STANDARD OPERATING PROCEDURE [SOP-3]

ETHICS COMMITTEE COMPOSITION

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provide the framework for constitution, selection, roles and responsibilities of the Institutional Ethics Committee (IEC) members, subject experts and procedures for maintaining confidentiality of all activities and documents. It would also include policy for continuous training of the IEC Members.

2. Scope

The SOP applies to all the members of the Institutional Ethics Committee and appointing authority for independent and competent functioning of IEC.

3. Multidisciplinary and multi-sectorial composition, adequate for its functioning

The IEC will be established by the **Head of the Institution (HOI) – Registrar; CHARUSAT**.TheChairpersonwillsuggestnamesofpotentialmembersbutthefinaldecision will

remain with the Head of the Institute.

- Its hierarchical position in the organization and authority under which it is established will be clearly indicated. The IEC will be multidisciplinary and multi-sectoral in composition.
- The IEC will be composed of at least 7members up to a maximum of 15(as per current CDSCO Requirements/ICMR Guidelines 2017).
- The members will include a combination of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view for participant's benefit.
    - Shall be from differing backgrounds to promote complete and adequate review of research.
    - Shall have the required qualifications as prescribed by applicable regulations and guidelines from time to time.
    - Shall have the expertise, time and commitment to perform all functions.
    - Shall not have any past record of scientific or ethical misconduct.
- The IEC will have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community /society.
- The committee will include at least one member whose primary area of expertise is in a non- scientific area, a clinician and at least two members who are independent of the institution/ research site.

4. Invitation to subject experts and representatives of vulnerable subjects

- The IEC will invite member(s) of specific patient groups or other special interest groups for an IEC Meeting (based on the requirement of research area, e.g. HIV patient groups in research related to HIV/ AIDS, Donor groups for stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have the right to vote.
- The IEC also invite subject experts for an IEC Meeting [when required based on the type of research protocol and non-availability of such subject expert in the committee

membership e.g. Pediatrician for researches involving children, Surgeon for researches involving a new interventional surgical device, Critical Care Specialist for trial involving participants in ICUs etc.] for eliciting their expert opinions on the specific research protocol. Such individuals will have to sign confidentiality agreement and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Guest/ Observer' and will not have the right to vote.

5. **Terms of reference defining membership, appointment, reconstitution and resignation**

- The Composition of the Committee will be as follows:
  - Chairperson[mandatorilyfromoutsidetheinstitutionasperregulatoryrequirementsas wellas for maintenance of its independence]
  - Deputy Chairperson or any member of IEC nominated by the chairperson [to officiate in absence of Chairperson/ when Chairperson himself/ herself is an investigator or has any other declared conflict of interest]
  - Member Secretary [from within the institution]
  - Deputy Member Secretary[optional]
  - Legal expert
  - Social scientist/ representative of non-governmental voluntary agency
  - Lay person from the community
  - 1 – 7 members from different departments/ specialties/ disciplines etc.
    - Basic medical scientists
    - Clinicians
    - Ethics Expert/ Ethicist/ Theologian [as invited member as and when need arises]
    - Subject Expert and representatives of different potential participant groups [as invited member as and when need arises]

Criteria for selection of IEC Members:

Sr. No.	Member [s]	Qualification
1	Chairperson/ Deputy Chairperson	• Non-affiliated; • Can be from scientific/ nonscientific discipline; Masters/ MD/ Retired from service. • A well-respected person from any background with prior experience of having served/ serving in an EC
2*	Basic Medical Scientist	• Affiliated/non-affiliated • Non-medical or medical person with qualifications in basic medical sciences; PG qualification; adequate experience in his/ her respective field; • In case of EC reviewing clinical trials with drugs, the basic medical scientist should preferably be a pharmacologist
3*	Clinician	• Affiliated/non-affiliated • Person whose training, background and occupation would incline them to view scientific activities with a behavioral or biomedical research discipline [PG Qualified like MD Medicine, Pediatrics/ MS Surgery, Orthopedics; not limited to]
4*	Layperson	• Affiliated/non-affiliated • Person having no specific qualification with respect to biomedical research, medicine or healthcare • Primary role will be to share insights about the communities

		from which participants are likely to be taken • Literate person from the public or community • May be a representative of the community from which the participants are to be drawn • Is aware of the local language, cultural and moral values of the community • Desirable: involved in social and community welfare activities
5*	Social Scientist	• Affiliated/non-affiliated • Someone expert in the study of human society and its personal relationship like anthropologist/ scientist/ penologist; • 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
6	Ethicist/ Ethics Expert	• Affiliated/non-affiliated • Person with background in law/ philosophy/bioethics
7	Theologian	• Affiliated/non-affiliated • Person involved in preaching of various religious activities
8*	Legal expert	• Affiliated/non-affiliated • Person with degree in law as per Bar Council of India; Preferably with training in medical law
9	Member Secretary	• Affiliated • Any senior faculty working in the institution; • Should have knowledge and experience in clinical research and ethics, be motivated and have good communication skills
10 **	Subject Expert	• Affiliated/non-affiliated • Person whose training, background and occupation would incline them to view scientific activities with a behavioral or biomedical research discipline respectively [Pediatrician in a research proposal involving children; anesthetist in a research proposal involving use of anesthetic drugs etc.]

