

NIRRH Ethics Committee for Clinical Studies 2.1 Constitution of an IEC	SOP Code: SOP/02/V1.2 Effective date : 01/09/2016 Page no. 1 of 11
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Title: Constitution of an IEC

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Table of Content

<u>No.</u>	<u>Content</u>	<u>Page No.</u>
1.	Purpose	3
2.	Scope	3
3.	Responsibility	3
4.	Flow Chart	3
5.	Detailed instructions	4
5.1	Ethical basis and mandate	4
5.2	Composition of IEC	5
5.3	Membership requirements	6
5.4	Resignation, Disqualification, Replacement of Members	7
5.5	Independent Consultants	7
5.6	Conditions of Appointment	8
5.7	Officers	8
5.8	Secretariat	8
5.9	Roles and Responsibilities of IEC members	9
5.10	Quorum Requirement	10
5.11	Dissolving of the IEC	10
6.	Glossary	11
7.	References	11
8.	ANNEX 1 Document History	11

1. Purpose

The Institutional Ethics Committee(IEC) of the Insitute was established on 21st October 1994 in order to provide independent guidance, advice,and decision (in the form of “approval/recommendation/disapproval”) on health research or other specific research protocols involving human subjects.

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for constitution, responsibilities and activities of the NIRRH EthicsCommittee for clinical studies .

IEC will have both scientists and non-scientists which are appointed by the Director/Officer-in-Charge. At least one fourth of the IEC strength may be institutional while the rest will be non- institutional members. To function as an independent committee in its reflection, advice, and decision, the Director /Officer-in-Charge will not be a member of the IEC; however for the smooth functioning of the EC all the necessary infrastructure and facilities will be provided by the Director /Officer-in-Charge.

2. Scope

The SOP applies to the functioning of all activities under theIEC of NIRRH. This includes the basic responsibilities of the IEC, composition, appointment of the members and conduct of the meeting.

3. Responsibility

It is the responsibility of the IEC members, secretariat and the Chairperson to read, understand and respect the rules set by the IEC of the National Institute for Research in Reproductive Health.

4. Flow chart

No.	Activity	Responsibility
1	Ethical basis and mandate ↓	IEC Members, Secretariat
2	Composition of the IEC ↓	Director/Officer-in Charge in consultation with the Institutional IEC members
3	Appointment of IEC members ↓	Director/Officer-in Charge of the Institute
4	Membership Requirements ↓	IEC Members and Secretariat
5	Resignation, Disqualification, Replacement of Members ↓	IEC Members and Secretariat

NIRRH Ethics Committee for Clinical Studies 2.1 Constitution of an IEC	SOP Code: SOP/02/V1.2 Effective date : 01/09/2016 Page no. 4 of 11
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6	Independent Consultants ↓	Director/Officer-in Charge of the Institute
7	Conditions of Appointment ↓	IEC Members and Secretariat
8	Secretariat including supportive staff ↓	Director/Officer-in- Charge in consultation with the IEC Secretary
9	Quorum Requirements	IEC Members and Secretariat

** Please note that IEC members includes the Chairperson for all practical purposes unless otherwise specified.*

5. Detailed Instructions

5.1 Ethical basis and Mandate

- The IEC seeks to fulfill the requirements for international assurances and is established and functions in accordance with the national law and regulations. To date the NIRRH IEC is registered with the OHRP and the FWA with accession number IORG0005580 and FWA00013637 respectively.
- Institutional Ethics Committee (IEC) will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. To ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner, the IEC may refer to the SOPs and Guidelines of the IEC –NIRRH.
- It will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
- It is a dictum that the goals of research, however important, should never be permitted to override the health and well being of the research participants.
- IEC should take up those proposals after ensuring the scientific soundness and technical appropriateness of the proposed research through appropriate Scientific Review Committee or Scientific Advisory Committee of the institute or **Research Advisory Committee of Model Rural Health Research Unit (MRHRU) or Scientific Advisory Committee of Field Units of NIRRH**. The Clinical, Basic, Socio-behavioural cum Operational Research and Genetics Scientific Review Committees including the (Institutional Committee for Stem Cell Research and Therapy) ICSCRT should have at least one Ethics Committee member (non-institutional) in their panel. The Committee however, in exceptional circumstances after due permission from Director/ Officer-in-Charge shall be evaluating the proposal with pending SRC decision.
- IEC will only review the research proposals (clinical, basic research, genetic, socio-behavioural or operational studies), which are conducted at the Institute. If the Principal Investigator at the Institute is undertaking a clinical, socio-behavioural/

