Standard Operating Procedures of Institutional Ethics Committee

ICMR – NIRRCH Ethics Committee for Human Studies

Title: Constitution of an IEC

SOP Code: 02/V1.5 Dated: 08th November 2024 Page Nos: 16-30

2.1. Purpose

The Institutional Ethics Committee (IEC) of the Institute 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 participants.

These standard operating procedures describe the Terms of Reference (TOR) which provide the framework for the constitution, responsibilities and activities of the ICMR-NIRRCH Ethics Committee for Human Studies.

IEC will have both scientists and non-scientists who the Director/Director-in-charge will appoint. Institutional members may preferably be at least half of the IEC strength while the rest will be non-institutional. To function as an independent committee in its reflection, advice, and decision, the Director /Director-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 /Director-in-charge.

2.2. Scope

The SOP applies to the functioning of all activities under the NIRRCH IEC. This includes the IEC's basic responsibilities, composition, appointment of members, and conduct of meetings.

2.3. 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.

2.4. Flow chart

Sr. No.	**Activity**	**Responsibility**
1	Ethical basis and mandate	IEC Members, Secretariat
2	Composition of the IEC	Director/Director-in-charge in consultation with the Chairperson of the IEC
3	Appointment of IEC members	Director/Director-in-charge of the Institute
4	Membership Requirements	IEC Members and Secretariat
5	Resignation, Disqualification, Replacement of Members	IEC Chairperson, Director/Director-in Charge
6	Independent Consultants	IEC Chairperson
7	Conditions of Appointment (TOR)	Director/Director-in-charge

8	Secretariat including supportive staff	Director/Officer-in-Charge in consultation with the IEC Member Secretary
9	Quorum Requirements	IEC Chairperson, Member Secretary and Secretariat

2.5. Detailed Instructions

2.5.1 Ethical Basis and Mandate

The IEC seeks to fulfill the requirements for Federal Wide assurance (FWA) for Indo-US collaboration research and is established and functions under national law and regulations. To date the ICMR-NIRRCH IEC is registered with the OHRP having the FWA with accession numbers IORG0005580 and FWA00013637 respectively.

a. Institutional Ethics Committee (IEC) will review and approve all types of research proposals involving human participants 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–NIRRCH.
b. It will ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.
c. 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.
d. IEC should take up those proposals after ensuring the scientific soundness and technical appropriateness of the proposed research through the appropriate Scientific Review Committee (SRC) or Scientific Advisory Committee (SAC) of the institute or Research Advisory Committee of Model Rural Health Research Unit (MRHRU) or Scientific/ Technical review committees of any Government organizations. The institutional Clinical, Basic, Socio-behavioral cum Operational and Implementation Research and Genetics Scientific Review Committees should have at least one non-institutional Ethics Committee member in their panel.
e. IEC will only review the research proposals (clinical, basic research, genetic, stem cell, socio-behavioral or operational studies), which are conducted at the Institute. If the Principal Investigator at the Institute is undertaking a clinical, socio-behavioral/ 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-ICMR-NIRRCH may offer its oversight on request and function as the EC for that hospital/ clinic as a Host institution and have MoU with it as the user institution (ICMR Guidelines). However, it is mandatory that the hospital/ clinic extends all the co-operation for monitoring the conduct of the study.
f. IEC is entrusted not only with the initial review of the proposed research proposals prior to initiation of the projects but also has 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 international guidelines wherever applicable.

g. 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.

2.5.2 Composition of the IEC

a. ECs should be multi-disciplinary and multi-sectoral.

b. There should be adequate representation of age and gender.

c. Preferably 50% of the members should be non-affiliated or from outside the institution.

d. The number of members in an EC should preferably be between 7 and 15 and a minimum of five members should be present to meet the quorum requirements.

e. The EC should have a balance between medical and non-medical members/ technical and non-technical members, depending upon the needs of the institution.

f. The Chairperson will not be affiliated to the Institute (ICMR-National Institute for Research in Reproductive & Child Health) to ensure the independence of the Committee. The Member Secretary and Joint Member Secretary will be from the same Institution and should conduct the business of the Committee.