*Mandatory;

**Invited member for a specific proposal without voting rights

Tenure of Membership

- The tenure of IEC will be for a continuous period of 3 years from the date of appointment.
- After 3 years, it may further be extended for not more than 3 years [50% reconstitution to be done every 3years]
- No member can hold the office for more than 6 consecutive years

Appointment of New Members

The IEC members will be appointed by the Head of Institute. They will be appointed under the following circumstances:

- When a new committee is being formed/reconstituted
- When regular member completes his/ her tenure
- If a regular member resigns before the tenure is completed
- If a regular member ceases to be a member for any reason including death or disqualification
- To fulfill the membership requirements as stated in this SOP

New members will be identified by the Chairperson according to the membership requirements and provided the potential member fulfils the conditions of appointment after discussion with the appointing authority. The names of new members to be appointed will be suggested by the IEC members and the Chairperson to the Head of Institute [HOI]. The final decision regarding appointment of members will be taken by the HOI.

Conditions to be fulfilled by a member after appointment

- Members to be appointed on the IEC will need to fulfill the following conditions:
  - Submit a current detailed CV with signature, date and photograph
  - Preferably, if available training certificates in Ethics and/ or GCP [if not available at time of induction as member in the IEC, the member must submit these within 6months of appointment].
- Members must be willing to:
  - publicize his/her full name, profession and affiliation
  - Sign the Confidentiality Agreement and Conflict of Interest Form and maintain

confidentiality regarding meetings, deliberations, research proposals, information on research participants and all related matters of IEC. ***[Annexure2]***

Resignation and Disqualification of Members

- Resignation:
  - An IEC member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson. The same will then be forwarded to the Head of Institute for a suitable replacement.
- Disqualification for conduct unsuitable of an IEC member:
  - A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been inappropriate of an IEC member.
  - The process will be initiated if IEC Chairperson or Member-secretary receives a communication in writing (provided by IEC member or a member of the public) alleging misconduct by a member.
  - The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC could be questioned, the Chairperson may suspend the membership of the concerned IEC member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.
  - The Chairperson will call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion in forthcoming meeting. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself /herself.

- The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting).
- The Chairperson will convey the disqualification to the concerned member through a written communication as well as to the Head of the Institute.

- Disqualification for not attending IEC meetings:
  - A member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IEC meetings without valid reason and prior intimation. The process conducted will be as follows:
    - The Member Secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC without valid reason and prior intimation to the IEC.
    - The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IEC meeting.
    - A written communication will be sent to the concerned IEC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned IEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson.
    - The matter will be discussed and reviewed at the IEC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.
    - The Chairperson or Member-Secretary will inform the IEC members about the cessation/ continuation of membership by a confidential written communication to other members of IEC or at the next meeting of IEC.

- For research involving human participants, eligibility criteria undertaken as Principal Investigator will be as follows:

  a. Registration certificate of concerned regulatory bodies wherever applicable.
  b. Copy of GCP Training Certificate
  c. Evidence of adequate Research experience (at least one or two research projects undertaken in past to qualify for Principal Investigator).

- Eligibility of different investigators will be decided by the Committee depending upon the type of research proposal submitted. With regards to research experience, a PI may be asked to submit evidence of 2 research projects undertaken in past to qualify forPI.

Types of projects reviewed by IEC

- TheIECwillreviewscientificandethicalaspectsofalltypesofresearchstudiesinvolvinghuman participants that fall under purview of biomedical and health research. In future it may be expand its review projects to sponsor by pharmaceutical companies, sponsored by Government of India/ NGOs, studies in collaborations with international organizations/universities.

  Clinical Trials], including Clinical Trial Registry.

Quorum Requirements

- The full committee meeting will be held as scheduled provided there is quorum.
- For the IEC meeting, a quorum will consist of at least 5 members for regulatory clinical trials with the following representation: one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary agency, one Lay person from the community, apart from Member Secretary and Chairperson as mandated by New Drugs and Clinical Trail Rules and ICMR 2017 Guidelines.
- Without satisfying this condition, any decision taken by the committee will remain null and void.
- In absence of the Chairperson, Deputy Chairperson nominated by the chairperson will chair the meeting.

6. Roles and responsibilities of members

Each IEC Member at the time of appointment will be provided with a copy of SOP, defining his/ her roles and responsibilities. These will be as follows:

1. **Chairperson**:
    - Appointment of members
    - Formation of committee for review/ new version of IECSOPs
    - Conduct of meeting & be accountable for independent and efficient functioning of the committee
    - Ensure active participation by all the members [particularly non-affiliated, non-medical/ non-technical in all discussions and deliberations
    - Appoint another member as Chairperson, in his/ her absence
    - Approval of minutes of meeting
    - Sign all documents on behalf of IEC
    - Ensure that any conflict of interest is well taken care of
    - Seek COI declaration from members and ensure quorum and fair decision making
    - Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.