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operational, or basic research study, which is done in collaboration with a hospital/clinic/organization (of government sector), which does not have an Ethics Committee, the IEC-NIRRH may offer its oversight on request and function as the EC for that hospital/ clinic. However, it is mandatory that the hospital/ clinic extends all the co-operation for monitoring the conduct of the study.

- IEC is entrusted not only with the initial review of the proposed research proposals prior to initiation of the projects but also have a continuing responsibility of regular monitoring of the approved projects to foresee the compliance of the ethics during the period of the project. Such an ongoing review shall be in accordance with the international guidelines wherever applicable.
- IEC is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. IECs should provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research through Scientific Review Committee.

5.2 Composition of the IEC

- The IEC will have equal representation of both the genders as well as the older and younger generations.
- To oversee the various specialties of research undertaken at the institute, the IECs should be multidisciplinary and multisectorial in composition with at least 11 members to include institutional members, from various faculties such as basic, clinical, operational, statistics, genetics and social sciences.
- The external experts will include the specialties like clinical pharmacologist, geneticist, pathologist, gynecologist, molecular biologist, toxicologist, epidemiologist/socio-behavioural scientist, legal advisor.
- Their expertise will be helpful while evaluating specific research studies addressed at the Institute. Thus the IEC members should be a mix of medical/ non-medical, scientific and non-scientific persons including community persons to help provide a patient's and public perspective and to represent the differed points of view.
- The Chairperson will not be affiliated to the Institute (National Institute for Research in Reproductive Health) to ensure the independence of the Committee. The Member Secretary will be from the same Institution and should conduct the business of the Committee.
- Though the decision will be by consensus, voting may be used (when consensus is not reached) for which a quorum of at least 5 is mandatory. No meeting will be considered valid if quorum is not reached.

The composition may be as follows:-

1. Chairperson

2. Institutional members to be included from various faculties such as basic, clinical, operational, statistics, genetics and social sciences.
3. One - two persons from basic medical science area
4. Two or three clinicians from various Institutes/Hospitals/Medical Colleges to include Gynecologist, clinical pharmacologist or any other speciality
5. One legal expert
6. One - two social scientist/ representative of non-governmental voluntary agency
7. Two community members (they could be clinic clients/non scientific who can voiceout the concerns of the potential participants)
8. Member Secretary

Alternate members:

- The IEC should nominate alternate Chairperson who can be selected from the non-institutional IEC members. The alternate Chairperson can oversee / conduct the meeting in the absence of the Chairperson.
- Considering the fact that there may be conflict of interests when the Member Secretary is the Principal Investigator/ co-investigator or is absent from the meeting, the IEC may consider appointing alternate Member Secretary who should be the institutional IEC member.
- The alternate member of required speciality (Legal Expert, Clinical Pharmacologist, Community Member) can be selected for fulfilling the quorum, in case the present member is not able to attend the meeting due to unprecedented prior commitments and the meeting is to be held on the same day.
- Alternate members are suggested by the IEC and appointed by the Director/ Officer-in-Charge.

5.3 Membership requirements

- ❖ In the interest of the Institute's research program, the IEC members including the Chairperson, Member Secretary will be selected by the Director/ Officer-in-Charge taking into consideration their expertise, research interests and experience in ethics.
- ❖ Selected members should possess the necessary research experience- scientific knowledge and expertise; knowledge of ethics, and their commitment and willingness to volunteer the necessary time and effort for the IEC work.
- ❖ Community members will be selected based on the basis that they are willing to publicize full name, profession and affiliation. Their Curriculum Vitae should be submitted to the EC office for records.
- ❖ The Chairperson and the EC members should be informed of the potential members by the Member Secretary in the meeting and their concurrence should be obtained.
- ❖ Members must disclose in writing any interest or involvement – financial, professional or otherwise – in a project or proposal under consideration.