g. Though the decision will be by consensus, voting may be used (when consensus is not reached or voting details are required by funding agencies) for which a quorum of at least 5 is mandatory. No meeting will be considered valid if a 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 the basic medical science area
4. Two or three clinicians from various Institutes/Hospitals/Medical Colleges including Gynecologist, clinical pharmacologists, or any other specialty
5. One legal expert
6. One - two social scientists/representatives of a non-governmental voluntary agency
7. Two community members (they could be clinic clients/ non-scientific members who can voice out the concerns of the potential participants)
8. Joint Member Secretary
9. Member Secretary

Alternate members:

a. The IEC should nominate an 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.
b. Considering the fact that there may be a conflict of interests when both the Member Secretary and Joint Member Secretary are the Principal Investigator and co-investigator or are absent from the meeting, the IEC may consider appointing an Alternate Member Secretary who should be the institutional IEC member.
c. The alternate member of the required specialty (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.
d. Alternate members are suggested by the IEC and appointed by the Director/ Director-in-charge.

2.5.3 Membership requirements

a. In the interest of the Institute's research program, the IEC members including the Chairperson, and Member Secretary will be selected by the Director/ Director-in-charge considering their expertise, research interests, and experience in ethics. Most of the time any existing senior member of the committee could be chosen to Chair the committee. In case of new affiliated members, the Director in consultation with the Chairperson appoints them after obtaining their concurrence.
b. 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.
c. Community members will be selected based on the basis that they are willing to publicize their full name, profession, and affiliation. Their Curriculum Vitae should be submitted to the EC office for records.
d. The Chairperson and the EC members should be informed of the potential new members by the Member Secretary in the meeting before obtaining their concurrence.
e. Members must disclose in writing any interest or involvement – financial, professional, or otherwise – in a project or proposal under consideration.
f. The IEC will decide the extent to which members who might have a conflict of interest and may participate before decision making process, Refer to SOP/03/V1.2 Confidentiality / Conflict of Interest Agreement.
g. Members will be required to sign a confidentiality agreement at the start of their term.
h. Members are appointed for a period of 3 years, & can continue for one additional term. They can be re-appointed after the gap of one term. It may be desirable to continue for a longer period the membership of some members who give valuable inputs. On completing the tenure of the Member Secretary, she/he will be appointed as a member for a period of 6 months to ensure a smooth transition and the necessary help to the Member Secretary as per the decision of the Director/ Director-in-charge. The

incumbent member secretary should be an affiliated member for a period not less than six months anytime before taking up the charge.

i. Their appointments may be renewed by the Director/ Director-in-charge of the National Institute for Research in Reproductive and Child Health for up to two consecutive terms or as required by the Director/ Director-in-charge.
j. The Ethics Committee will include some rotation in the 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.
k. For institutional Ethics Committee members, it is mandatory that the new members act as observers for at least three meetings prior to their induction into the EC.

2.5.4 Resignation, Disqualification, Replacement of Members

a. Members may resign their positions by submitting a letter of resignation to the Chairperson. The letter of resignation should be addressed to the Director and must be submitted to the Chairperson who then recommends it to the Director.

b. Members may also be disqualified from continuance in the following circumstances:
   i. Absence for three consecutive meetings. (Both physical presence and technical review)
   ii. The Chairperson can provide written opinion to the (other) members and there is 2/3rd majority.
   iii. Member does not comply to the responsibilities set for the members (intolerable behavior / non-punctual/ not thorough with the job assigned)
   iv. In case of Legal or Conflict of interest misconduct.

c. Members that have resigned or have been disqualified may be replaced by Director/ Director-in-charge.

2.5.5 Independent Consultants – Refer SOP/05/V1.2

a. The IEC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by Independent Consultants.
b. Independent Consultants are suggested by the Chairperson of the IEC in consultation with the Member Secretary and/or members and appointed by the Director/ Director-in-charge.
c. 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 experts for research on Stem Cells, Geneticists for genetic disorders, Psychiatrist for projects on vulnerable participants with impact on their mental health, Ayurveda experts for projects related to the evaluation of Ayurvedic formulations, etc. Similarly, based on the requirement of the 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.

d. Independent Consultants may attend the meeting via teleconference or video-conferencing or convey their comments by email/handwritten.

2.5.6 Conditions of Appointment

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

a. Willingness to abide by the requirements laid in the SOP
b. Willingness to publicize his/her full name, profession, and affiliation;
c. 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;
d. All IEC Members and Independent Consultants must sign Confidentiality / Conflict of Interest Agreements regarding meeting deliberations, applications, information on research participants, and related matters.

