STANDARD OPERATING PROCEDURE

INSTITUTIONAL ETHICS COMMITTEE

MAMATA DENTAL COLLEGE

Date: 20 February 2026

Prepared by

Dr. R Arpita

Member Secretary, IEC, MDC

Approved & confirmed by

Dr. B. Anuradha

Chairman, IEC, MDC

Dr. G. Venkateswara Rao

Principal, MDC

Distribution: Members of IEC, MDC, Investigators

Available at the Institute website: https://mamatadentalcollege.com

MAMATA DENTAL COLLEGE

Mamata General Hospital Campus, Mamata Hospital Road, Khammam, Telangana – 507002, India

TABLE OF CONTENTS

FORMS

1. Introduction

Mamata Dental College, Khammam, is a reputed institution committed to excellence in dental education and research. The college provides a conducive academic and clinical environment that supports high-quality research in various disciplines of dental and allied health sciences. As research increasingly involves human participants, it is essential to ensure that such studies are conducted in accordance with established ethical principles.

Research involving human participants raises important ethical concerns related to their rights, safety, dignity, and well-being. To address these concerns, Mamata Dental College has constituted an *Institutional Ethics Committee (IEC)* in compliance with regulatory requirements. The IEC plays a vital role in guiding researchers on ethical issues and ensuring that all biomedical and health research conducted under the institution adheres to accepted ethical standards.

This Standard Operating Procedure (SOP) document outlines the composition, roles, and functioning of the IEC in reviewing research proposals for scientific validity, ethical acceptability, and risk–benefit assessment. The IEC functions in accordance with the *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017)* issued by the Indian Council of Medical Research (ICMR) and follows the requirements of the Naitik portal.

Objectives of the Standard Operating Procedures (SOP) of the IEC, Mamata Dental College, Khammam:

1. To ensure quality, scientific rigor, and consistent ethical review of all submitted biomedical and health research proposals.
2. To assess the qualifications and competence of investigators involved in the proposed research.
3. To maintain strict confidentiality of all submitted information, including proprietary data.
4. To review research proposals within defined timelines in a transparent and efficient manner.
5. To monitor the progress of approved research at specified intervals and review the final reports of completed studies.

2. Name of the ethics committee

This Ethics Committee is identified as Institutional Ethics Committee, Mamata Dental College, in short IEC-MDC.

3. Address of the office of ethics committee

MAMATA DENTAL COLLEGE

Mamata General Hospital Campus, Mamata Hospital Road, Khammam, Telangana – 507002, India

Email: mamatadental@yahoo.co.in

Website: https://mamatadentalcollege.com

Telephone No: +919849490529

4. Authority under which the ethics committee has been constituted

The Principal, MDC shall constitute the IEC in accordance with the SOP.

5. Scope and purpose

This SOP applies to all biomedical, clinical and health research projects involving human participants conducted under the aegis of Mamata Dental College. It ensures that every such study is reviewed and overseen by the IEC in accordance with the Indian Council of Medical Research (ICMR) 2017 guidelines and applicable laws. The purpose is to protect research participants' rights, safety and well-being and to promote ethical research practices. All faculty, staff and students engaged in human research must comply with this SOP.

6. Definitions

- **Institutional Ethics Committee (IEC):** A committee constituted by the institution's head to review and monitor research involving human participants. It ensures compliance with national ethical guidelines.
- **Principal Investigator (PI) / Co-investigator:** The lead researcher(s) responsible for the conduct of a study.
- **Human Research:** Any systematic investigation involving human participants (including clinical trials, behavioural research, surveys, etc.).
- **Vulnerable Participants:** Persons requiring special protections (e.g. children, pregnant women, cognitively impaired, socio-economically disadvantaged).

- **Confidentiality:** The obligation of the researcher/IEC to protect participant data from unauthorized access or disclosure.
- **Material Transfer Agreement (MTA):** A formal contract governing transfer of bio specimens between institutions.
- **Legal Representative (LAR):** A person authorized to consent on behalf of a participant unable to consent (e.g. parent for a child)**.**

7. Governance

IEC Composition

The IEC shall be multi-disciplinary and independent. As per ICMR 2017, it should have 7–15 members with a balance of medical, scientific, and non-medical expertise. It **should include**:

