



Standard Operating Procedures (SOP -02/01)

For
Constituting the Independent Ethics Committee



Independent Ethics Committee (Clinical Research) India

1. Purpose

The Independent Ethics Committee IEC(CR) INDIA India established on 31/10/1999 in order to provide independent guidance, advice and decision (in the form of 'approval / recommendation / stipulation / disapproval') on health research or other specific research protocols involving Clinical subjects.

The primary purpose of this committee will be to

1. Ensure the protection of the rights, safety and well-being of Clinical subjects involved in a research project and
2. Provide public assurance of that protection.

The IEC(CR) INDIA is composed of both scientists and non-scientists. It is independent in its reflection, advice and decision.

This Standard Operating Procedure (SOP) describes the Terms Of References (TORs), which provide the framework for constitution, responsibilities, and activities of the Independent Ethics Committee.

2. Scope

The SOP applies to all activities performed by the Independent Ethics Committee (Clinical Research) India.

3. Responsibility

It is the responsibility of the Independent Ethics Committee members and the Secretariat to read, understand, follow and respect the SOP set by the Independent Ethics Committee (Clinical Research) India.

4. Flow Chart

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
1	Ethical basis	IEC(CR) INDIA Members
2	Composition of the Independent Ethics Committee	Chairperson, IEC(CR) INDIA Members and
3	Membership requirements	Chairperson, IEC(CR) INDIA Members and



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IEC(CR) INDIA**

<u>No.</u>	<u>Activity</u>	<u>Responsibility</u>
4	Tenure of Membership	Chairperson, IEC(CR) INDIA Members and
5	Appointment of new members	IEC(CR) INDIA Members and Secretariat
6	Resignation and disqualification of members	IEC(CR) INDIA Members and Secretariat
7	Independent Consultants	IEC(CR) INDIA Members and Secretariat
8	Conditions of appointment	IEC(CR) INDIA Members and Secretariat
9	Hierarchy	IEC(CR) INDIA Chairperson
10	Chairperson	IEC(CR) INDIA
11	Secretariat	IEC(CR) INDIA Chairperson
12	Roles & Responsibilities of IEC(CR) INDIA	IEC(CR) INDIA Chairperson
13	Quorum requirements	IEC(CR) INDIA Members and Secretariat
14	Responsibilities of the Independent Ethics Committee, Kolkata	IEC(CR) INDIA Members and Secretariat

5. Detailed Instructions

5.1 Ethical basis

- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of a proposed research project.
- In evaluating protocols and ethical issues, the IEC(CR) INDIA is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed research is being considered.
- The IEC(CR) INDIA also seeks to be informed, as appropriate, by other ethics committees approving other trial sites and researchers of the impact of the research it has approved. The IEC(CR) INDIA is guided in its reflection, advice and decision by the ethical principles expressed in Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly,



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Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004)

- It makes further reference to the International Ethical Guidelines for e.g.: The Nuremberg Code (1945), Belmont Report (1979), The Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Clinical Subjects (Geneva 2002), and the European Convention on Clinical rights and Biomedicine (1997).
- The IEC(CR) INDIA established its own Standard Operating Procedures based on the Operational Guidelines for Ethics Committees that review Biomedical Research (WHO, 2000), International Conference on Harmonisation - Good Clinical Practices (ICH-GCP) Guidelines (1996), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) and Ethical Guidelines for Biomedical Research on Clinical Participants by ICMR (2006)
- The IEC(CR) INDIA is established and functions in accordance with the relevant national law and regulations in force from time to time.

5.2 Composition of the Independent Ethics Committee

- The IEC(CR) INDIA will be multidisciplinary and multisectorial in composition
- The IEC(CR) INDIA will be composed of **at least 8 to a maximum of 12 members.**
- The members should be a mix of medical/ non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.
- The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by that given institute / centre.
- The IEC(CR) INDIA will have representation that is varied in terms of gender, age and social background. The Composition may be as follows:
 - Chairperson
 - One/ two persons from basic medical science area
 - One / two clinicians from various institutes
 - One legal expert or retired judge
 - One social scientist/ representative of non-governmental agency
 - One philosopher / ethicist / theologian
 - One lay person from community
 - Member Secretary



