wise ICs will be maintained by the Secretariat in the YUEC records. The details of each IC (Name, designation, affiliation, contact details and updated curriculum vitae) will be maintained in the YUEC records.

4.1.5 Independent consultants, not included in the panel, can also be inducted on a case-by-case basis, when required

4.2 Consulting an IC during ethical review process

- 4.2.1 A YUEC 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 YUEC Secretariat or from outside the roster (if felt necessary by the YUEC) - 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.
- 4.2.2 The Member-Secretary in consultation with Chairperson (or at YUEC 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.
- 4.2.3 Member-Secretary on behalf of YUEC will invite IC(s) in writing to assist in the review of the research study and provide his/her independent opinion in writing, 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.

4.3 Communication with ICs

- 4.3.1 The Secretariat may request a copy of the updated curriculum vitae of the IC (those outside roster) for YUEC records and future reference.
- 4.3.2 The Member Secretary will request IC to declare conflict of interest, if any, in writing and sign confidentiality and conflict of interest agreements.
- 4.3.3 The Secretariat will forward copies of the confidentiality agreement (Ann01/SOP04/Vv2 and conflict of interest agreement (Ann02/SOP04/v2), to the IC(s), for careful reading, understanding and signing.
- 4.3.4 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/YUEC members.
- 4.3.5 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement.
- 4.3.6 The IC(s) will sign and date the Confidentiality and Conflict of Interest Agreement.

- 4.3.7 The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.
- 4.3.8 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).

4.4 Review of research study proposal

- 4.4.1 The Secretariat will provide study protocol documents along with the Study Assessment Form for IC(s) (Ann03/SOP04/v2 to the IC(s). The IC(s) may be provided with a copy of 'Guidelines for Reviewers'.
- 4.4.2 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.
- 4.4.3 The assessment report provided by the IC(s) becomes a permanent part of the study file.
- 4.4.4 The assessment report will be reviewed by Member Secretary in YUEC's next meeting when the concerned study is being discussed.
- 4.4.5 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.
- 4.4.6 If deemed necessary, the Chairperson or Member-secretary may invite the IC(s) to attend YUEC meeting for providing additional information or clarifications that may be sought by YUEC members or Chairperson. However, the IC will not participate in the decision making process on the research study.
- 4.4.7 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 Yenepeya University norms existing from time to time.

4.5 Tenure of Services of IC

- 4.5.1 The roster of ICs maintained at the YUEC secretariat will be updated every 3 years or as required, from time to time.

4.5.2 For IC appointed for a particular study, the services of IC get automatically terminated once the final decision regarding the study is taken by YUEC. YUEC will document the termination of services of the IC by providing a letter thanking the IC for the services rendered.

4.6 Responsibilities of IC

- 4.6.1 If the IC agrees to review a research proposal, he/she will comply with YUEC requirements of signing confidentiality and conflict of interest agreements.
- 4.6.2 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.
- 4.6.3 The IC may attend YUEC 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.
- 4.6.4 The IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

5. Glossary

Independent Consultant: An independent consultant is a subject expert in a specified 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 decision-making process of the YUEC.

6. Annexures

- 6.1 Ann01/SOP04/v2: Confidentiality Agreement for an independent consultant
- 6.2 Ann02/SOP04/v2: Conflict of Interest Agreement for an independent consultant
- 6.3 Ann03/SOP04/v2: Study Assessment Form for an independent consultant

Ann01 /SOP04/v2

Confidentiality Agreement Form for Independent Consultant

I, _____ (Name and Designation) as a non-member of Yenepeya University Ethics Committee (YUEC) understand that the copy/copies given to me by YUEC is/are confidential. I shall use the information only for the indicated purpose as described by YUEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from YUEC 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, YUEC

Ann02/SOP04/v2

Conflict of Interest Agreement Form for Independent Consultant

1. I understand that it is the policy of Yenepoya University Ethics Committee (YUEC) 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 YUEC.
2. I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the YUEC 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 YUEC and refrain from reviewing it.

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, YUEC

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

Date:

Signature of the IC

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

Ann03/SOP04/v2

Study Assessment Form for an Independent Consultant to YUEC

YUEC 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:	

7. Flow Chart

No.	Activity	Responsibility
1	Recommendation of a name of one or more IC(s)	YUEC Chairperson, Member Secretary or Member
2	Selection and Appointment of IC(s)	Member-Secretary in consultation with Chairperson
3	Invitation to IC(s) on behalf of YUEC	Chairperson/Member-Secretary
4	Co-ordination with IC(s) for fulfilling administrative requirements	YUEC Secretariat
5	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	IC, Chairperson
6	Maintenance of a specialty-wise list/ roster of ICs	YUEC Secretariat
7	Reviewing documents pertaining to research project	IC