- ❖ The IEC 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/V1.0 Confidentiality / Conflict of Interest Agreement.
- ❖ Members will be required to sign a confidentiality agreement at the start of their term. Members are appointed for a period of 3 years and the Member Secretary will also serve the tenure for 3 years. On completing the tenure of the Member Secretary, he/she will be appointed as a member for a period of 6 months for ensuring smooth transition and the necessary help to the Member Secretary as per the decision of the Director/Officer-In-Charge. The new member secretary should be affiliated member for at least six months before taking up the charge.
 - ❖ Their appointments may be renewed by the Director/ Officer-in-Charge of the National Institute for Research in Reproductive Health for up to two consecutive terms or as required by the Director/ Officer-in-Charge.
 - ❖ The Ethics Committee will include some rotation in appointment of new members after a period of five-years, but it will also strive to ensure continuity within the IEC. At no point of time will more than 25% of members be replaced.
 - ❖ For institutional Ethics Committee members, it is mandatory that the new members will act as observers for at least three meetings prior to their induction into the EC.

5.4 Resignation, Disqualification, Replacement of Members

- Members may resign their positions by submitting a letter of resignation to the Chairperson.
- Members may also be disqualified from continuance in the following circumstances:
 - Absence for three consecutive meetings
 - Should the Chairperson provide written arguments to the (other) members and there is unanimous agreement
 - Member does not comply to the responsibilities set for the members (stubborn- sets up stage for argument/ non-punctual/ not thorough with the job assigned)
- Members that have resigned or have been disqualified may be replaced by Director/ Officer-in-Charge.

5.5 Independent Consultants – Refer SOP/05/V1.0

- The IEC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants.
- Independent Consultants are suggested by the Chairperson of the IEC in consultation with the Member Secretary and appointed by the Director/ Officer-in-Charge.
- Their professional qualifications may be in the areas of community and/or patient representation, or subject experts unique to the study proposal under ethics review. Subject experts could be invited to offer their views, for instance, stem cell biology expert for research on Stem Cells, Paediatrician for study on Genetic disorders, etc. Similarly, based on the requirement of research area, for example HIV, genetic disorders *etc.* it is desirable to include a member from specific patient groups in the

Committee. Independent Consultants are appointed only for the review of the study sought. They will not be able to vote or be involved in decision-making.

- Independent Consultants may attend the meeting via teleconference or video-conferencing.

5.6 Conditions of Appointment

Chairperson, Member Secretary, Members, Alternate Chairperson, Alternate Members and Independent Consultants are appointed to the IEC under the following conditions:

- Willingness to abide by the requirements laid in the SOP
- Willingness to publicize his/her full name, profession, and affiliation;
- All financial accountability, reimbursement for work and expenses, if any, within or related to the IEC should be recorded and made available to the public upon request;
- All IEC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants and related matters

5.7 Officers and their responsibilities

The following officers through their respective responsibilities contribute to the good functioning of the IEC:

Chairperson:

He/She is responsible to chair the meetings and liaise directly with the Director/Officer-in Charge of the Institute, report the meeting outcomes to the Director, invite independent consultants to provide special expertise to the EC on proposed research protocol. He/She should work in close co-ordination with the Member Secretary, review and sign along with the member secretary all the minutes, proposals and work towards the smooth function of the EC.

Alternate Chairperson :

He/She is responsible to chair the meetings in the absence of the Chairperson and act as alternate Chair during meetings.

Member Secretary:

He/She is responsible for the administrative aspect of the EC (see 5.8 - below)

Alternate Member Secretary:

He/She is responsible for the proceedings of the meeting in the absence of the member secretary/ if member secretary has conflict of interest for a study under review.

5.8 Secretariat

The Secretariat is composed of the Member Secretary and the administrative supporting staff which includes a full time peon, ethics analyst and lower division clerk. It is mandatory that the clerical assistant and peon should be a permanent employees to ensure

efficient record keeping and retrieval of documents. The supporting staff are appointed by the Director/Officer-in Charge of the Institute

The Secretariat shall have the following functions:

- Organizing an effective and efficient tracking procedure for each proposal received
- Preparation, maintenance and distribution of study files
- Allocation of project reviews to specific members to facilitate efficient dispensation of the projects.
- Organizing IEC meetings regularly
- Preparation and maintenance of meeting agenda and minutes
- Receive and check for the completeness of the documents for review by the EC.
- Co-ordinate with the investigators for the translation (English-Hindi-Marathi) of the PIS and ICD documents.
- Arranging Community Members' meeting after the Board meeting for finalization of the Participant Information Sheet and Informed Consent Form. (Assent information sheet and assent form wherever applicable) . This helps in making the documents lucid and in simple language, to make for easier decision making by the Committee and reduces considerable time of the committee.

