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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INTRODUCTION

Maganbhai Adenwala Mahagujarat University (MAM University) has been established by the Mahagujarat Medical Society, Nadiad vide Gujarat State Private University Act 2009 on 1st day June 2022 with the objective of propagating knowledge of Indian System of Medicine, its development and analysis through education, research, extension services and effective dissemination as envisaged. This is envisaged to be achieved through the prestigious J. S. Ayurveda Mahavidyalaya, its constituent institute which has earned very good reputation in the field of Ayurveda since its inception 83 years ago. It offers Undergraduate (B.A.M.S.) & Postgraduate (Ayurved Vachaspati) degrees, Ph.D. (Ayurveda Varidhi), Certificates Courses and Value-Added Courses in Ayurveda. With a view to offer the student a platform and tools to develop requisite skills to become a good health service provider, MAM University has also been running the Dinsha Patel College of Nursing which offers PG – M.Sc., UG – B.Sc., Post Basic B.Sc. and Diploma in Nursing like GNM & ANM.

Ensuring high standards of Ayurveda and nursing research requires oversight and regulation by qualified professionals. To uphold these standards, our Institute has developed a set of guidelines known as the "Standard Operating Procedure" (SOP), which the researchers and Institutional Ethics Committee (IEC) members must strictly follow. The IEC-MAM University is responsible for ensuring that fundamental research ethics principles—autonomy, beneficence, non-maleficence, and justice are upheld in the planning, execution and reporting of the studies. As the IEC plays a crucial role in safeguarding participants' rights and well-being while guiding researchers in conducting ethical research, the SOP serves as an essential reference for any research-focused institution. This SOP helps members of IEC-MAM University adopt a structured approach when evaluating ethical aspects of research proposals.

OBJECTIVES

1. Support the efficient operation of the Institutional Ethics Committee for human research of the Maganbhai Adenwala Mahagujarat University (IEC-MAM University), Nadiad
2. To maintain the high-quality standard of ethical review process for health and biomedical research proposals
3. Ensure compliance with the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (ICMR, 2017), the Drugs and Cosmetics Act (1940), the Drugs and Cosmetics Rules (1945), the New Drugs and Clinical Trials Act and Rules (2019), and the Ayush GCP Guidelines

ABBREVIATIONS

ASU	Ayurveda Siddha Unani
CDSCO	Central Drugs Standard Control Organization
COI	Conflict of Interest
CTRI	Clinical Trial Registry of India
DCGI	Drugs Controller General of India
HMSC	Health Ministry's Screening Committee
ICD	Informed Consent Document
ICMR	Indian Council of Medical Research
IEC-MAM Uni	Institutional Ethics Committee – Maganbhai Adenwala Mahagujarat University
LAR	Legally Approved Representative
MoU	Memorandum of Understanding
PI	Principal Investigator
PIS	Patient Information Sheet
SAE	Serious Adverse Event
SOP	Standard Operating Procedures
ToR	Terms of Reference

1. MEMBERSHIP REQUIREMENT & COMPOSITION

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.

2. TERMS OF REFERENCE OF THE COMMITTEE

Procedures for nominating members:

1. The Head of the Institute (HOI) is responsible for selecting and nominating the Chairperson and Member Secretary of the Institutional Ethics Committee (IEC).
2. The HOI, in consultation with the Chairperson (CP), is responsible for selecting and nominating other IEC members who possess adequate academic and research experience to scrutinize proposals in terms of scientific, medical, and ethical concerns.
3. After selection, the HOI will send an official invitation to the nominated members of the IEC to join.
4. Willing members must confirm their acceptance by submitting the required documents along with their acceptance letter to the HOI.
5. The HOI will issue appointment orders to the eligible members.
6. Members must sign the declaration and confidentiality agreement.

Appointment of the IEC Members:

- The Head of the Institution is responsible for appointing all the Institutional Ethics Committee (IEC) members, including the Chairperson.
- Each appointed member must receive an official appointment letter, which should outline the Terms of Reference (TORs) and should include at minimum:
  - The roles and responsibilities of the member of the committee
  - The duration of the appointment
  - The conditions of the appointment
- The standard tenure for the IEC membership is 2–3 years, with the possibility of extension as per Standard Operating Procedures (SOPs). A certain percentage of IEC members should be periodically rotated to maintain continuity.
- The IEC members may receive an honorarium for attending meetings.
- The appointed members must be committed to fulfilling the responsibilities and requirements of the IEC.

Roles and Responsibilities of the IEC:

1. Protecting the Research Participants – Primary responsibility of the IEC is to safeguard the dignity, rights, safety, and well-being of research participants.

2. Ensuring Ethical Conduct of Research – The IEC must oversee and ensure that the research is conducted ethically.

3. Declaration of Conflicts of Interest – Any conflict of interest must be disclosed to the Chairperson at each meeting and recorded in the minutes.

4. Comprehensive Review of Research Proposals - The IEC should conduct initial and ongoing reviews of all scientific, ethical, medical, and social aspects of research proposals objectively, independently, and in a timely manner. Members should actively participate in meetings, discussions, and deliberations.

5. Adherence to Ethical and Scientific Standards -The IEC must ensure compliance with universal ethical principles and international scientific standards, while respecting local community values and customs.

6. Educational and Developmental Role - The IEC should support the education and development of the research community within the institution, including researchers, clinicians, and students, keeping local healthcare needs in mind.

7. Clear Responsibilities and SOP Compliance - The roles and responsibilities of IEC members should be clearly defined. Members should receive the Standard Operating Procedures (SOPs) at the time of their appointment.

8. Chairperson's Support Role - The Chairperson must assist the Member Secretary and Alternate Member Secretary (if applicable) in their duties. The Chairperson should be trained in documentation and filing procedures under a confidentiality agreement.

9. Privacy and Confidentiality - The IEC must ensure privacy protection for research participants. The confidentiality of IEC documents, meetings, and data must be maintained.

10. Monitoring and Risk Minimization - The IEC must review progress reports, final reports, and Adverse Events (AE) / Serious Adverse Events (SAE) to provide necessary recommendations regarding care of the participants and risk minimization. It should also suggest appropriate compensation for research-related injuries, where applicable. The IEC must conduct monitoring visits at study sites as needed.

11. Continuous Learning and Regulation Updates - The IEC should participate in continuing educational activities on research ethics and stay updated with relevant guidelines and regulations.

Avoiding Redundant Research - The IEC should ensure harmonization of similar research studies conducted by different investigators within the same institution. Duplicative ('Me too') research should be discouraged, and submission of the same research to multiple funding agencies should not be permitted.

