



Independent Ethics Committee (IEC)
Regd. No. 1433/1999 G.B.B.S.D

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 Independent Ethics Committee (IEC), Mumbai

2. Scope

If the Chairperson or the IEC Members determine that a study will involve procedures or information that is not within the area of expertise of the IEC members, the Chairperson/ Member Secretary on behalf of the IEC may invite individual(s) with competence in special area(s) to assist in the review of issues that require expertise beyond or in addition to 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 and approve the name of the special Independent Consultants (IC) to be endorsed by the Chairperson for the given project.

4. Flow chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Recommendation of a name of an Independent Consultant	IEC Members/Chairperson
2	Selection of Independent Consultants	Chairperson
3	Co-ordination with Independent Consultants for fulfilling administrative requirements	IEC Secretariat
4	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	Consultant/Secretariat/ Chairperson IEC
5	Reading and understanding documents pertaining to research project	Independent Consultant



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<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
6	Adhering to highest standards of ethical conduct and implementing Agreements signed	Independent Consultant
7	Termination of the Services	Consultant / IEC

5. Detailed instructions

5.1 Recommendation of a name of an Independent Consultant

- During the review process of any given clinical project which involve procedures or information that is not within the area of expertise of the IEC members, the Chairperson/ Member Secretary on behalf of the IEC may invite individual/individuals with competence in special area(s) to assist in the review of issues that require expertise beyond or in addition to those available with the IEC.
- The Secretariat will provide roster of Consultants and the areas of their expertise.
- The Independent Consultant will be identified by the IEC members.
- The IEC members will conduct a qualification review of the prospective consultant and make a decision based on expertise, availability and independence criteria.
- The IEC Chairperson will nominate the Independent Consultants whose expertise will be taken for the given clinical project.
- The Secretariat will contact the consultant and request him/her to provide the following documents:
 - A curriculum vitae
 - Confirmation letter to opine on the project.

5.2 Selection of Independent Consultants

- The CV of the Independent Consultant will be reviewed by the IEC members and 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 and a new Independent Consultant will be selected.



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5.3 Co-ordination with Independent Consultants for fulfilling administrative requirements

- The Secretariat will forward 2 copies of Confidentiality Agreement for Independent Consultant *AF/03/01-SOP03/01* and ask them to read it carefully.
- If the Independent Consultant has any doubts, the questions are directed to the Secretariat in writing. The Member Secretary will provide explanations/clarifications. 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 Independent Consultants will sign and date both the copies of the Confidentiality / Conflict of Interest Agreement document before a member of the Secretariat.
- They will give the forms back to the Secretariat to obtain sign and date of the IEC Chairperson. The Secretariat will obtain the signatures of IEC Chairperson and forward one copy of the Confidentiality / Conflict of Interest Agreement to the Independent Consultant for their records (duly signed and dated by them and IEC Chairperson).

5.5 Reading and understanding documents pertaining to research project

- The Secretariat provides study protocol documents to the appropriate consultant for review along with the study Assessment form *AF/01/01-SOP06 /01*.
- The consultant must complete a assessment report to be reviewed by the IEC at the time the study is reviewed and forwards the comments/assessment report duly signed and dated for Independent Ethics Committee office records
- The assessment report becomes a permanent part of the study file.
- The assessment report is reviewed in the meeting when the concerned Project is discussed.
- The Independent Consultant could be invited to attend a meeting if deemed necessary by the Chairperson/ IEC members for getting additional information/clarifications. However, the Independent Consultant does not participate in the project nor will have a right to vote. He/She can also be contacted for additional information or clarifications if sought by the Chairperson/ Secretariat/ IEC members. All communications from the IEC should be routed through the Secretariat.



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5.6 Adhering to highest standards of ethical conduct & implementing Agreements signed.

- The Independent Consultant must adhere to the highest standards of ethical conduct and must ensure that the cardinal principles of ethics i.e. autonomy of the individual, beneficence, nonmaleficence and justice are followed while reviewing the project.
- The Independent Consultant must implement the clauses of the signed Confidentiality Agreement Form *AF/03/01-SOP03/01*.

5.7 Termination of the Services

- As the Consultant is appointed for a particular task or project, the services get automatically terminated once the final decision regarding the project is taken by the IEC.
- Remuneration for Independent Consultant will be provided to reimburse expenses on travel, time spent, documents referred to in library/ internet, incidental expenses.

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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