

Title: Selection and Responsibilities of Independent Consultants

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide procedures for engaging the expertise of a professional as an Independent Consultant (IC) to the Institutional Ethics Committee (IEC), INU, Bengaluru.

2. Scope

If the Chairperson, Member Secretary or the IEC determine that a study involves procedures or information that is not within the collective expertise of the IEC members, the Chairperson/ Member Secretary on behalf of the IEC will invite individual(s) with competence in special area(s) to assist in the review of issues that require expertise beyond or in addition to that/ those available with the IEC.

3. Responsibility

Upon the advice or recommendation of the secretariat or any IEC member, it is the responsibility of the IEC to nominate the name of one or more special Independent Consultant(s) (IC) and be endorsed by the Chairperson for the given project.

4. Flow chart

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

5. Detailed instructions

5.1 Recommendation of a name of an Independent Consultant

- The IEC will select a panel of IC(s) from the different specialties of Medicine and the chairperson will issue an appointment letter to the IC(s)
- An IEC member/ Chairperson may suggest that the 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 the IEC or from outside the roster; if during the review process of any given research project he/she is of the opinion that the project involves procedures or information that is not within the area of collective expertise of the IEC members,
- The IEC will decide regarding the need for acquiring the services of IC(s) and identify and select the IC(s) to be invited from within or outside the roster of ICs maintained by the IEC secretariat; based on area of expertise, independence and availability.
- The Chairperson/ Member Secretary on behalf of the IEC will invite IC(s) selected by the IEC in writing to assist in the review of the project and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through any mode of communication
- The Secretariat will request IC to declare competing interests, if any and sign a confidentiality agreement. The Secretariat may obtain and retain a copy of the updated curriculum vitae of ICs in the IEC office for records and future reference
- The Secretariat will maintain and provide a specialty-wise roster of Consultants

5.2 Selection of Independent Consultants

- The final approval from the IEC Chairperson to refer the project to the specified Independent Consultant will be taken by the Secretariat. If any IEC member disagrees with the selection of the Independent Consultant, the procedure in 5.1 will be repeated.

5.3 Co-ordination with Independent Consultants for fulfilling administrative requirements

- The Secretariat will forward a copy of the Confidentiality Agreement and Conflict of Interest Agreements to IC(s) *AX 04/SOP 03/V1* -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/ IEC members.

5.4 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 document.
- 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).
- The Independent Consultant is expected to implement the clauses of the signed Confidentiality Agreement Form *AX 04/SOP 03/V1*.

5.5 Reviewing documents pertaining to research project

- The Secretariat will provide study protocol documents along with the Study Assessment Form for IC(s) *AX 02/SOP 06/V1* to the IC(s) after Confidentiality and Conflict of Interest documents have been signed by IC and Chairperson and received by the IEC. The IC(s) will be provided with a copy of 'Guidelines for review' *AX 05/SOP 06/V1*. 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 in the IEC meeting when the concerned Project 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 IC(s) the IC(s) to attend an IEC meeting for providing additional information or clarifications that may be sought by IEC members or Chairperson. However, the IC will not participate in the decision making process on the project
- Termination of the Services
- As the IC(s) is appointed for a particular task or project and the services of IC(s) get automatically terminated once the final decision regarding the project is taken by the IEC. The IEC will document the termination of the services of IC by providing a letter thanking the IC for the services rendered. If deemed necessary, IC may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet, incidental expenses, etc.

6. Glossary

Independent Consultant	An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.
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7. Annexure

Annexure 1 *AX 01/SOP 04/V1* Study Assessment Form for Independent Consultant

Annexure 1
AX 01/SOP 04/V1
Study Assessment Form for Independent Consultant

IEC Protocol Number:	
Protocol Title: _____ _____	
Comments on the protocol:- _____ _____	
Comments on the Informed Consent Document: _____ _____ _____	
Comments on any other issues/ aspects: _____ _____	
Remarks:	<input type="checkbox"/> Recommend approval
	<input type="checkbox"/> Recommend approval after incorporation of changes suggested
	<input type="checkbox"/> Recommend disapproval (Please state Reasons) _____ _____
	<input type="checkbox"/> Any other (Please specify with reasons) _____ _____
Name of the Consultant reviewing the project:	_____
Signature with Date:	_____