3. TERMS & CONDITIONS FOR APPOINTMENT, TENURE AND THE QUORUM REQUIRED

1. Terms & Conditions for Appointment

A member should be willing to provide full name, profession, and affiliation. All the reimbursement for work and expenses, if any, related to the Committee will be made available to the appropriate authority upon request. A member must sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters. Additionally, all the IEC administrative staff must sign a similar confidentiality agreement. Members are expected to:

- Show full commitment and responsibility
- Respect divergent opinions
- Maintain confidentiality
- Review proposals without bias or external influence

New members will be appointed under the following circumstances:

- When a regular member completes the tenure
- If a regular member resigns or leaves before completing the tenure
- If the volume of proposals and frequency of reviews require additional members
- When appointing a new member, it is advisable to induct a replacement from the same category to maintain committee norms

2. Tenure of Membership –

- The tenure of IEC membership will be a continuous period of three (3) years.
- Extension of membership will be decided by the Head of the Institute (HOI).
- Membership extensions will be limited to one or two terms to prevent conflicts of interest and introduce fresh perspectives in the review process.

3. Quorum requirements for the meetings –

- A minimum of five members must be present in the meeting. The quorum should include both medical, non-medical or technical and non- technical members.
- Minimum one non-affiliated member should be part of the quorum.
- Preferably the layperson should be part of the quorum.
- The quorum for reviewing regulatory clinical trials should be in accordance with current New Drugs and Clinical Trials Rules 2019 requirements.
- No decision is valid without fulfilment of the quorum.

4. PROCEDURE OF RESIGNATION REPLACEMENT AND REMOVAL OF MEMBERS

Membership will be terminated under the following circumstances:

1. If a member resigns from the committee.
2. If a member is unable to fulfill their duties as a committee member.
3. In the event of a member's demise.
4. To ensure continuity, expertise retention, and the introduction of new perspectives, a rotation system will be implemented for membership.

Resignation Process:

- Any member wishing to resign before completing their tenure must submit a written resignation to the Chairperson.
- A one-month notice period is required before the resignation takes effect. However, the Chairperson reserves the right to either relieve the member immediately or after the notice period, based on the circumstances.

5. TRAINING OF THE EXISTING AND NEW MEMBERS

Objectives:

- To ensure that all members of the Institutional Ethics Committee (IEC) are adequately trained and familiarized with guidelines related to research and ethics
- To maintain the highest standards of ethical review and oversight

Scope:

This policy applies to all members of the IEC, including the Chairman, Member Secretary, and members.

Responsibilities:

- All IEC members must familiarize themselves with relevant guidelines, including:
  - GCP Guidelines for ASU medicine (2013)
  - ICMR National Ethical Guidelines (2017)
  - New Drugs and Clinical Trials Rules (2019)
- Member-secretary or an IEC member will provide an introductory training to the new member/s
- All IEC members must undergo a refresher course in Good Clinical Practice (GCP) in online or offline mode
- The appointing authority will provide support and encouragement for members to attend such training programs.
- The SOPs will be updated periodically based on changing requirements, and members will be informed of any changes.

Training mode

- The Chairman, Member Secretary, and members will be encouraged to attend training programs, conferences, workshops, seminars, and courses in research ethics to improve the quality of review and related activities.
- Training can be taken in both the online and offline mode from authentic and approved source/institutions.

Training Requirements:

- IEC members must complete the required training within 6 months of appointment and every 1 years thereafter.
- Training programs must be approved by the appointing authority.
- Members must provide proof of completion of training to the Member Secretary.

Record Keeping of trainings:

- The Member Secretary/secretariate will maintain records of members' training, including dates, topics, and proof of completion.
- Records will be updated regularly and made available to the appointing authority upon request.

6. POLICY FOR MONITORING CONFLICT OF INTEREST

COI occurs when secondary interests (financial, personal, academic, or political) override primary interests such as participant welfare or research integrity. It can arise at the institutional, researcher, or IEC level.

Purpose:

The purpose of this policy is to define conflict of interest (COI) in the context of human research ethics review and outline the procedures to identify, manage, and prevent COIs among IEC members, investigators, and institutional staff, thereby ensuring the independence, objectivity, and integrity of the IEC's decisions.

Scope:

This policy applies to:

- All IEC members (permanent and temporary)
- Investigators and co-investigators submitting protocols for review
- Any external experts/consultants involved in IEC review process

Definition of Conflict of Interest (CoI):

A CoI arises when the primary interests of an individual (i.e., protecting the rights and welfare of research participants) are unduly influenced by secondary interests such as financial gain, personal relationships, academic competition, or institutional affiliations.

Institution Policy / SOP to monitor or prevent CoI:

1. The IEC shall ensure that –
    - All members declare their potential conflicts prior to appointment and before each meeting.
    - Members with a conflict shall recuse themselves from the review and decision-making for the relevant proposal.
    - The IEC functions independently and avoids bias in decision-making.

2. Researchers Must:
    - Disclose any conflicts of interest in documents and submit to IEC before the meeting starts. Format of CoI declaration form is also prepared by IEC and will be available from member secretary whenever require.

- Avoid reviewing grants, publications, or proposals from close colleagues, relatives, or students.

3. IEC Must:
    - Evaluate all submitted studies.
    - Suggest appropriate actions if COI is detected.
    - IEC members must disclose their COI (Confidentiality Agreement & COI Form) and recuse themselves from reviewing affected proposals.
    - Follow SOPs for COI management.
4. Meeting Conduct & Decision-Making
    - Members must declare COI before discussions and leave the room during deliberations. This must be recorded in minutes.
    - Quorum is required for decision-making.
    - Investigators & study team members cannot participate in IEC decisions related to their project.

7. TYPES OF THE RESEARCH

1. Clinical Research:

- Clinical Trials (Drug & Vaccine Research)
- Diagnostic Trials
- Observational Studies
- Clinical Pharmacology Research
- Epidemiological Studies
- Operational Research

2. Laboratory Research:

- Pharmacognosy & Phytochemical Studies
- Toxicology Studies
- Microbiological Studies

3. Socio-Behavioral Research:

- Public Health & Community-Based Studies
- Psychosocial & Lifestyle Research

4. Observational Studies:

- Cohort Studies
- Case-Control Studies

5. Interventional Studies:

- Randomized Controlled Trials (RCTs)
- Behavioral Interventions

8. PROCEDURE FOR SUBMISSION OF THE PROPOSALS

1. For Fresh Research Proposals –

1. Circular from Member Secretary inviting research proposals for IEC clearance
2. PI must submit proposals within 3 weeks with all the required documents.
3. Submission: One hard copy and one soft copy must be submitted to the IEC Office on any working day.
4. Each proposal will receive a Registration/Identification Number upon the receipt.

2. For Ongoing Projects –

1. Circular from MS directing PIs to submit progress reports for IEC review
2. PI must submit research progress with supporting documents within 3 weeks
3. Submission: One hard copy and one soft copy must be submitted to the IEC Office on any working day.