2.5.7 Officers and their responsibilities:

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

Sr. No	Members of EC	Definition/description
1.	Chairperson/ Vice Chairperson (optional) Non-affiliate Qualifications - A well-respected person from any clinical/ biomedical background with prior experience of having served/ serving in an EC and can dedicate time for EC activities.	i. Conduct EC meetings and be accountable for the independent and efficient functioning of the committee ii. Ensure active participation of all members (particularly non-affiliated, non-medical/non-technical) in all discussions and deliberations iii. Ratify minutes of the previous meetings iv. In case of anticipated absence of both Chairperson and Vice Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and

		will have all the powers of the Chairperson for that meeting. v. Seek COI declaration from members and ensure quorum and fair decision making. vi. Sign the minutes with the member secretary vii. Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
2.	Member Secretary/ Joint Member Secretary (in case of absence / Conflict of Interest of Member secretory) Affiliate Qualifications – a. Should be a staff member of the institution b. Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills c. Should be able to devote adequate time to this activity which should be protected by the institution	i. Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review ii. Schedule EC meetings, prepare the agenda and minutes iii. Organize EC documentation, communication and archiving iv. Ensure training of EC secretariat and EC members v. Ensure SOPs are updated as and when required vi. Ensure adherence of EC functioning to the SOPs vii. Prepare for and respond to audits and inspections viii. Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review. ix. Assess the need for expedited review/ exemption from review or full review. x. Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives. xi. Ensure quorum during the meeting and record discussions and decisions

3.	Basic Medical Scientist(s) Affiliate / non-affiliate Qualifications – a. Non-medical or medical person with qualifications in basic medical sciences b. In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist	i. Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report ii. For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
4.	Clinician(s) Affiliated/ non-affiliated Qualifications – a. Should be individual/s with recognized medical qualification, expertise and training	i. Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics ii. Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report) iii. Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation. iv. Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents
5.	Legal expert/s Affiliated/ non-affiliated Qualifications – a. Should have a basic degree in Law from a recognized university, with experience b. Desirable: Training in medical law	i. Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc. ii. Interpret and inform EC members about new regulations if any
6.	Social scientist/ philosopher/ ethicist/theologian	

	Affiliated/ non-affiliated Qualifications – a. Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities	i. Ethical review of the proposal, ICD along with the translations. ii. Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any iii. Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
7.	Lay person(s) Non-affiliated Qualifications a. Literate person from the public or community b. Has not pursued a medical science/health-related career in the last 5 years c. May be a representative of the community from which the participants are to be drawn d. Is aware of the local language, cultural and moral values of the community e. Desirable: involved in social and community welfare activities	i. Ethical review of the proposal, ICD along with translation(s). ii. Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks. iii. Serve as a patient/participant/ community representative and bring in ethical and societal concerns. iv. Assess on societal aspects if any.

2.5.8 Secretariat:

The Secretariat is composed of the Member Secretary and the administrative supporting staff which includes a full-time technical officer lab attendant or assistant. The administrative supporting staff must be permanent employees to ensure efficient record-keeping and document retrieval.

The supporting staff are officially appointed by the Director/Director-in-charge of the Institute for their specific role in the EC secretarial activities.

2.5.8.1 The Secretariat shall have the following functions:

1. Organizing an effective and efficient tracking procedure for each proposal received.
2. Preparation, maintenance, and distribution of study files
3. Receive and check for completeness of the documents for review by the EC.
4. Allocation of project reviews to specific members to facilitate efficient dispensation of the projects.
5. Organizing IEC meetings regularly
6. Preparation and maintenance of meeting agenda and minutes
7. Coordinate with the investigators for the translation (English-Hindi-Marathi) of the PIS and ICD documents.
8. Compile comments received from primary reviewers one day prior to EC meeting
9. Send timely reminders to investigators to ensure the completeness of documents on time.
10. Any other duty assigned by the Member Secretary
11. After approval by the Ethics Committee the Secretariat will submit the Annual report to the Member Secretary for submission to the Director/Director -in Charge.
12. Will also organize an audit of the ongoing studies.
13. Will undergo GCP training at timely intervals
14. Organize and update the project information on the digital database
15. Ensure old files closed for more than five years are converted to digital format and stored while the hard copies are discarded using appropriate procedures
16. Rejected proposals will also be converted to digital format for records and stored while the hard copies are discarded using appropriate procedures after a period of 5 years

2.5.8.2 Maintaining the IEC's documentation and Archival:

1. Communicating with the IEC members and investigator applicants.
2. Arrangement of training for personnel and IEC members
3. Organizing the preparation, review, revision, and distribution of SOPs (see SOP/01/V1.6)
4. Work in unison with the EC members and the investigators to reduce the turnaround time of the study proposals sent to the EC for review.