2. **Deputy Chairperson**:
    - Manages role of Chairperson in his/her absence, as and deputed by Chairperson

3. **Member Secretary**:
    - Manage administrative work of IEC
    - Call for proposals; assess need for full committee/ expedite review
    - Review and check submitted proposals for completeness
    - Propose and circulate the agenda for meetings
    - Ensure number of clinical trials in a single meeting among the proposals received.
    - Review and reporting of Serious Adverse Event [s][SAE]
    - Review protocol deviations
    - Communication with various stake holders [researchers, regulatory body etc.]
    - Archiving of all IEC documents
    - Monitor conduct of trials and their progress
    - Prepare for audits
    - Prepare meetings and agenda for subcommittees
    - Preparing minutes of meeting
    - Review of Standard Operating Procedures[SOP]
    - Preparation of annual reports
    - Updating of new rules and regulations
    - Arrange for capacity building among IEC members
    - Arrange for subject experts, when required

4. **Lay Person**:

- Ethical review of the proposal, ICD along with translation(s).
- Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.
- Serve as a patient/participant/ community representative and bring in ethical and societal concerns.
- Assess on societal aspects, if any
- Review of compensation processes
- Review of post-trial benefits
- Review of non-trial related injuries
- Issues with vulnerability
- Monitoring of ongoing research projects

5. **Social Scientist**:

- Ethical review of the proposal, ICD along with the translations
- Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any
- Serve as a patient/participant/ societal/ community representative and bring in ethical and societal concerns.
- Review of compensation processes
- Analysis of risks and benefits, review of post-trial benefits
- Review of non-trial related injuries
- Issues with vulnerability
- Monitoring of ongoing research projects

6. **Lawyer**:

- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement(CTA),regulatoryapproval,insurancedocument,othersiteapprovals,researcher'sundertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations, if any
- Review of compensation processes
- Compliance with current National Laws
- Analysis of risks and benefits
- Review of post-trial benefits
- Issues with vulnerability
- Monitoring of ongoing research projects

7. **Basic Scientist**:

- 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
- For clinical trials, pharmacologist to review the drug safety and pharmaco-dynamics [Investigator brochure]
- Analysis of risks and benefits
- Review of post-trial benefits
- Review of non-trial related injuries
- Issues with vulnerability
- Monitoring of ongoing research projects

8. **Clinician**:

- Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)
- Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents
- Review of informed consent process
- Analysis of risks and benefits
- Review of post-trial benefits
- Review of non-trial related injuries
- Issues with vulnerability
- Monitoring of ongoing research projects

Office Assistant/ Co-ordinator

- Maintaining 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
- 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
- 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
- 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

7. Training of Ethics Committee members in applicable rules and regulations and Ethics Committee SOPs

- An individual selected as a new member of the IEC will be required to attend one meeting as an 'Observer' before being inducted as a member of the IEC [without voting rights]. This would not be applicable when a new IEC is formed.
- Member Secretary or an IEC member will provide introductory training in Research Ethics, GCP and SOPs to the new member, followed by an evaluation.
- A newly inducted member should submit certificate of training in 6 months by attending required training at workshops etc.
- All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/ or re-training program related to research ethics, as a delegate, faculty, facilitator, etc.
- The IEC itself may conduct workshops on ethics in clinical research, GCP, SOPs preparation or changing regulations or guidelines at least once a year to impart training and update the IEC Members and Institutional faculty members.
- These workshops shall also fulfill the need to fill gaps in current IEC members' knowledge as determined from regular self-assessments or issues raised during review of research protocols at full committee meeting or whenever new guidelines or regulations come into force.
- The IEC may nominate *and / or sponsor the expenses of (as applicable)* an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc. outside the institute on too.

8. Conflict of interest and confidentiality of members

It is the responsibility of each IEC member, reviewing research project or attending IEC meetings, to read, understand, accept and sign the agreement contained in the Confidentiality and Conflict of Interest Form.

- The Office Coordinator will provide Confidentiality and Conflict of Interest Form, get it signed at the time of acceptance of membership and will be filed with the IEC office.
- He/ she will obtain the signature of the IEC Chairperson on the Confidentiality form and provide IEC member a photocopy of the Confidentiality and Conflict of Interest Form for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement with their signature.
- The IEC Coordinator will keep the original copies of the signed Agreements in the IEC office in a separate file and if possible, photocopies of the agreement in the individual member's files.

- Every member will individually submit Conflict of Interest Declaration prior to review of a research project involving himself/ herself and will not be part of discussion and decision making process of the full committee. ***[Annexure2.1]***