Role	Affiliation	Qualifications/Experience	No.
Chairperson	External	Experienced senior person (e.g. retired doctor/scientist, social worker); *non-affiliated* to college. Ensures impartiality.	1
Institutional Head	*Not on IEC*	The college Principal (or equivalent) should **not** serve on the IEC; they act as the appellate authority if needed.	N/A
Member Secretary	Affiliated	Senior faculty member (e.g. professor/researcher) in biomedical or dental fields; knowledgeable in research ethics and regulations.	1
Basic Medical Scientist(s)	Affiliated/ External	Medical scientist with postgraduate qualification (e.g. pharmacologist); relevant experience in biomedical research (1–2).	1–2
Clinician(s)	Affiliated/ External	Qualified medical/dental specialists; at least one member from the institute and one external clinician to address clinical aspects.	1–2
Legal Expert	External	Law degree (LLB) with ≥3 years' experience; preferably knowledgeable in medical law.	1
Social Scientist/Ethicist	External	Expert in social sciences, ethics or humanities; sensitive to local cultural values.	1
Lay Person(s)	External	Literate community representative not engaged in health professions; aware of local values.	1–2
Gender Requirement	—	At least **one woman** must be on the IEC.	—

Notes: All members must serve in their personal capacity and volunteer their time. Each member should provide a signed CV and training certificates (e.g. research ethics, GCP) and agree to confidentiality/COI policies. The Member Secretary supports the Chair and manages day-to-day functions; an Alternate Member Secretary may be appointed. The IEC Secretariat (e.g. administrative staff) assists documentation under confidentiality. All members will act in the manner independent of any influence of the existing relationship with any organization, institute or individual.

Special Invitees

As appropriate, the Committee will decide the need for participation of qualified special invitees to have unbiased scientific and / or ethical opinion for the study protocol to be discussed. Special invitees shall participate in the discussion and deliberations, but will not vote on a research proposal. However, the opinion of the special invitee shall be recorded.

Quorum

A quorum of **at least five** members (including both medical and non-medical/lay members, and at least one non-affiliated member) is required for any meeting. Preferably, the lay member is present in quorum. Decisions without quorum are invalid. For clinical trials, quorum must also meet CDSCO requirements (which currently align with ICMR).

Conflict of Interest (COI)

IEC members **must declare** any real or potential COI at each meeting. They should **recuse themselves** from discussions/votes where they have a COI (e.g. if a project involves their department). All members sign confidentiality and COI agreements upon appointment. The IEC should have a documented COI policy; any declared conflict is recorded in the minutes. The EC Chair or Member Secretary should ensure conflicted members do not influence decisions.

Terms of Appointment

Members are appointed for a fixed term (typically *2–3* years), renewable once or as per institutional rules. Appointment letters should specify roles, term, expectations, honorarium (if any) and meeting commitments.

- A member should be willing to reveal his / her full name, profession and affiliation; all reimbursement for work and expenses, if any, within or related to the Committee as these details will be made available to the appropriate authority upon request.
- A member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants and related matters; in addition, all of the Committee administrative staff should sign a similar confidentiality agreement.

Appointment of New Members

New members will be appointed under the following circumstances:

- When a regular member completes his / her tenure.
- If a regular member resigns or drops out before the tenure is completed.
- If volume of proposals and frequency of review demands appointment of new members.

When a new member shall be appointed, it is advisable to induct a member in the same category to fulfill the norms the same category.

Procedure for appointment of Members:

- The Secretary of the institution after appointing the chairperson shall, in consultation with the Chairperson, nominate the members of IEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.
- The normal term for IEC member will be for 24 months.
- Director can renew the appointment of the member on the basis of Contribution.
- During the term, Director can disqualify any member if the contribution is not adequate and, or there is long period of (member) non availability.
- Member can discontinue from membership of IEC after giving at least 1 month advance notice.
- Director can replace the member of IEC as and when required.
- Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.
- Conditions of appointment: Non institutional committee members are paid an honorarium for each meeting

Tenure of Membership

- The tenure of Committee Membership will be a continuous period of 5 (five)years.
- Extension of membership will be decided by Head ofInstitute.

- There will be limit to the number of times that membership can be extended. To avoid Conflict of Interest (COI) and to bring new ideas and dimensions in the review, limitation the extension should be up to 1 or 2times.

8. Terms of reference of ethics committee

Chairperson:

- The Chairperson of the Committee should be from outside the Institution to maintain the independence of the Committee.
- The Chairperson is responsible for conducting all committee meetings, and leads all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson presides overall administrative matters pertinent to the committee's functions.
- In Emergent situation, the Chairman will nominate a Committee Member as Chairperson OR in case of absence of the Chairperson, it is better that the members elect an acting chairperson among themselves preferably from the outside of the Institute to avoid conflict of interest.
- The Acting Chairperson will have all the powers of the Chairperson for the respective meeting.

Member Secretary:

The member secretary is a senior faculty from the institution with a postgraduate degree, and with a minimum experience of five years in the institution. Should have undergone training in "Good Clinical Practice" and "guidelines for conducting biomedical research on human beings". Should have a minimum of three years' experience as a member of an institutional ethics Committee. Should have worked as a convener/member of any committees/core teams of the Institution. In consultation with the Chairperson, the Member Secretary will be responsible for the following functions.