9. INITIAL SCRUTINY OF THE SUBMITTED PROPOSALS –

i. **Verification of Documents:**

- The IEC Office will check if all the required documents, as per the submission checklist, are included.
- Missing or incomplete documents will lead to returning the proposal to the PI for corrections.

ii. **Registration & Identification:**

- Each complete proposal will be registered and assigned an identification number for tracking.

iii. **Preliminary Review:**

- Proposals will be screened for scientific validity, ethical concerns, and regulatory compliance before being forwarded for detailed review.
- Any proposal that does not meet the basic requirements will be sent back with comments for revision.

iv. **Assignment for Review:**

- Eligible proposals will be assigned to primary reviewers (scientific, ethical, and subject experts) for further evaluation.

10. PROCEDURE TO REVIEW THE SCRUTINIZED PROPOSALS IN GENERAL

i. **Assignment to Reviewers:**

- After initial scrutiny, the proposals are assigned to scientific, ethical, and subject matter experts for detailed evaluation.

ii. **Primary Review:**

- Reviewers assess the scientific validity, ethical considerations, risk-benefit ratio, methodology, and regulatory compliance of the proposal.

iii. **IEC Meeting & Discussion:**

- The proposal is presented at an IEC meeting, where members discuss concerns, suggest modifications, or request clarifications from the PI.

iv. **Decision Making:**

- The IEC may approve, request modifications, or reject the proposal based on the review findings.
- Modifications, if required, must be submitted by the PI within a specified timeframe for re-evaluation.

v. **Communication of Decision:**

- The final decision is communicated in writing to the PI along with any required changes or conditions for approval.

11. REVIEW OF THE PROTOCOL DEVIATION / VIOLATION / NON-COMPLIANCE

i. Objectives

- To guide the investigators on addressing Protocol Deviation, Violation, or Non-Compliance with the IEC-approved protocol
- To ensure strict adherence to national and international ethical and regulatory guidelines
- To provide appropriate justification for any deviations concerning ethical, scientific, statutory, or administrative aspects

ii. Scope

- Applicable to all human-related research protocols (including biological samples and secondary data) approved by the IEC

iii. Responsibility

- The IEC Office will receive reports of Protocol Deviation /Violation / Non-Compliance in the prescribed format.
- These cases will be included in the IEC meeting agenda for discussion and decision-making.
- IEC members will review reports and take appropriate actions accordingly.

iv. Protocol Deviation, Violation, and Non-Compliance – Definition

Any unauthorized modification in the protocol from the IEC-approved latest version like:

- Enrolling participants not meeting inclusion/exclusion criteria
- Administering an incorrect drug, dose, or regimen
- Using a methodology/procedure different from the approved protocol
- Modifying study documents (e.g., ICF, questionnaire, CRF) without IEC approval

v. Detection of Protocol Deviation/Non-Compliance/Violation

- Identified by IEC members or DSMB representatives monitoring research activities
- Detected during annual/periodic reviews, SAE reports, or site visits
- May also be reported by sponsors, funding agencies, CROs, or study sites

vi. Procedure for Reporting

1. **PI Submission:** The Principal Investigator (PI) reports the deviation/violation in the prescribed format within the stipulated time.
2. **Inclusion in the meeting Agenda:** The Member Secretary (MS) includes the matter in the full board IEC meeting for discussion.

3. **Review & Communication:** Meeting proceedings are recorded in the minutes and communicated to the PI.

vii. Procedure for Handling Suspected Non-Compliance

1. **Verification:** The Member Secretary, in consultation with the IEC Chairperson, verifies and authenticates the reported issue.
2. **Inclusion in the meeting Agenda:** The matter is included in the IEC full board meeting for further discussion.
3. **Discussion & Evidence Review:** IEC members analyze records, study data, site reports, and participant concerns. Investigators and other relevant personnel may be questioned.
4. **Classification of Non-Compliance:** Minor issue with no significant ethical risk or one which requires investigation and corrective action
5. **Action Based on Severity:** The IEC may issue warnings, instruct corrective measures, or terminate the study in severe cases. If necessary, the issue will be reported to higher authorities, regulatory bodies, or funding agencies for further action.

12. PROCEDURE TO REVIEW THE PROPOSALS INVOLVING VULNERABLE SUBJECTS

Vulnerable populations are individuals or groups who may have an increased likelihood of being wronged or of incurring additional harm in research due to diminished autonomy or social disadvantages. The Institutional Ethics Committee (IEC) of Maganbhai Adenwala Mahagujarat University is committed to ensuring additional safeguards to protect the rights, safety, and well-being of such participants.

i. Defining Vulnerable population & its Common Characteristics:

- Children and minors
- Pregnant women and fetuses
- Mentally or cognitively impaired individuals
- Elderly or terminally ill patients
- Prisoners or institutionalized individuals
- Economically or educationally disadvantaged individuals
- Refugees or displaced populations
- Gender or sexual minorities
- Individuals with serious health conditions
- Social, economic, or political disadvantage, making them susceptible to exploitation.
- Limited autonomy, either temporarily or permanently (e.g., unconscious individuals, differently abled persons).
- Compromised voluntariness due to situational factors.
- Influenced by expectations of benefits or fear of retaliation, affecting consent.

ii. Principles of Research Involving Vulnerable Populations

- They have equal rights to participate in research to ensure they benefit from scientific advancements.
- Research solely involving a vulnerable group must address their specific health needs.
- Participants should be empowered to make their own decisions regarding consent.
- When individuals lack the capacity to consent, a Legally Authorized Representative (LAR) must be involved.
- Privacy and confidentiality must be strictly protected to prevent further vulnerability.
- Additional safeguards must be in place to protect their dignity, rights, safety, and well-being.

Stakeholders	Obligations/Duties
Researchers	- Recognize vulnerability and implement additional safeguards. - Justify inclusion/exclusion of vulnerable groups. - Address conflicts of interest (COI). - Ensure a balanced benefit-risk ratio with well-defined SOPs. - Confirm competence for informed consent or obtain LAR consent when necessary. - Respect participant dissent and seek approval from relevant authorities. - Adhere to relevant guidelines and regulations.
Ethics Committees (ECs)	- Assess whether participants in a study are vulnerable. - Review justification for inclusion/exclusion of vulnerable populations. - Ensure COI does not increase harm or reduce benefits. - Evaluate risks/benefits and recommend risk minimization strategies. - Suggest additional safeguards, such as more frequent monitoring. - Full committee review required for vulnerable group research, with community representatives if possible. - Special care for research on mental illness/cognitive impairment. - Have SOPs for handling proposals involving vulnerable groups.
Sponsors	- Justify inclusion of vulnerable populations in research. - Provide for monitoring, quality assurance (QA), and quality control (QC). - Ensure participant and researcher protection, especially for sensitive research topics.

iii. Submission requirements for vulnerable population

Investigators must submit additional documentation, including -

- Justification for inclusion of vulnerable groups.
- Specific risk minimization strategies.
- Details of the consent process (including use of legally authorized representatives or assent forms for children).
- Procedures for enhanced monitoring of participant safety.

