MAGANBHAI ADENWALA MAHAGUJARAT UNIVERSITY

COLLEGE ROAD, NADIAD - 387001

Standard Operating Procedure (SOP)

For

Institutional Ethics Committee (IEC)

(VERSION 1, Effect from 1st FEBRUARY 2024)

This SOP has been prepared based on National Ethical Guidelines for Biomedical Research Involving Human Participants, ICMR 2017 the guidelines of ICMR for research involving human participants, Good Clinical Practice ICH-GCP and GCP-ASU guidelines and New Drugs and Clinical Trial rules, 2019.

Version: First version – 01

Preparing Date: 01/01/2024

Effective From: 01/02/2024

Effective Up to: 31/12/2027

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MEMBERSHIP REQUIREMENT & COMPOSITION OF IEC

The composition of an Institutional Ethics Committee (IEC) should be diverse, incorporating a multi-disciplinary and multi-sectoral approach. It should ensure adequate representation across different age groups and genders. Ideally, at least 50% of the members should be external or unaffiliated with the institution. The committee should consist of approximately 7 to 15 members, with a minimum of five members required to fulfill quorum requirements. Additionally, there should be an appropriate balance between medical and non-medical, as well as technical and non-technical members, based on the institution's specific needs.

The composition, affiliations, qualifications, and the defined roles and responsibilities of each member should be as per the following table which is available in National Ethical Guidelines for Biomedical Research Involving Human Participants, ICMR 2017.

S. No	**Members of IEC**	**Definition/Description**	**Responsibilities**
1	Chairperson/ Vice Chairperson (optional) (Non-affiliated)	A well-respected individual from any background with prior IEC experience.	- Conduct meetings, ensure efficiency, and approve minutes. - Encourage participation and handle COI issues. - Nominate Acting Chairperson if absent. - Address complaints and data requests.
2	Member Secretary/ Alternate Member Secretary (optional) (Affiliated)	A staff member with clinical research, ethics knowledge, and good communication skills.	- Organize reviews, meetings, and documentation. - Train IEC members, ensure SOP compliance. - Maintain audit readiness and record decisions.
3	Basic Medical Scientist(s) (Affiliated/ Non-affiliated)	Medical/non-medical expert in basic sciences, preferably a pharmacologist for drug trials.	- Review interventions, methodology, and statistics. - Assess SAEs, protocol deviations, and progress. - Evaluate drug safety and pharmacodynamics.

4	Clinician(s) (Affiliated/ Non-affiliated)	A qualified medical professional with expertise and training.	- Review research design, sample size, and site suitability. - Ensure medical care, monitor SAEs, and assess investigator competency.
5	Legal Expert(s) (Affiliated/ Non-affiliated)	Law graduate with experience, preferably trained in medical law.	- Review ICD, MoUs, regulatory approvals, and insurance. - Inform IEC members about new legal regulations.
6	Social Scientist/ Philosopher/ Ethicist/ Theologian (Affiliated/ Non-affiliated)	Expert in social sciences, philosophy, or religious studies, sensitive to ethical issues.	- Ethical review of proposals and ICDs. - Assess societal, cultural, and religious implications. - Represent community concerns.
7	Lay Person(s) (Non-affiliated)	A literate community representative not involved in health sciences in the last 5 years.	- Ethical review of proposals from participant's perspective. - Assess risks and benefits. - Represent societal interests.

Quorum Requirements for IEC Meetings –

1. A minimum of five members must be present in the meeting room for the IEC meeting to proceed.
2. The quorum should include a mix of medical and non-medical or technical and non-technical members to ensure a well-rounded review process.
3. At least one non-affiliated member must be present as part of the quorum to maintain external oversight.
4. Preferably, a layperson should be included in the quorum to bring in the perspective of the general public.
5. The quorum for reviewing regulatory clinical trials must comply with the current CDSCO requirements.
6. No decision taken during the meeting is considered valid unless the quorum requirements are met.

7. To maintain independence, the head of the institution should not be a part of the IEC but should act as an appellate authority responsible for appointing the committee and handling disputes.
8. The Chairperson and Member Secretary may hold dual roles within the ethics committee. Based on their qualifications, they may serve as clinicians, legal experts, basic scientists, social scientists, or laypersons while also fulfilling their respective leadership roles.
9. The IEC may include a set of alternate members who can be invited to meetings as decision-makers in case of the absence of regular members. These alternate members will have the same terms of reference as the regular IEC members.
10. The IEC may maintain a panel of subject experts, such as pediatricians for child-related research or cardiologists for heart disease studies. These experts may be invited to provide opinions on specific research proposals but will not have decision-making power or voting rights.
11. The IEC may invite subject experts as independent consultants or include representatives from specific patient groups (e.g., those with HIV, genetic disorders, or cancer) as members or special invitees to provide insights on specific research proposals. These individuals may be granted decision-making powers as appropriate.
12. As far as possible, research proposals should undergo prior scientific review by a separate scientific committee before being referred to the IEC. While IEC primarily evaluates ethical aspects, it may also raise scientific queries, as both good science and ethical standards are essential for research quality and participant protection.

Membership Requirements for IEC – Every member of the IEC must:

- Provide an updated CV with a signature.
- Provide a consent letter to be a part of IEC.
- Submit training certificates on human research participant protection and Good Clinical Practice (GCP) guidelines.
- If not trained, must undergo training and submit training certificates within six months of appointment.
- Be willing to undergo training or update their skills/knowledge during their tenure.
- Declare a Conflict of Interest (COI) in accordance with IEC policy, if applicable, at the appropriate time.

