



**IHEC – MGMCRI SOPs
Selection and Responsibilities of
Independent Consultants**

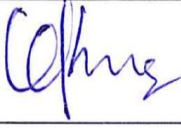

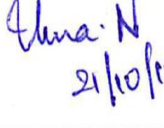
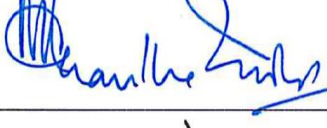
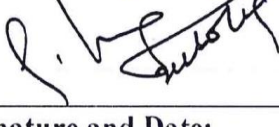


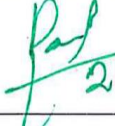
**SOP Code: SOP 04/V2
Effective from 21/10/2019**

Title: Selection and Responsibilities of Independent Consultants of Institutional Human Ethics Committee (IHEC), MGMCRI

SOP Code: SOP 04/V2

Effective Date: 21-10-2019

SOP Constitution and Approval:

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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 Human Ethics Committee (IHEC), MGMCRI.

2. Scope

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

3. Responsibility

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

4. Detailed instructions

4.1 Recommendation of names of ICs and making a list of ICs for the IHEC

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



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4.2 Consulting an IC during IHEC review process

- a) An IHEC member/ Member Secretary/Additional 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 list of ICs maintained by the IHEC 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 IHEC members.
- b) The Member Secretary/Additional Member Secretary in consultation with Chairperson (or at full board meeting; as deemed necessary) will decide identify and select the IC(s) outside the list to be invited based on area of expertise, independence and availability.
- c) Member Secretary/Additional Member Secretary on behalf of the IHEC 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 list) for IHEC records and future reference.
- The Member Secretary/Additional 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/V2) and Conflict of Interest Agreement (AX 01-B/SOP 04/V2) to the Independent Consultant's for careful reading, understanding and signing.
- The Member Secretary/Additional 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/ IHEC members.



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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/V2 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/Additional Member Secretary in the IHEC 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 IHEC meeting for providing additional information or clarifications that may be sought by IHEC 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.



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4.6 Tenure of Services of IC

- The roster of ICs maintained at the IHEC office will be updated every 3 years or as required (as per individual IHEC 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 IHEC. The IHEC 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 IHEC 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 IHEC meeting for providing additional information or clarifications, if invited by Member Secretary/Additional 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.

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.
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6. Annexures

- Annexure 1: AX01-A/SOP 04/V2- Confidentiality Agreement for an IC
AX01-B/ SOP 04/V2 - Conflict of Interest Agreement for an IC
- Annexure 2: AX02/ SOP 04/V2 - Study Assessment Form for an IC



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Annexure 01-B: AX01-B/SOP 04/V2

Conflict of Interest Agreement Form for Independent Consultants

- I understand that it is the policy of the IHEC 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 IHEC.
- I do not have any actual or potential conflict of interest in relation to the particular proposal submitted for review by the IHEC 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 IHEC 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

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

Signature

Date

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



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Annexure 2: AX 02/SOP 04/V2

Study Assessment Form for an Independent Consultant

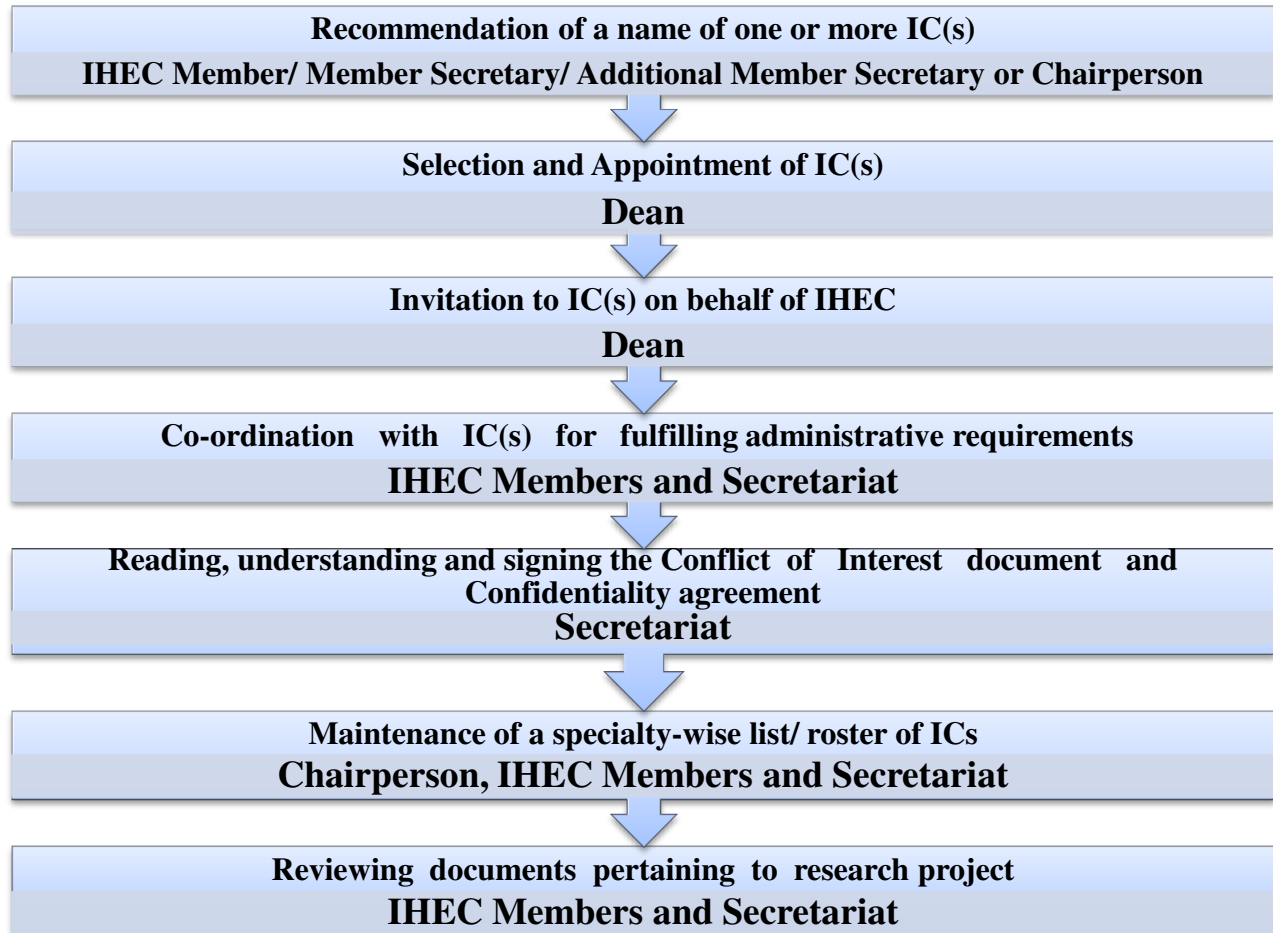
IHEC Number:	Protocol	
Protocol Title: _____ _____		
Comments on the Protocol:- _____ _____		
Comments on the Informed Consent Document:- _____ _____		
Comments on any other issues/ aspects:- _____ _____		
Remarks:-	<input type="checkbox"/> Recommend approval <input type="checkbox"/> Recommend approval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



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7. Flow Chart



8. References

- *Forum for Ethics review Committees in India (FERCI). Standard Operating Procedures of Institutional Ethics Committee (cited 5th October 2019). Available from: <http://www.ferci.org/sops/>*
- *Indian Council of Medical Research (ICMR). National Ethical guidelines for biomedical and health research involving human participants, October 2017 (cited 6th October 2019) available from: http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf*