	<p><u>FERCI MODEL SOPs</u></p> <p><u>Selection and Responsibilities of Independent Consultants</u></p>	<p><u>SOP 04/V1</u></p> <p><u>Effective Date: aa/bb/cccc</u></p>
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Title: Selection and Responsibilities of Independent Consultants

SOP Code: SOP 04/V1

Effective Date: aa/ bb/ cccc

[The IEC members (author/s, reviewer/s) and Chairperson will sign and date the SOP on this first page]

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for selecting and engaging expertise of medical professionals as ‘Independent Consultants’ (IC) to the Institutional Ethics Committee (IEC).

2. Scope

This SOP covers the procedures for selecting, appointing ICs and getting their expert opinion during the IEC review process. It also defines the responsibilities of IC.


3. Responsibility

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

4. Detailed instructions

4.1 Recommendation of names of ICs and making a roster of ICs for the IEC

- Chairperson/ Member Secretary/ IEC members will nominate the names of ICs from different specialties of Medicine.
- Member Secretary in consultation with Chairperson will select a panel of IC(s) for the IEC.
- Member Secretary will issue an appointment letter to the IC(s) after confirming their willingness through telephonic/ electronic communication.
- After receiving written approval from ICs, a list of speciality wise ICs will be maintained by the secretariat in the IEC records. The details of each IC (Name, designation,

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affiliation, contact details and updated curriculum vitae) will be maintained in the IEC records.

4.2 Consulting an IC during IEC review process

- An IEC member/ Member Secretary/ 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 study if it is felt that the study involves procedures or information that is not within the area of collective expertise of the IEC members.
- The Member Secretary in consultation with Chairperson (or at full board 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.
- Member Secretary on behalf of the IEC will invite IC(s) in writing to assist in the review of the research study and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the IC through telephonic/ electronic communication.

4.3 Communication with ICs

- The Secretariat may request a copy of the updated curriculum vitae of the IC (those outside roster) for IEC records and future reference.
- The Member Secretary will request IC to declare conflict of interest , if any, in writing and sign confidentiality and conflict of interest agreements.
- The Secretariat will forward copies of the Confidentiality Agreement (*AX 01-A/SOP 04/V1*) and Conflict of Interest Agreement (*AX 01-B/SOP 04/V1*) for careful reading, understanding and signing.

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- 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.

4.4 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.
- 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).

4.5 Review of research study proposal

- The Secretariat will provide study protocol documents along with the Study Assessment Form for IC(s) *AX 02/SOP 04/V1* to the IC(s). The IC(s) may be provided with a copy of 'Guidelines for Reviewers'.
- 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 by Member Secretary in the IEC meeting when the concerned study 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 the IC(s) to attend an IEC meeting for providing additional information or clarifications that may be sought



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by IEC members or Chairperson. However, the IC will not participate in the decision making process on the research study.


- If deemed necessary, IC may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet or any other incidental expenses, etc.

4.6 Tenure of Services of IC

- The roster of ICs maintained at the IEC office will be updated every 2- 5 years or as required (as per individual IEC policy)
- For IC appointed for a particular study, the services of IC get automatically terminated once the final decision regarding the study 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.

4.7 Responsibilities of IC

- If IC agrees to review a research proposal, he/she will comply with IEC requirements of signing confidentiality and conflict of interest agreements.
- IC will review the research study and complete the Assessment Form (duly signed and dated) within a stipulated period or by a stipulated date.
- IC will attend an IEC meeting for providing additional information or clarifications, if invited by Member Secretary/ Chairperson. However, the IC will not participate in the decision making process on the research study.
- IC will remain available for telephonic and email communication till the review process of the given research proposal is complete.

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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.

6. Annexures


- Annexure 1 *AX 01-A/SOP 04/V1* - Confidentiality Agreement for an IC
 AX 01-B/SOP 04/V1 - Conflict of Interest Agreement for an IC
- Annexure 2 *AX 02/SOP 04/V1*- Study Assessment Form for an IC

Annexure 01-A: AX 01-A/SOP 04/V1

Confidentiality Agreement Form for an Independent Consultant

I, _____
 _____ (Name and Designation) as a non-member of Institutional Ethics Committee (IEC) understand that the copy / copies given to me by the IEC is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

<p>_____</p> <p>Signature of the Consultant</p>	<p>_____</p> <p>Date</p>
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<p>_____</p> <p>Chairperson of IEC</p>	<p>_____</p> <p>Date</p>
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Annexure 01-B: AX 01-B/SOP 04/V1


Conflict of Interest Agreement Form for Independent Consultants

- I understand that it is the policy of the IEC that no 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 the IEC.
- I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the IEC to me.
- 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 IEC and refrain from reviewing it.

I, _____ (name) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____	_____
Signature of IC	Date

_____	_____
Chairperson's Signature	Date

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


Signature Date

[The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records]

Annexure 2: AX 02/SOP 04/V1

Study Assessment Form for an Independent Consultant

IEC Protocol Number:	
Protocol Title:	
Comments on the protocol:-	
Comments on the Informed Consent Document:	
Comments on any other issues/ aspects:	

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Remarks:	<input type="checkbox"/> Recommend approval <input type="checkbox"/> Recommend approval after incorporation of changes suggested <input type="checkbox"/> Recommend disapproval (Please state Reasons) <hr/> <input type="checkbox"/> Any other (Please specify with reasons) <hr/>
Name of the Consultant reviewing the project: Signature with Date:	<hr/> <hr/> <hr/>

7. Flow Chart

No.	Activity	Responsibility
1	Recommendation of a name of one or more IC(s)	IEC Member, Member Secretary or Chairperson
2	Selection and Appointment of IC(s)	Member Secretary in consultation with Chairperson
3	Invitation to IC(s) on behalf of IEC	Chairperson/ Member-Secretary
4	Co-ordination with IC(s) for fulfilling administrative requirements	IEC 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	IEC Secretariat
7	Reviewing documents pertaining to research project	IC