- Sign a confidentiality and conflict of interest agreement.

Tenure of Membership –

- The appointment of members will be for three (3) years, after which they may be either replaced or reappointed with a fresh appointment letter before their tenure ends.
- At the end of three years, the committee will be reconstituted, replacing one-third of the members following a defined procedure. The longest-standing members will be phased out, and new members will fill the vacant posts.
- A member can be replaced in the event of death, long-term non-availability, or any action deemed unfit as per guidelines.
- New members will be appointed as necessary.

Resignation of a Member –

- A member can resign by submitting a resignation letter addressed to the Chairman and delivered to the Member Secretary. The Secretary will inform the appointing authority for formal acceptance and initiate a replacement procedure.
- Members may step down with prior notice and proper information to the appointing authority.

Disqualification of a Member –

- A member may be disqualified due to misconduct or continuous absenteeism from meetings without prior intimation as per the laid-down procedure.

Maintenance of IEC Records –

- A list of IEC members, their appointment letters, bio-data, and consent forms will be maintained by the Member Secretary.
- This list and copies of working procedures will be available to investigators upon a written request to the Chairman.

Hierarchy –

- The Chairman is the head of the committee.
- The Member Secretary is the custodian of all committee documents and records.
- Other IEC members are regular committee members with equal ranking.

Responsibilities of IEC – MAM UNI

The primary responsibility of IEC- MAM UNI is to review and monitor research proposals involving human participants, ensuring their dignity, rights, safety, and well-being before approval. IEC- MAM UNI ensures adherence to ethical principles such as:

- Autonomy
- Beneficence
- Non-maleficence
- Respect for Free and Informed Consent
- Respect for Human Dignity
- Respect for Vulnerable Persons
- Respect for Privacy and Confidentiality
- Justice

IEC- MAM UNI follows Good Clinical Practice (GCP), ICMR guidelines, and the New Drugs and Clinical Trials Rules, 2024. Responsibilities include:

- Protecting the safety, dignity, rights, and well-being of research participants.
- Ensuring that only patients who provide informed consent participate in research.
- Aligning research with ethical values and local customs.
- Ensuring equitable subject recruitment.
- Ensuring research is supervised by qualified professionals.
- Verifying compliance with approved protocols.
- Supporting the research community in addressing local healthcare needs.

Responsibilities of Individual IEC Members

1. **Chairperson**
    - Conduct EC meetings and ensure active participation of all members.
    - Approve minutes of previous meetings.
    - Seek conflict of interest (COI) declarations and ensure fair decision-making.
    - Handle complaints and requests concerning EC data.
2. **Member Secretary**
    - Organize and manage proposal review procedures.
    - Schedule meetings, prepare agendas, and document discussions.
    - Maintain EC documentation and archiving.
    - Ensure training of EC members.

- Assess the need for expedited or full review.
- Ensure quorum and record discussions/decisions.

3. **Basic Scientist(s)**
    - Conduct scientific and ethical reviews, emphasizing methodology, risk-benefit analysis, and drug safety in clinical trials.
4. **Clinician(s)**
    - Review protocols, medical care provisions, and investigator qualifications.
    - Access protocol deviations and serious adverse events (SAEs).
5. **Legal Expert**
    - Evaluate ethical aspects, informed consent documents (ICD), clinical trial agreements (CTA), and compliance with regulations.
6. **Social Scientist/Philosopher/Ethicist/Theologian**
    - Assess social, cultural, and ethical implications of research.
    - Represent community perspectives in ethical discussions.
7. **Layperson**
    - Evaluate research risks and benefits from the participant's perspective.
    - Represent patient/community concerns.

Code of Conduct for IEC Members –

- Members must be committed to the ethical review process.
- They must maintain confidentiality and respect diverse opinions.
- Reviews must be unbiased and free from external influence.
- Attendance at all meetings is expected.
- Conflicts of interest must be declared.
- Members must uphold professionalism, integrity, and impartiality.
- Continuous learning is encouraged to maintain competence.

Independent Consultants/Invited Subject Experts

- IEC may appoint subject experts for independent opinions.
- Experts will not participate in decision-making.
- They must adhere to confidentiality agreements.
- Experts will provide written opinions within seven working days.
- Expenses may be reimbursed if necessary.

Fees Related to Ethics Committee Activities

- A processing fee of INR 20,000 or 5% of the sanctioned budget (whichever is higher) will be charged for research proposals out of MAM University as well as funded by pharmaceutical companies or multinational agencies.
- Fee waivers may be granted by authorities of MAM-University for in-house academic, non-funded, departmental studies or any of the project.

Expenditure from University Account for IEC – Funds will be used for:

- Honoraria for IEC members and invited experts.
- Training programs.
- Administrative and meeting-related expenses.

Payment of Honorarium

- External IEC members will receive INR 2,000 per meeting.
- Travel expenses may be reimbursed.
- Honorarium will not be paid to Internal members of the committee. However, member secretary will receive 10,000/- per annum for preparing the documentation and maintaining the records etc.

Administration and Management

- MAM University must provide an IEC office with sufficient infrastructure, staff, and secretarial support.
- The secretariat includes the Member Secretary, IEC members, and a coordinator.
- Functions include administrative support, documentation, tracking proposals, organizing meetings, and maintaining records.

Preparation of Annual Activity Report - The Member Secretary, in consultation with the Chairperson, will prepare an annual report including:

- A quantitative evaluation of IEC activities.
- A list of research proposals reviewed during the year.