- Information on special protections or benefits provided to participants.

iv. Review procedure:

- All protocols involving vulnerable populations shall undergo full board review.
- The IEC shall ensure that the proposal includes sufficient justification for including vulnerable participants.
- A subject expert or community representative with experience in the specific vulnerable group should be involved in the review process.
- The risk–benefit ratio must be critically assessed to ensure that potential risks are minimized.

v. Informed consent, assent, monitoring and oversight:

- Informed consent must be obtained from participants or their legally authorized representatives (LARs).
- For children (ages 7–18), assent must be obtained in addition to parental or guardian consent.
- The consent process must be tailored to the participant's level of comprehension and should be conducted in a language they understand.
- Extra care should be taken to avoid coercion or undue influence.
- Approved studies involving vulnerable populations will be subject to more frequent monitoring (e.g., quarterly progress reports).
- The IEC may conduct site visits to ensure adherence to ethical standards.
- Any adverse events or protocol deviations must be reported immediately and reviewed with priority.

vi. Others:

- All other principles i.e. confidentiality and privacy, compensation and care record keeping and reporting are same as mentioned in general SOP.

13. PROCEDURE FOR DECISION MAKING

i. **Quorum Requirements:** A decision will be made only when at least 50% of the original strength of the IEC is present, including the following members:

1. Basic medical scientist (preferably a pharmacologist)
2. Clinician
3. Lawyer
4. NGO representative
5. Lay person

ii. Steps in the Decision-Making Process:

1. **Declaration of Conflict of Interest:**
   - Any member with a conflict of interest must inform the Chairperson before the meeting
   - The conflict must be recorded in the meeting minutes by the Member Secretary (MS)
   - Members with a conflict of interest must not participate in decision-making
2. **Discussion of Proposals:**
   - Adequate time must be given for discussion of each research proposal.
   - The Principal Investigator (PI) must not be present during the final decision-making process.
   - Only members who have participated in the discussion during the PI's presentation can contribute to the decision-making.
3. **Final Decision Process:**
   - Consensus among the members is preferred.
   - If consensus is not possible, a decision may be reached through voting.
   - The final decision may be:
     - Approval
     - Approval with conditions and recommendations
     - Request for modifications and re-submission
     - Rejection

Course of Proposal When Decision is "Revision" –

1. Revision with Major Modifications

↓

2. Present Before Full Committee for Reconsideration

↓

3. If Further Revisions Are Required,

Revision with Major Modifications again and

Present Before Full Committee for Reconsideration again

↓

4. If the Decision is Rejection of the Proposal,

Adequate and appropriate reasons should be provided for the rejection

14. PROCEDURE FOR COMMUNICATING COMMENTS OF THE IEC TO THE PRINCIPAL INVESTIGATOR

Responsibility: Member Secretary (MS)

Procedure:

1. **Regular Review**
    - The progress of all approved studies will be reviewed by the IEC from the time of approval until study completion.
2. **Follow-up Intervals**
    - Periodic reviews will be conducted at least once a year.
    - Depending on the study's nature, the IEC may require more frequent reviews.
3. **Review Process**
    - Follow-up reviews will follow the same requirements and procedures as the initial and main reviews.
4. **Communication of IEC Comments**
    - The Principal Investigator (PI) will receive the IEC's comments in writing within 10 days of the meeting.
5. **Contents of Communication**
    - Name and address of the IEC
    - Date and place of the IEC decision
    - Name and designation of the applicant
    - Title of the reviewed research proposal
    - Registration number of the project
    - Comments on the study progress, documentation adequacy, and data maintenance
    - Signatures of the Chairperson and Member Secretary with date

15. PROCEDURE FOR COMMUNICATING THE DECISION OF IEC TO THE PRINCIPAL INVESTIGATOR

Responsibility:

- Member Secretary (MS) is responsible for implementing this SOP.

Procedure:

1. **Communication of Decision**
    - IEC decisions will be communicated to the applicant in writing within 10 days of the meeting in the specified format.
2. **Approval Certificate**
    - If approved, an approval certificate signed by the Chairperson (CP) and MS will be issued.
    - The applicant can collect it from the MS office within one week of intimation after signing in the prescribed form.
3. **Approval Validity**
    - Approvals are valid for three years or the project duration, whichever is less.
    - The PI must seek re-approval after three years if necessary.
4. **Contents of Decision Communication**
    - Name and address of IEC
    - Date and place of decision
    - Name and designation of the applicant
    - Title of the reviewed research proposal
    - Clear identification of protocol number
    - Clear statement of the decision
    - Any advice by IEC to the applicant
    - In case of conditional approval, suggested changes
    - In case of rejection, reasons for rejection
    - Signature of the MS with date

16. PROCEDURE FOR CONDUCTING IEC MEETING

Procedure:

1. **Scheduling IEC Meetings**
    - The MS, in consultation with the CP, will convene IEC meetings every 3 or 4 months.
    - If the number of proposals is high, additional meetings may be arranged.
2. **Proposal Submission**
    - All proposals must reach the MS at least 3 weeks before the scheduled meeting.
3. **Eligibility Check**
    - OS (Office Staff) and MS will check the eligibility of received proposals.
    - Only proposals that clear the IRC (Institutional Review Committee) review will be considered for IEC review.
4. **Proposal Review Process**
    - Eligible proposals will be sent to IEC members at least 10 days before the meeting for scrutiny.
    - The PI, along with the Guide/Co-Guide, must present the proposal during the IEC meeting.
    - External subject experts may be invited for opinion but cannot participate in the decision-making process.
5. **Meeting Documentation & Frequency**
    - The MS must meticulously record the meeting deliberations and decisions in the Minutes of Meeting (MoM).
    - The MoM must be signed by the CP and MS before circulation to IEC members.
    - IEC meetings should be held regularly on specified dates.
    - IEC meetings should be tentatively conducted every three months but they may be held more frequently, say monthly, if necessary.
6. **Progress & Final Report Submission**
    - The PI must submit an annual progress report in the prescribed format to the IEC.
    - A final report of the completed study must also be submitted to the IEC by the PI.

17. DECISION MAKING PROCESS ON PRESENTED PROPOSALS

Responsibility: All members of the IEC are responsible for this process.

Quorum Requirements: At least 50% of the total IEC strength must be present.