- Inviting all the Committee members to come onboard.
- Receiving all the research proposals.
- Forwarding all the documents to be reviewed to the Committee members
- Preparation and dissemination of agenda for all Committee meetings
- Inviting special attendees from relevant area including therapeutics, of the scheduled meetings, if needed.

- Preparation and circulation of minutes within seven (7) working days from the date of the meeting.
- Notification of review outcome to Principal Investigator or Sponsor or CRO of research proposals within seven (7) working days from the date of the meeting.
- Generate and dispatch review letters of respective research proposals.
- Retention and safe keeping of all records and documentation
- Performance of other duties assigned by the Chairperson.
- Administrative matters pertinent to the Committee's functions.
- Signing on behalf of the Chairperson, in consultation with the Chairperson.
- Doing all the communications on behalf of the Committee.

In case of anticipated absence of the Member Secretary, the Acting Member Secretary will be nominated by the Chairperson and / or the Member Secretary and documentation for the same will be maintained. The Acting Member Secretary will perform the duties of the Member Secretary and have all the powers of the Member Secretary for that meeting.

Members:

- Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC.
- They should not have any known record of professional misconduct.
- The basic medical scientists and clinicians should have post graduate qualifications.
- The Lay Person should not have any graduate or post graduate qualification in any science discipline. He/she is a literate person from the public or community. He/she is aware of the local language, cultural and moral values of the community
- The legal expert should have a basic degree in law from a recognized university with a minimum experience of three years in the legal field .
- The social scientist is someone expert in the study of human society and its personal relationship like anthropologist, scientist and penologist. He/She also may be a representative of a non-governmental organization.

- A newly appointed member who has not undergone any training in ethics/good clinical practice /ethical guidelines of biomedical research on human beings does not have the voting rights. He/she has to undergo training within six months of the appointment.
- The member gets the voting rights once he/she undergoes training.

Per ICMR, the IEC's primary duty is to protect participants' rights, dignity, safety and welfare. Key responsibilities include:

- **Ethical Review:** Review scientific and ethical aspects of all proposals (initial, amendments, continuing review, SAE reports) objectively and independently. Ensure research follows local customs and international standards.
- **Records & Confidentiality:** Maintain secure, confidential records of all IEC activities. Only authorized personnel may access EC files.
- **Education:** Advise and educate investigators on ethical conduct and regulations. Reviewers should be identified (primary/secondary) and may consult outside experts as needed.
- **Monitoring:** Establish monitoring plans (routine or "for cause") especially for high-risk research. Review progress reports, protocol deviations, SAE/AE reports, and final reports. Follow up on corrective actions or suspensions in case of serious non-compliance.
- **Compensation:** Ensure compliance with rules on compensation/insurance. Recommend fair compensation for research-related injuries (see Compensation/Insurance section).
- **Continuous Improvement:** Update SOPs as regulations evolve, train new IEC members, and pursue accreditation/registration (e.g. CDSCO registration for trials) as required.

9. Procedure of resignation, replacement and removal of members

The membership will stand to be terminated under the following circumstances:

- The tenure of the members in the MDC-IEC is for 2 years. After the completion of 2 years, at least 1/3rd of the members will be replaced by new members.
- The replacement of a member will be done with new member of the same category (clinician/lay person/social scientist/philosopher, etc).
- The Principal of the college will take the decision on continuation of a member. They may take suggestions from the Chairperson and the Member Secretary.

- A member can have maximum two continuous terms in MDC-IEC. He/she may become a member again in MDC-IEC after a gap of at least two years. The Principal will communicate to those who are replaced, acknowledging their service and contribution to the ethics committee.
- For the Chairperson and the Member Secretary replacements, same procedure will be followed. The Chairperson and Member secretary could get a second term after completion of the tenure. The Chairperson and Member Secretary can have maximum two consecutive terms.
- The Principal will send an appointment proposal letter to the members who will replace existing members and also to the existing members who are going to continue. After obtaining consent, final appointment letter will be issued.
- **Termination of Membership:** This refers to termination from membership even before the member completes his/her tenure. Reasons for termination may be resignation of the member from the MDC-IEC, resignation of the member from the institution, death of the member or disqualification of the member.
- **Voluntary termination:** It is due to resignation of the member. The resignation has to be submitted in writing to Chairperson, MDC-IEC. One month prior notice is necessary for the resignation. It will be effective from the date of acceptance by the Chairperson.
- **For affiliated members:** If a member resigns from the institution (Institutions of MDC), even if he/she does not submit resignation to MDC-IEC, the membership to MDC-IEC stands automatically cancelled. This termination is effective once the member is relieved from the institution.

Disqualification: A member is disqualified from membership under following circumstances.

