

	Institutional Ethics Committee (IEC) Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai – 400 012. Web: www.kem.edu	SOP 04/V5 Effective from 1st Aug 2017, Valid up to 30th July 2019
	Selection and Responsibilities of Subject expert	



Title: Selection and Responsibilities of Subject expert

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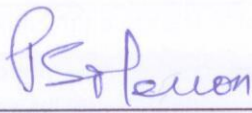
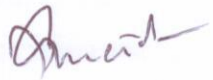

 Dr. Padmavathy Menon, Chairperson, IEC - I (Signature with Date)	 Dr. Alan Almeida, Chairperson, IEC - II (Signature with Date)
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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide procedures for Obtaining the expertise of a professional as an subject expert either affiliated or non-affiliated, to the Institutional Ethics Committee (IEC).

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 subject experts 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 subject expert	IEC Secretariat
2	Recommendation of a name of one or more subject expert(s)	IEC Member, Member Secretary or Chairperson
3	Selection and Appointment of subject expert (s)	Chairperson
4	Co-ordination with subject expert (s) for fulfilling administrative requirements	IEC Secretariat
5	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	Subject expert , Chairperson
6	Reviewing documents pertaining to research project,	Subject expert
7	Termination of the Services	Member-Secretary/ Chairperson

5. Detailed instructions

5.1 Maintenance of a specialty-wise list/ roster of subject experts

The Secretariat will maintain and provide a specialty-wise roster of subject experts which may or may not be affiliated with the institution. The roster of subject experts maintained at the IEC office will be updated every 2- 5 years or as required (as per individual IEC policy)

5.2 Recommendation of a name of an subject experts

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The IEC will select a panel of subject experts from the different specialties of Medicine and the chairperson will issue an appointment letter to the subject experts.

An IEC member/ Chairperson may suggest that the opinion be sought from one or more subject experts and may suggest the name of a particular subject expert from the roster of subject experts 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. Subject experts will be either affiliated or not affiliated to the institute.

The IEC will decide regarding the need for acquiring the services of subject experts and identify and select the subject experts to be invited from within or outside the roster of subject experts maintained by the IEC secretariat; based on area of expertise, independence and availability.

The Chairperson/ Member Secretary on behalf of the IEC will invite subject expert 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 subject expert through any mode of communication

The Secretariat will request subject expert 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 subject expert in the IEC office for records and future reference

5.3 Selection of subject expert

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


5.4 Co-ordination with subject expert with institution for fulfilling administrative requirements

- The Secretariat will forward a copy of the Confidentiality Agreement and Conflict of Interest Agreements to subject experts AX 04/SOP 03/V5 -for careful reading, understanding and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the subject experts if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert/ IEC members.

5.5 Reading, understanding and signing the Conflict of Interest document and Confidentiality Agreement

- The subject expert 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 subject expert.
- The subject expert is expected to implement the clauses of the signed Confidentiality Agreement Form AX 04/SOP 03/V5.

5.6 Reviewing documents pertaining to research project

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- The Secretariat will provide study protocol documents along with the Study Assessment Form for subject experts AX 01/SOP 04/V5 to the subject expert after Confidentiality and Conflict of Interest documents have been signed by subject expert and Chairperson and received by the IEC. The subject expert will be provided with a copy of 'Guidelines for review' AX 04/SOP 05-A/V5. The subject expert 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 subject expert 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 subject expert in writing. Additional Information provided by the subject expert will be considered as a part of the Assessment Report.

If deemed necessary, the Chairperson or Member-secretary may invite subject expert the subject expert to attend an IEC meeting for providing additional information or clarifications that may be sought by IEC members or Chairperson. However, the subject expert will not participate in the decision making process on the project

5.7 Termination of the Services


As the subject expert is appointed for a particular task or project and the services of subject expert 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 subject expert by providing a letter thanking the subject expert for the services rendered . If deemed necessary, subject expert may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet, incidental expenses, etc.

6. Glossary

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

Annexure 1 AX 01/SOP 04/V5 Study Assessment Form for subject expert

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Annexure 1
AX 01/SOP 04/V5
Study Assessment Form for Subject Expert

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 subject expert reviewing the project: Signature with Date:	_____ _____