Maintaining the IEC's documentation and Archival

- Communicating with the IEC members and investigator applicants
- Arrangement of training for personnel and IEC members
- Organizing the preparation, review, revision and distribution of SOPs (see SOP/01/V1.1)
- Work in unison with the EC members and the investigators to reduce the turn-around time of the study proposals sent to the EC for review.
- Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

5.9 Roles and Responsibilities of IEC members

- Regularly attend and actively participate in the EC meetings
- Review, discuss and consider research proposals submitted for evaluation. Reviewers for each proposal will review the study. Later, if any other issues the other IEC members can voice their comments/suggestions.
- The community members will assume the responsibility of finalizing the Participant Information Sheet and Informed consent documents which helps the scientist to make the documents lucid and in simple language, easily understandable by potential participants.
- 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 meetings. Declare any conflict of interest
- Participate in continuing education activities in biomedical ethics and biomedical research
- If deemed necessary, should suggest any changes that may be necessary to be included in the SOPs of the IEC.
- Conduct monitoring visits for any research proposal, if needed.

5.10 Quorum Requirements

- A minimum of five members or one third of the total members must be present at a meeting besides Member Secretary and Chairperson in order to issue a valid advice and/or decision, provided quorum is met.
- Professional qualifications of the quorum requirements should consist of:
 - ❖ One legal expert
 - ❖ One Clinician
 - ❖ One socio-behaviouralscientist/ one basic scientist depending on the projects to be discussed
 - ❖ at least one member who is independent of the institution/research site.
 - ❖ at least one member whose primary area of expertise is in a non-scientific area i.e. lay person or community member
- As per revised Schedule Y of Drugs & Cosmetics Act, 1940, amended in 2005, the ethics committee approving drug trials should have in the quorum at least one representative from the following groups:
 - ❖ One basic medical scientist (preferably one pharmacologist).
 - ❖ One clinician
 - ❖ One legal expert
 - ❖ One social scientist/ representative of non-governmental organisation/ philosopher/ ethicist/ theologian or a similar person
 - ❖ One lay person from the community.

5.11 Dissolving of the IEC

- At any point in time, should the Institute cease to exist, the IEC is automatically dissolved.
- The IEC may also be dissolved at any time by the Director/Officer-in-Charge of the National Institute for Research in Reproductive Health following written notification to each of the members

6. Glossary

NIRRH Ethics Committee for Clinical Studies 2.1 Constitution of an IEC	SOP Code: SOP/02/V1.2 Effective date : 01/09/2016 Page no. 11 of 11
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Confidentiality: Prevention of disclosure, to other than authorized individuals, of IEC/IRB's information and documents

IEC : Institutional Ethics Committee is an independent body (either a review board or committee) whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection.

Scientists : Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed

7. References

- World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICHGCP) 1996.
- Schedule Y 2005
- Forum for Ethical Review Committees in Asia and the Western Pacific SOPs 2006
- ICMR Ethics Guidelines 2006

8. ANNEX

ANNEX 1 Document History AF/EC/01/02/V1.2

ANNEX 1

AF/EC/01/02/V1.2

Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1	20 th March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	24 th September 2014	Multidisciplinary nature of affiliated members mentioned under point 5.2, page number 5 and 6 Point 5.1 point 3 deleted lines related to In-principle approval letter Full form of ICSCRT written on

NIRRH Ethics Committee for Clinical Studies 2.1 Constitution of an IEC	SOP Code: SOP/02/V1.2 Effective date : 01/09/2016 Page no. 12 of 11
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			page no.4
Dr. Ragini Kulkarni	Version 1.2	1 st September 2014	Point 5.3 Membership requirements tenure of the members is reduced from 5 years to 3 years
Dr. Ragini Kulkarni	Version 1.2	1st September 2014	Point 5.1