5. Follow-up on the status of projects and remind investigators for updating documents and submit progress reports in timely manner.
6. Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the Committee members.

2.5.9 Roles and Responsibilities of IEC members:

1. Regularly attend and actively participate in the EC meetings
2. Review, discuss and consider research proposals submitted for evaluation.
3. Reviewers for each new proposal will review the study and provide comments at least fifteen days prior to the meeting. Further, the reviewers will provide comments for all other projects including but not limited to review of revised proposals, amendments etc. within a period of a maximum of two weeks from the date of receipt of the projects. Later, if there are any other issues the other IEC members can voice their comments/suggestions.
4. In order to facilitate timely review of projects, preparation of minutes etc.,for new projects, at least one IEC-affiliated member, including the member secretary and joint member secretary, will review the submissions. The affiliated reviewing member will compile and finalize comments with the assistance of IEC secretariat staff, adhering to the established review timelines.
5. Discuss serious adverse event reports and recommend appropriate action(s) Review the progress reports and monitor ongoing studies as appropriate.
6. Evaluate final reports and outcomes
7. Maintain confidentiality of the documents and deliberations of IEC meetings. Declare any conflict of interest
8. Participate in continuing education activities in biomedical ethics and biomedical research
9. If deemed necessary, should suggest any changes that may be necessary to be included in the SOPs of the IEC.
10. Conduct monitoring visits for any research proposal
11. Inform the Ethics secretariat about changes in Affiliation/ Occupation or GCP/ Ethics Training

2.5.10 Quorum Requirements for EC meetings:

1. A minimum of five members to be present in the meeting room.
2. The quorum should include both medical/ non-medical and technical /non-technical members.
3. A minimum of one non-affiliated member should be part of the quorum.
4. Preferably the layperson should be part of the quorum.
5. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
6. No decision is valid without fulfillment of the quorum.

- As per New Drugs & Clinical Trials Rules 2019, the ethics committee approving drug trials should have in the quorum at least one representative from the following groups:
    1. One basic medical scientist (preferably one pharmacologist).
    2. One clinician
    3. One legal expert
    4. One social scientist/ representative of a non-governmental organization/ philosopher/ ethicist/ theologian or a similar person
    5. One layperson from the community.

2.5.11 Dissolving of the IEC:

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

2.6. ANNEX

ANNEX 1	Document History	AF/01/02/V1.5

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Document History

Author	Version	Date	Description of the Change
Dr. Ragini Kulkarni	Version 1	20th March 2013	First approved copy
Dr. Ragini Kulkarni	Version 1.1	24th September 2014	The multidisciplinary nature of affiliated members is mentioned under point 5.2, page number 5 and 6 Point 5.1 Point 3 deleted lines related to the In-principle approval letter Full form of ICSCRT written on page no.4
Dr. Ragini Kulkarni	Version 1.2	24th September 2014	Point 5.1 RAC for MRHRU & SAC of NIRRCH Field units added in bullet 4 Point 5.3 Membership requirements tenure of the members is reduced from 5 years to 3 years
Dr. Ragini Kulkarni	Version 1.3	7th November 2017	Point 5.2 ' Older and younger generations deleted Point 5.2 Number of members revised Point 5.9 deleted para related to community members (earlier bullet no.3) In bullet 3 replace 'monitor SAE reports' by 'discuss SAE reports'
Dr. Beena Joshi	Version 1.4	1st May 2019	Point 5.1 bullet 4 modified Point 5.5 point about independent consultant modified
Dr. Vikrant Bhor	Version 1.5	8th November 2024	All bullets are numbered. Modifications done in the following points: 2.5.1 ICSCR is deleted 2.5.2 Changes are made in membership requirements. Jt

			secretary is included in IEC 2.5.3 (b- ii & iii are reworded) 2.5.4 Independent consultant for subjects are specified 2.5.7 Modified as per ICMR Guidelines 2017 2.5.8.1 Details for rejected proposals is added as Point 16 2.5.9 point 3 is changed from 2 days to 15 days. Also, the roles and responsibilities of EC members are modified