- The quorum must include:
    - One basic medical scientist
    - One clinician
    - One legal expert
    - One NGO representative
    - One lay person
    - At least one external member

Decision-Making Procedure:

1. **Proposal Eligibility:**
    - Only applications that pass the initial scrutiny and are complete in all aspects will be considered.
2. **Discussion Process:**
    - Adequate time must be given for each proposal to ensure a thorough review.
    - The PI or anyone from the project team must not be present during the decision-making.
    - Only IEC members who participated in the review and discussion can take part in decision-making.
3. **Final Decision:**
    - Decisions should be based on consensus among all members.
    - If consensus is not reached, the decision should be made through voting.

18. RECORD KEEPING AND ARCHIVING

Responsibility: The IEC office is responsible for maintaining, securing, and archiving all the documents.

Archiving and Document Security Procedures:

1. **Document Filing & Storage:**
   - All IEC documents and communications will be dated, filed, and archived in a secure location.
   - Documents related to research proposals will be archived for at least 3 years after the study's completion/termination.
2. **Access Control:**
   - Only individuals authorized by the CP of IEC will have access to IEC documents.
3. **Document Handling by IEC Members:**
   - No document (except the agenda) will be retained by any IEC member.
   - After each meeting, IEC members must return the CDs containing research proposals and related documents.
   - The IEC office will archive one copy and destroy other copies after one year.
4. **Types of Documents to be Archived:**
   - Constitution & Composition of IEC, MAM University, Nadiad
   - Curriculum Vitae (CV) of all the IEC members, including records of their training in human ethics (if applicable)
   - Standard Operating Procedures (SOPs) of IEC, MAM University, Nadiad
   - Annual Reports
   - Records of IEC income and expenses, including allowances/reimbursements for the secretariat and IEC members
   - Published guidelines for proposal submissions established by the IEC
   - Copies of all study protocols with enclosed documents, progress reports, and Serious Adverse Event (SAE) reports
   - Agendas and Minutes of the IEC meetings, duly signed by the CP/MS
   - Copies of all relevant national & international ethics guidelines and laws, along with amendments
   - Correspondence records between IEC members, PIs, and regulatory bodies
   - Records of notifications for premature study termination, including reasons
   - Final reports of approved projects, including microfilms, CDs, and video recordings

19. FORMAT FOR INVITING PERSONS TO BE MEMBER OF IEC

No. MAM UNI/DO/IEC/20 Date:

From,
The Vice Chancellor,
Maganbhai Adenwala Mahagujarat University,
Nadiad
To,

_____

_____

Sub: Consent to be Chairperson/IEC Member – Reg.

Dear Sir/Madam,

We are in the process of constituting/revamping the Institutional Ethics Committee (IEC) for MAM University, Nadiad.

Considering your knowledge about the ethical matters in relation to research, I hereby invite to accept the post of Chairperson/Member of our IEC.

Kindly send your acceptance in the prescribed format. An official appointment letter will be issued upon receipt of your acceptance letter.

Looking forward to your positive response

Yours sincerely,

20. FORMAT OF LETTER FOR WILLINGNESS TO BE CP/MEMBER

No. MAM UNI/DO/IEC/20 Date:

From,
The Vice Chancellor,
Maganbhai Adenwala Mahagujarat University,
Nadiad

To,

_____

_____

Sub: Acceptance of Appointment as Chairperson/Member of IEC, MAM University, Nadiad

Dear Sir/Madam,

This is in response to your letter [Reference No.] dated [Insert Date]. I hereby affirm my willingness to serve as the Chairperson/Member of the Institutional Ethics Committee (IEC), MAM University, Nadiad.

I acknowledge the responsibilities entrusted to me and assure you of my commitment to upholding the high ethical standards of IEC, MAM University, Nadiad.

Please find my updated Curriculum Vitae (CV) attached along with this letter for your reference.

Sincerely,

21. FORMAT OF CV OF THE IEC MEMBERS

Name: _____ **Age:** _____

Sex: _____

Designation: _____

Institution: _____

Mobile No.: _____

E-mail: _____

Educational Qualifications:

No.	Degree/Diploma/Certificate	Year	Institute/University

Experience in other academic committees:

No.	Post/Position held	Year	Institute/University

Place: Signature

Date:

22. FORMAT FOR UNDERTAKING OF SECRECY BY THE IEC MEMBERS

Name:

Designation:

Institute:

As a member of the IEC, I may receive important documents that contain confidential information about the patient, drug, procedure or equipment. I will not disclose this information to any person who is not involved in the IEC. I also promise that the documents related to the research will be returned to the MS after the IEC meeting.

Place:

Date: Signature

23. FORMAT OF OFFICE ORDER FOR CIRCULATION REGARDING THE INFORMATION OF COMMITTEE MEMBERS

The following dignitaries are appointed as members of the Institutional Ethics Committee (IEC), MAM University, Nadiad. The tenure of this committee is for **three years** from the date of the appointment.

Committee Members:

1. Chairperson
2. Co-Chairperson
3. Member Secretary
4. Basic Medical Scientist
5. Basic Medical Scientist
6. Basic Medical Scientist
7. Clinician
8. Clinician
9. Clinician
10. Ethicist
11. Social Scientist
12. NGO Representative
13. Legal Expert
14. Layperson

Date

By order,
Registrar
MAM University, Nadiad

24. FORMAT OF APPROVAL CERTIFICATE

MAGANBHAI ADENWALA MAHAGUJARAT UNIVERSITY, NADIAD

Institutional Ethics Committee (IEC)

Ethics Clearance Certificate

Approval No : MAM Uni/IECHR/2025/

To,

_____
_____
_____

Subject- Approval of the Institutional Ethics Committee for research project.

Dear Investigator(s),

Ethics Committee received your corrected application entitled "_____
_____
_____."

Since you have made changes according to the suggestions of the committee **OR** your proposal is found suitable and require no changes to made, your proposal is approved. You will have to follow the following instructions –

- Maintain confidentiality of the study participants and data.
- Submit progress report periodically

Inform immediately to Secretary and /or Chairman of the committee in case of serious adverse effects.

Member Secretary	Chairperson
IEC, MAM University, Nadiad	IEC, MAM University, Nadiad

25. CONSENT FORM PART 1 (PATIENT'S INFORMATION SHEET)

1. Title of the Study:

2. Invitation to Participate in the Study:

We welcome you to participate in this study. Your participation is entirely voluntary, and you have the right to decide whether to take part. This document provides details about the study, including potential benefits, risks, and procedures involved. You are encouraged to take your time, ask questions, and discuss this with your family or doctor before deciding.

3. Purpose of the Study

Explain the aim of the study in simple terms.

4. Why Have I Been Chosen?

State the criteria for participant selection.