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5.3 Membership requirements

- The Chairperson and Members of Independent Ethics Committee are responsible for appointing new committee members.
- Members are selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC(CR) INDIA work.
- Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration (Refer to SOP 03/01-Confidentiality / Conflict of Interest Agreements).
- The IEC(CR) INDIA will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision (Refer to SOP 03/01- Confidentiality / Conflict of Interest Agreements).
- Members will be required to sign a confidentiality agreement at the start of their term. (Refer to SOP 03/01-Confidentiality / Conflict of Interest Agreements)
- The confidentiality agreement protects the privacy and confidentiality of all parties whose information may be disclosed to the IEC(CR) INDIA in the course of it work.

5.4 Tenure of Membership.

- The tenure of Independent Ethics Committee members will be for a continuous period of five (5) years from the date of appointment.
- Extension of membership will be decided by a vote of two-thirds of the members present and voting in a quorum at a regular committee meeting.
- There will be no limit to the number of times that membership can be extended.

5.5 Appointment of new members

New members will be appointed under the following circumstances:

1. When a regular member completes his / her tenure.
2. If a regular member resigns before the tenure is completed.
3. If a regular member ceases to be a member for any reason including death, disqualification.
4. To fulfill the membership requirements as per 5.2 of this SOP

New members will be identified according to the requirement (i.e. as per the composition specified in Section 5.2 of this SOP), membership requirement (Section 5.3 of this SOP) and provided the potential member fulfils the conditions of appointment as defined in 5.8 of this SOP after discussion by the IEC(CR) INDIA. A decision will be arrived at by simple majority



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The Chairperson will issue the appointment letter to the member

5.6 Resignation and Disqualification of Members.

- Members may resign their position by submitting a letter of resignation to the Chairperson.
- Members may be disqualified from continuance should any of the IEC (CR) INDIA members provide written arguments to the Committee. There should be three fourth majorities of quorum and voting members.
- If a regular member fails to attend more than 3 meetings of the Independent Ethics Committee in succession without prior intimation, his / her membership will be reviewed by the IEC(CR) INDIA and terminated if necessary.

5.7 Independent Consultants

- The IEC(CR) INDIA may be further supported in its reflection on specific protocols or request for advice on specific issues by Independent consultants.
- The Independent Consultant will be appointed by the IEC(CR) INDIA.
- Their professional qualifications may be in the areas of community and/or patient representation, medicine, statistics, social sciences, law, ethics, and religion.
- Independent consultants are appointed for the given project on which his/her opinion is required. The Independent Consultant will give their assessment and opinion but will not participate in the approval process of the project concerned.

5.8 Conditions of appointment

Members and Independent consultants will be appointed to the IEC(CR) INDIA if they accept the following conditions.

- Willingness to publicize his/her full name, profession and affiliation.
- The reimbursement for work and expenses, if any, within or related to the IEC(CR) INDIA should be recorded and made available to the public upon request.
- All IEC(CR) INDIA members and Independent consultants must sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.

5.9 Hierarchy



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- There will be one Chairperson, one Member Secretary and one Associate Member Secretary.
- The Chairperson will be the head of the committee.
- The Member Secretary and the Associate Member Secretary will be the guardian of all documents and funds in the committee possession.
- All other members will be regular committee members with equal ranking.
- The Chairperson, Secretary, Associate Member Secretary are elected by the IEC(CR) INDIA members for 2 years terms. These may be re-elected but not for more than 3 consecutive terms, should they resign or be disqualified the IEC(CR) INDIA members will elect a replacement until the completion of the normal term.

