


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


**SOP Code:** SOP04/v2

**Effective Date:** 01/08/2016

**Prepared by:**

Dr. Ravi Vaswani Member, YUEC	Signature with date  30/7/16
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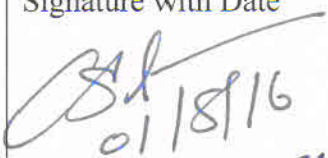
**Reviewed by:**

Dr. Leena Pramod YUEC SOP Team	Signature with Date  30/7/16
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**Approved by:**

Dr. Sayeegeetha Hegde Chairperson, YUEC	Signature with Date  3/8/16.
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**Notified by:**

Registrar Yenepoya University vide Notification No. YUReg/ACA/YUEC/FERCAP/01/2016	Signature with Date  01/8/16 <b>Dr. G. Shree Kumar Menon</b> Registrar Yenepoya University Mangaluru - 575 018
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## **1. Purpose**

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for selecting and engaging concerned subject experts as 'Independent Consultants' (IC) to the Yenepoya Ethics Committee - 1 (YEC-1) and receiving additional specialist inputs, should the YEC-1 so desire it.

## **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/YEC-1 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 YEC-1 Secretariat.

## **4. Detailed instructions**

### **4.1 Recommendation of names of ICs and making a roster of ICs for YEC-1**

- 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 YEC-1, 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 YEC-1 records. The details of each IC (Name, designation, affiliation, contact details and updated curriculum vitae) will be maintained in the YEC-1 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 YEC-1 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-1 Secretariat or from outside the roster (if felt necessary by the YEC-1) - 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 YEC-1 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 YEC-1 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 YEC-1 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/YEC-1 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 YEC-1'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 YEC-1 meeting for providing additional information or clarifications that may be sought by YEC-1 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 Yenepoya University norms existing from time to time.

#### **4.5 Tenure of Services of IC**

- 4.5.1 The roster of ICs maintained at the YEC-1 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 YEC-1. YEC-1 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 YEC-1 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 YEC-1 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 YEC-1.

#### **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 Yeneponya Ethics Committee - 1 (YEC-1) understand that the copy/copies given to me by YEC-1 is/are confidential. I shall use the information only for the indicated purpose as described by YEC-1 and shall not duplicate, give or distribute these documents to any person(s) without prior permission from YEC-1 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-1



**Ann02/SOP04/v2**

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

1. I understand that it is the policy of Yenepoya Ethics Committee - 1 (YEC-1) 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-1.
2. I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the YEC-1 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-1 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, YEC-1

I acknowledge that I have received a copy of this Agreement signed by YEC-1 Chairperson and me.

Date:

Signature of the IC

***Please note:** We thank you for accepting to be an independent consultant for Yenepoya Ethics Committee - 1, as per the rules/regulations/norms. The original signed and dated agreement will be kept on file in the custody of the YEC-1 Secretariat. A copy will be given to you for your records.*

**Ann03/SOP04/v2**

Study Assessment Form for an Independent Consultant to YEC-1

YEC-1 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)	YEC-1 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 YEC-1	Chairperson/Member-Secretary
4	Co-ordination with IC(s) for fulfilling administrative requirements	YEC-1 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	YEC-1 Secretariat
7	Reviewing documents pertaining to research project	IC