5. Do I Have to Take Part?

Participation is completely voluntary. If you decide to join, you will receive a copy of this information sheet and will be required to sign a consent form. Even after agreeing, you can withdraw from the study at any time without giving a reason, and this will not affect your medical care.

6. What Will Happen If I Take Part?

Describe study procedures, such as physical exams, questionnaires, treatments, and follow-ups. Mention the frequency and duration of visits.

7. What Do I Have to Do?

Specify any lifestyle modifications, medication changes, or other responsibilities of the participants.

8. What Is the Drug or Procedure Being Tested?

Provide full details about the drug (type, dosage, route of administration, side effects) or procedure (invasive/non-invasive, risks, safety measures).

9. What Are the Alternatives to the Diagnosis or Treatment?

List alternative options available for diagnosis or treatment so that the participants can make an informed decision.

10. What Are the Side Effects of Participating in the Study?

List possible side effects in simple terms and provide contact details in case of unexpected symptoms.

11. What Are the Possible Disadvantages or Risks?

If pregnant or planning pregnancy, participation is not advised. Women of reproductive age may need pregnancy screening and contraception. Men should be informed if the study may affect sperm or reproductive health.

12. What Are the Possible Benefits?

There may be no direct benefit to you, but the study could help future patients.

13. What If New Information Becomes Available?

If new findings emerge during the study, we will inform you, and you can decide whether to continue participation. If you withdraw, we will ensure continuity of your medical care.

14. What Happens When the Research Stops?

If the study is discontinued, you will be informed about the reason and available alternatives.

15. What If Something Goes Wrong?

If you have complaints or experience any serious issues, the study may be stopped, and appropriate action will be taken to address your concerns.

16. Will My Participation Be Kept Confidential?

Your personal information and medical records will be kept confidential. While study data may be shared for scientific purposes, your identity will not be disclosed.

17. What Will Happen to the Results of the Research?

The findings may be published in scientific journals and presented at conferences.

18. Who Is Organizing and Funding the Research?

State whether the study is funded by the government, NGOs, pharmaceutical companies, or institutions, and specify what the funds will be used for.

19. Who Has Reviewed the Study?

The study has been reviewed and approved by the Institutional Ethics Committee (IEC), MAM, Nadiad.

20. Contact for Further Information:

For any questions, please contact:

Principal Investigator (PI): _____

Cell Number: _____

Email: _____

Designation: _____

Institute: _____

Place: _____

Signature of PI

26. CONSENT FORM PART 2

Title of the Project:

……

……

Research Project Number: ……

Participant Identification Number: .....

Name of the Principal Investigator: .....

Mobile Number: .....

I have read the Patient/Participant Information Sheet, or its contents have been explained to me in my own language. I fully understand the details provided in the sheet. Any doubts I had were clarified by the study team.

The study team has explained to me the purpose, methods/procedures, risks involved, and duration of the study. I am aware that my participation in this research is entirely voluntary, and I have the right to withdraw at any time, even in the middle of the study, without providing any reason. I understand that withdrawing from the study will not affect my medical care at the Institute.

I also understand that information collected about me from my participation in this research, as well as sections of my medical records, may be reviewed by responsible individuals from MAM University, Nadiad. I give permission for these individuals to access my records for research purposes.

I agree to participate in the above study.

Signature/Left Thumb Impression of the Participant

Place:

Date:

27. COVERING LETTER

From,

Name of the Principal Investigator:

Designation:

Department:

Institute:

To,

The Chairperson/Member Secretary

Institutional Ethics Committee (IEC)

MAM University, Nadiad

Subject: Submission of Research Proposal for Approval

Respected Sir/Madam,

I hereby submit the research proposal titled "……." for review and approval. I kindly request permission to conduct the above-mentioned research as per the institutional and ethical guidelines.

I would be grateful for your consideration and approval of my proposal.

Place:

Date: / /

Yours sincerely,

Name of the Principal Investigator

Designation

Department

Institute

28. CHECKLIST OF ENCLOSURES FOR SUBMISSION TO THE IEC

I am submitting the following documents for review and approval:

1. Proposed Research Protocol
2. Informed Consent Document (ICD):
    - Part 1: Participant Information Sheet (PIS) – in English, Hindi & Gujarati
    - Part 2: Informed Consent Form (ICF) – in English, Hindi & Gujarati
3. Permission Letter obtained from the Executive Director / HOD / Concerned HOD (if the study is interdepartmental) – Photocopies only
4. Certificate of Approval from the Institutional Research Committee (IRC) (if applicable) – Photocopies only
5. Case Record Form (CRF) / Questionnaire as applicable to the research proposal
6. Single CD containing scanned soft copies of all the above documents in PDF format

Note:

- The Consent Form (Part 1 & 2) must be translated from English into Hindi & Gujarati accurately.

29. FORMAT FOR SUBMISSION OF THE RESEARCH PROPOSAL

1. Principal Investigator (PI)

- Name: _____
- Designation: _____
- Department: _____
- Institution Details: _____
- Email ID: _____
- Contact No.: _____

2. Co-Investigator (If applicable)

- Name: _____
- Designation: _____
- Department: _____
- Institution Details: _____
- Email ID: _____
- Contact No.: _____

3. Additional Co-Investigator (If more than one)

- Name: _____
- Designation: _____
- Department: _____
- Institution Details: _____
- Email ID: _____
- Contact No.: _____

4. Updated Curriculum Vitae (CV) of Principal Investigator

Attach the latest CV of the Principal Investigator

5. Updated Curriculum Vitae (CV) of Co-Investigator(s)

Attach the latest CV(s) of the Co-Investigator(s)

30. FORMAT OF RESEARCH PROTOCOL

1. Title of the Study (Maximum 20 words):

…….

……

……..

2. Background of the Study (Maximum 300-350 words):

……

……

3. Scientific Justification of the Study:

……

……

4. Aims and Objectives:

- Aim: (Overall goal of the study)
- Objectives: (Specific measurable objectives)

5. Review of Literature:

- Provide a summary of the existing studies relevant to the research.