5.10 Chairperson

- The committee members will elect a Chairperson from among themselves.
- The Chairperson will be responsible for conducting all committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson will preside over all elections and administrative matters pertinent to the committee's functions.
- In case of anticipated absence, the Chairperson will nominate a committee member as Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

5.11 Secretariat

- The Secretariat will be composed of the IEC(CR) INDIA Member Secretary, Member Treasurer, IEC(CR) INDIA Associate Member Secretary (if necessary) and the administrative supporting staff.
- The Member Secretary, Treasurer and the Associate Member Secretary are elected by the committee members from among themselves. The administrative staff of the Secretariat will be appointed by the IEC(CR) INDIA and they will be supervised by the Member Secretary.
- The Secretariat shall have the following functions.
 - **Functions of the Member secretary**
 1. Organizing an effective and efficient tracking procedure for each proposal received.
 2. Preparation, maintenance and distribution of study files.
 3. Organizing IEC(CR) INDIA meeting regularly
 4. Preparations and maintenance of meeting agenda and minutes.
 5. Maintaining the IEC(CR) INDIA documentations and to Archive the documents.
 6. Communicating with the IEC(CR) INDIA members and applicants.



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7. Notification of review outcome to Principal Investigator of research proposal.
8. Arrangement of training for personnel and IEC(CR) INDIA members.
9. Organizing the preparations, review, revision and distribution of SOPs and guidelines.
10. Providing the necessary administrative support for EC related activities to the Chairperson of the committee (e.g. communicating a decision to the applicant).
11. Providing updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
12. To receive fees and issue official receipts for the same.

○ **Functions of the Associate Member Secretary**

The Associate Member Secretary performs the same functions of Member Secretary in his/her absence.

○ **Functions of the Member Treasurer**

1. To supervise incoming accounts and ensure that disbursement of amounts are done correctly
2. To ensure statutory audit is performed annually
3. To ensure that proper taxes are paid to competent authority

○ **Functions of the Administrative Officer**

1. To support the Member Secretary and Treasurer in all their functions
2. To perform any other functions as instructed by Member Secretary

5.12 Roles and Responsibilities of IEC(CR) INDIA members

- Participate in the IEC(CR) INDIA Meeting.
- Review, discuss and consider research Proposals submitted for evaluation.
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate.
- Evaluate final reports and outcomes.
- Maintain confidentiality of the documents and deliberations of IEC(CR) INDIA meetings.
- Declare any conflict of interest.
- Participate in continuing education activities in biomedical ethics and biomedical research.

5.13 Quorum Requirements



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- Meeting will be held as scheduled provided there is quorum. A quorum will be defined as one-half of the current regular members of the committee, rounded off to the next higher whole number (e.g. 6 out of 12); as per the Schedule Y (20th January 2005), the quorum must include members with the following representations:-
 - a) One Basic medical scientist (preferably one pharmacologist)
 - b) One Clinician
 - c) One Legal Expert
 - d) One Social Scientist/representatives of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person.
 - e) One Lay person from the community.

5.14 Responsibilities of the Independent Ethics Committee

- The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research subjects.
- The Committee will keep all information submitted to them confidential specially the proprietary information.
- The Committee will maintain concise but clear documentations of its views on the research proposal.
- The Committee will review the progress of each research project at appropriate and specified intervals, but not less than once a year and will also review the final report of the studies approved by them.
- The Committee will review the qualification of all investigators participating in the proposed research study.

6. Glossary

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IEC(CR) INDIA/ information and documents
IEC(CR) INDIA	Independent Ethics Committee is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of Clinical subjects involved in a clinical trial (at sites which do not have EC/EC not functional as per Schedule Y) and to provide public assurance of that protection.
Independent Consultants	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed



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7. References

1. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
(Geneva 2000 www.who.int/tdr/publications/publications/- last accessed 24 March 2008)
2. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf>
(last accessed 24 March 2008)
3. CIOMS International Ethical Guidelines for Biomedical Research Involving Clinical Subjects http://www.cioms.ch/frame_guidelines_nov_2002.htm
(last accessed 24 March 2008)
4. ICMR's Ethical Guidelines for Biomedical research on Clinical Participants, ICMR (2006)- http://www.icmr.nic.in/ethical_guidelines.pdf
(last accessed 24 March 2008)
5. Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005)
[http://www.cdsc.nic.in/html/Schedule-Y%20\(Amended%20Version-2005\)%20original.htm](http://www.cdsc.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm) (last accessed 24 March 2008)
6. European Convention on Clinical rights and Biomedicine (1997).
<http://conventions.coe.int/treaty/en/treaties/html/164.htm>
(last accessed 24 March 2008)