6. Work Already Done –

- If any pilot studies or others, specify: (Include previous research or preliminary studies, if applicable

7. Materials and Methods:

a. Study Design:

- Describe the type of study, e.g., observational, interventional, randomized control trial, etc.

b. Study Setting:

- Exact location where the study will be conducted.

c. Approximate Total Duration of the Study:

- Provide estimated time frame.

d. Number of Groups to Be Studied:

- Specify how many groups will be compared.

e. Detailed Description of the Groups:

- Explain study groups and control groups, if any.

f. Sample Size of Each Group:

- Number of participants per group

g. Total Sample Size of the Study:

- Total number of participants

h. Scientific Basis for deciding the Sample Size Used in the Study:

- Justify the sample size calculation

i. Sampling Technique Used in the Study:

- e.g. simple random sampling, stratified sampling, etc.

j. Inclusion Criteria:

- Specify participant eligibility criteria

k. Exclusion Criteria:

- Specify criteria for excluding participants

l. Whether Placebo Used in Study (Yes/No):

- Provide details if applicable.

m. Whether Drugs/Medical Devices Used in the Study (Yes/No):

- Provide details, if applicable

n. If Drugs/Medical Devices Used:

i. Whether the Drug/Medical Device is for a Newer Indication? (Yes/No)

ii. Whether the Drug/Medical Device is Used for the First Time in Humans? (Yes/No)

iii. If Used for Newer Indication/First Time in Humans, Has Permission Been obtained from DCGI? (Yes/No)

iv. Formulation of the Drug Used:

v. Name of the Drug/Medical Device (Non-Proprietary Name, Brand Name, Company/Manufacturer Details):

vi. Dose of the Drug Used:

vii. Frequency of Administration:

viii. Route of Administration:

ix. Duration of Use:

x. Steps Taken to Prevent Adverse Drug Reactions (ADRs):

xi. Mode of Management in Case of Severe ADRs:

xii. Agreement for Compensation in Case of Drug-Related Injury:

xiii. Any Other Relevant Details:

o. If Research Proposal is a Clinical Trial:

i. Registration with the Clinical Trial Registry of India (CTRI) [Provide Details]:

ii. Clinical Trial Design (e.g., Open-Label, Parallel, Factorial, etc.):

iii. Clinical Trial Done at (Single Site/Multicentric):

iv. Allocation Ratio of Different Groups:

v. Randomization (Yes/No):

vi. Type of Randomization:

vii. Method Used to Generate Random Sequence Numbers:

viii. Allocation Concealment Mechanism:

ix. Type of Blinding Used (If any) [Provide Details]:

p. Parameters to Be Studied:

- Include quantitative data with units of measurement

q. Method(s)/Technique(s)/Instrument(s)/Reagent(s)/Kit(s) Used to Measure Quantitative Parameters:

Include Manufacturer Details:

r. Procedure in Detail (Explain with Flowchart if Possible):

Step-by-step description of the study process

s. Statistical Methods of Analysis:

i. Significance Level Decided Before Starting Study:

ii. Statistical Tests to Be Used for Data Analysis:

iii. Software(s) to Be Used for Statistical Analysis:

8. Hypothesis (If any):

Provide a clear statement of the hypothesis being tested

9. References (Minimum 10 References in Vancouver Format Only):

Provide references following the Vancouver citation style

10. Additional Information:

A. Whether the Study is Intradepartmental or Interdepartmental?

(Specify)

B. If Interdepartmental, Whether Consent Obtained from the Concerned Departments?

(Yes/No)

C. If Interdepartmental, Whether the Permission Letter from the Concerned HOD is Enclosed? (Yes/No)

D. Any Extra Materials/Finance Required/Obtained to Carry Out the Study?

(Provide details, if applicable)

E. If Yes, Source of Finance:

(Specify whether funding is from government agencies, institutions, self-funding, or other sources)

Instructions for Submission:

- Submit 10 hard copies along with a soft copy (PDF format) on a CD.
- Ensure that the Informed Consent Documents (ICD) are translated from English into Hindi / Gujarati accurately.
- Attach necessary approvals (HOD permission, IRC approval, etc.).

31. DECLARATION BY THE INVESTIGATOR(S)

I, Name of the Principal Investigator……, hereby declare and certify that:

A. The research proposal submitted herein is not a duplication of any previously reported research.

B. I will obtain approval from the Institutional Ethics Committee (IEC), MAM University, Nadiad, before initiating the study.

C. I will obtain prior IEC approval before implementing any significant changes to the research study.

D. I certify that the research will be conducted in strict compliance with the Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) guidelines as prescribed by the national and international regulatory authorities.

E. I will maintain all necessary records related to the research and will produce them for IEC scrutiny whenever required.

Date: _____

Place: _____

Signature of the Principal Investigator

Name: _____

Designation: _____

Department: _____

Institution: MAM University, Nadiad

Address with PIN Code: _____

Mobile Number: _____

Email ID: _____

Signature of Co-Investigator	*Signature of Co-Investigator*	*Signature of Co-Investigator (s) (if> 2)*
Name of the Guide	Name of the Co-guide	Name of the Co-guide
Designation	Designation	Designation
Department	Department	Department
Institute	Institute	Institute
Place with PIN code	Place with PIN code	Place with PIN code
Mobile number	Mobile number	Mobile number
Email ID	Email ID	Email ID

32. UNDERTAKING BY THE INVESTIGATORS –

1. Principal Investigator Details:

- Full Name:
- Title:
- Institution:
- Address:
- Email ID:
- Contact Number:

2. Clinical Trial Site Details:

- Name & Address of the Institution/Hospital:
- Education, Training & Experience:

3. Clinical Laboratory Facilities:

- Name & Address of Clinical Laboratories Used in the Study:

4. Ethics Committee Details:

- Name & Address of Ethics Committee (IEC): [IEC Name & Address]
- Review Responsibility: Approval & Continuous Monitoring of the Study

5. Research Team Members:

- Co-Investigator(s) & Sub-Investigator(s): *(Provide names, designations, and responsibilities in the study.)*

6. Clinical Trial Details:

- Protocol Title:
- Study Number:

7. COMMITMENTS:

I, Name of Principal Investigator, hereby agree with the following:

i. Protocol Review & Compliance:

- I have thoroughly reviewed the clinical trial protocol. I confirm that it includes all the information necessary to conduct the study.
- I will not initiate the study without obtaining all the necessary approvals from the Ethics Committee and Regulatory Authorities.

ii. Adherence to Protocol & Amendments:

- I will strictly follow the approved protocol and will not implement changes without prior approval from the Sponsor and IEC, except in cases of immediate hazard to the participants or minor administrative changes.

iii. Supervision & Conduct of the Trial:

- I will personally conduct and supervise the clinical trial at my site.

iv. Informed Consent & Ethics Compliance:

- I will ensure that all the participants are fully informed about the drug under investigation and that it is being used for the research purpose.
- I will adhere to the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices (GCP) Guidelines for obtaining informed consent.

v. Reporting Adverse Events:

- I will immediately report all the adverse events to the Sponsor and Regulatory Authorities as per the GCP guidelines.

vi. Investigator's Brochure & Risk Awareness:

- I have read and understood the Investigator's Brochure, including all potential risks and side effects of the investigational drug.

vii. Qualification of Research Team:

- I will ensure that all the team members (Co-Investigators, Sub-Investigators, Staff) are qualified and trained to perform their roles in compliance with the regulatory requirements.

viii. Record Keeping & Audits:

- I will maintain accurate and complete records and make them available for the audit or inspection by the Sponsor, IEC, Central Licensing Authority, or their representatives.

ix. Reporting Protocol Changes & Unanticipated Risks:

- I will promptly report all the protocol changes and unanticipated risks affecting trial participants to the IEC.

x. Serious Adverse Events (SAE) Reporting:

- I will report all the SAEs to the Central Licensing Authority, Sponsor, and IEC within 24 hours of occurrence.
- If a delay occurs, I will provide a valid reason for the same to the Central Licensing Authority.
- I will submit a detailed SAE analysis report to the Central Licensing Authority, IEC Chairperson, and Head of the Institution within 14 days, as per the regulatory requirements.

xi. Confidentiality & Data Security:

- I will ensure confidentiality of all the participants' data and maintain secure handling of study records.

xii. Regulatory & Ethical Compliance:

- I will adhere to all the applicable laws, regulations, and ethical guidelines for conducting clinical trials.

8. Principal Investigator Signature:

Date: _____

Place: _____

Signature: _____

Name:

Designation: _____

Department: _____

Institution: MAM University, Nadiad

Mobile Number: _____

Email ID: _____

9. Signature of Investigator with date –

No.	INVESTIGATORS	DESIGNATION	SIGNATURE
		PI	
		Co-Investigator	
		Co-Investigator	
		Guide	
		Co-Guide	
		Co-Guide	

33. CHECK LIST OF THE GUIDELINES FOR SUBMISSION OF RESEARCH PROPOSAL TO THE IEC

Sl. No.	ITEMS
1	Submission to Dean/Faculty In-charge (research) and final approval/permission letter from the competent authority, Head of the Institution (MAM University, Nadiad)
2	Approval/Permission letter from the competent authority of the District/Regional/State/Nation/Other Govt. Offices/Departments/Regulatory agencies (Wherever Applicable)
3	Approval/Permission letter from the other committee(s) as per the existing National/International Regulations & Guidelines (Wherever Applicable)
4	Approval/Permission from the respective Head of the Department(s)/HODs concerned [In Intradepartmental/Interdepartmental Research Proposal(s)]
5	Approval/Permission from the 'Copyright Owners' if any scientific method(s) is used in the research protocol [Wherever Applicable]
6	'Good Clinical Practice (GCP) Training Certificates' for the Principal Investigator (PI)/Guide, Co-Investigator(s)/Co-Guide(s) [In the last 3 years of period]
7	Declaration of 'Total Number of Research Projects' currently handled by the Principal Investigator (PI)/Guide, Co-Investigator(s)/Co-Guide(s) including their details
8	Adherence of research protocol in the format provided by the IEC, MAM University, Nadiad
9	Declaration of 'Conflicts of Interest' by the Investigator(s) (If involved in the research)
10	Covering letter with date and signature of the Principal Investigator (PI)
11	Updated 'Curriculum Vitae' of the Principal Investigator (PI)/Guide, Co-Investigator(s)/Co-Guide(s)
12	Adequate scientific justification for the study with references
13	Adequate review of literature pertinent to the current research protocol
14	Detailed description of 'Methodology' of the Research Protocol

15	Details of drug(s)/Medical Device(s) as provided in the research protocol [If applicable]
16	If Regulatory Clinical Trial (CT), approval from the DCGI
17	If Clinical Trial (CT), its registration with the CTRI
18	'MTA' between collaborating centre(s) [If applicable]
19	'QA/QC' Certificate for laboratory / laboratories used in the research project for data generation
20	If Research is Multicentric, then MoU between the Institute(s)/Organization(s)
21	Details of the management strategies for 'Adverse Events' related to research
22	Agreement of 'Compensation' issues (Wherever Applicable)
23	Agreement of 'Health Insurance Policies' (Wherever Applicable)
24	Agreement of 'Post Trial Access' (Wherever Applicable)
25	Agreement with 'Sponsor/Donor Agency' (Wherever Applicable)
26	Statement on Audio-Visual Consent Recording(s) [Wherever Applicable]
27	Statement on whether the Research Protocol is 'Intra-departmental/Inter-departmental/Inter-institutional'
28	Source(s) of funding including its details
29	Signature of the Principal Investigator (PI) & Co-Investigator(s) in 'Declaration Form'
30	Official seal of the Principal Investigator (PI) & Co-Investigator(s) in 'Declaration Form'
31	Communication address (Including Designation, Department & Organization), Contact details and Email ID of the Principal Investigator & Co-Investigator(s) in the main Research Protocol including in the ICD
32	Informed Consent Document (ICD) - Part-1 [Participant Information Sheet (PIS)] in English language
33	Informed Consent Document (ICD) - Part-2 [Informed Consent Form (ICF)] in English language
34	Informed Consent Document (ICD) - Part-1 [Participant Information Sheet (PIS)] in Gujarati language
35	Informed Consent Document (ICD) - Part-2 [Informed Consent Form (ICF)] in Gujarati language

36	Informed Consent Document (ICD) - Part-1 [Participant Information Sheet (PIS)] in Hindi language (Wherever Applicable)
37	Informed Consent Document (ICD) - Part-2 [Informed Consent Form (ICF)] in Hindi language (Wherever Applicable)
38	'Assent' Form (Wherever Applicable)
39	Proforma/Case Record Form (CRF)/Questionnaire/Interview Guide(s)/Guides for Focused Group Discussion (FGDs) applicable to the Research Protocol [In English Version]
40	Proforma/Case Record Form (CRF)/Questionnaire/Interview Guide(s)/Guides for Focused Group Discussion (FGDs) applicable to the Research Protocol [In Gujarati Version]
41	Details of 'Advertisement Materials' for enrolment of study participants [In English & Gujarati Version(s)]
42	In Expedited Review: Adequate justification as per the 'ICMR Guidelines-2017'
43	If 'Vulnerable Population' Involved: Scientific justification for their inclusion including how their safety, autonomy & wellbeing is taken care of / maintained
44	Incentives for the Study Participant(s): Provide details (If Applicable)
45	Research Study Related Cost/Expenditure (For Investigation(s) / Drug(s) / Medical Devices(s) etc.: Provide details regarding the source of financial support for the same)
46	Declaration of Publication Policy: Provide details as to who all are to be included as in the 'Author(s) list including their order of preference while publishing the research data
47	Statement on Storage of Sample(s): Provide details including its reuse if any/Appropriate method(s) for its discard
48	Investigator(s) Brochure (IB) [If Applicable]
49	The 'Complete Research Protocol' should reach the IEC office at least 20 days in advance of the scheduled IEC meeting including soft & 10 sets of hard copies
50	References in the 'Vancouver' format only