A) Misconduct

- If the Chairperson or the Member Secretary receives a communication in writing from public /investigators/ another member of IEC regarding misconduct of the member
- If the Chairperson observes/gets information on any type of professional /ethical misconduct (not maintaining confidentiality /not declaring of conflict of interest/any type of bias towards research studies/investigators , reviewed by MDC-IEC)

Action to be taken: The Chairperson satisfies himself/herself that prima facie a case exists before initiating any action. If in the opinion of the Chairperson, the matter of significance and integrity of the IEC could be questioned, he/she will first keep the member under suspension till the final

decision is taken. During the period of suspension, the member will not perform any duties of a member of MDC-IEC. The Chairperson will call for a meeting of MDC-IEC, following the usual rules of quorum. The suspended member will be given sufficient opportunity to defend himself/herself in the meeting. The decision will be taken by consensus.

B) Disqualification due to continuous absence:

- A member will be disqualified if he/she does not attend more than three consecutive meetings of IEC. If the member has given a prior intimation to Chairperson/member Secretary about the absence, the member will be given an opportunity to continue with the membership. This member will be issued a warning from Chairperson. However, the membership will cease if this habit repeats once again.
- In case of absence without intimation for more than three consecutive meetings of MDC-IEC, the member is liable for disqualification. The member will be issued a one month notice by the Chairperson seeking explanation for the absence. If the member gives satisfactory explanation for the continued absence and assures attendance for future meetings, the Chairperson may decide on continuation of the membership. In the absence of any reply from the member, the Chairperson will discuss the matter of disqualification of membership in the meeting of MDC-IEC. Final decision on disqualification is taken by the Chairperson.
- In all the above cases of disqualification, the Chairperson communicates to the Secretary, MDC in writing. The decision of disqualification is communicated to the member by the Secretary.

10. Protocol Submission and Review Process

Submission Requirements and Checklist

Researchers must submit a complete application with all required documents to the IEC Secretariat. According to ICMR, an **EC submission checklist** should include (see Table below): the application form, cover letter, typed proposal, translated consent forms, data collection tools, investigator CVs, conflict of interest statements, training certificates, approvals (e.g. drug authority, funding), and any required policies (e.g. insurance). The IEC may tailor this list to the institution and study type.

- All communications with the Committee will be in writing (Physical or electronic)
- Before receiving the review materials, it is advisable to obtain COI declaration and CA (Confidentiality Agreement) from the Member Secretary, Chairperson & Members. If it is

required by Sponsor/CRO/ Investigator/Institution. A copy of this agreement will be filed with the official records of the Committee and another copy will be returned to the Sponsor / CRO / Investigator /Institution.

- The Committee will require the submission in Printed (member copies + 1 PI Reference copy (if required) + Guest Member copy (if any) & electronic copy (whenever possible) of study dossier as listed for every research proposal.
- All the relevant revised documents which are resubmitted for review should be submitted in two copies (Committee reference copy + one copy) if the resubmission involves only those changes which are suggested by the Committee with no other modification.
- In case of any amendment to the research proposal or any modification which is not suggested by the Committee and is not administrative, submission should be as directed in sub-clause 3 above.

Checklist

Item	Details
1. Cover Letter	To Member Secretary, with study title and summary.
2. Application Form	IEC application as per format (study title, objectives, investigators, etc.).
3. Protocol/Proposal Document	Complete research protocol outlining objectives, design, methods.
4. Informed Consent Documents (ICD/ICF)	Latest version in English and local language(s); include translation/back-translation certificates.
5. Case Report Forms/Questionnaires	All data collection tools to be used.
6. Recruitment Materials	Advertisements, posters or flyers (if any).
7. Investigator Brochure	For drug/biotech/device trials (e.g. containing safety data).
8. Funding Details	Sponsor information, budget and resource allocation.
9. CVs of Investigators	Signed, current curriculum vitae for all study staff.
10. Conflict of Interest (COI) Statement	Disclosure of any personal/financial interests of investigators.

Item	Details
11. Ethics/GCP Training Certificates	For PI and key personnel (preferably within last 5 years).
12. Ongoing Studies List	List of PI's current research (to judge burden).
13. Investigators' Undertakings	Signed declarations (e.g. commitment to follow IEC decisions).
14. Regulatory Approvals	Copies of CDSCO DCGI/Drug authority sanction, DCGI letter (for new drugs), or other regulatory clearance as applicable.
15. Institutional Approvals	E.g. Hospital/Department permission, Stem Cell Research Committee (IC-SCR) approval if stem cells are involved.
16. Material Transfer/Collaboration Documents	MOU if multi-institution study; MTA if sharing biospecimens.
17. Insurance Policy (for interventional studies)	Proof of participant insurance, showing coverage and validity.
18. Others	Any other document required by IEC SOP (e.g. lab certificates, regulatory letters, etc.).

Note: The Secretariat shall promptly screen submissions for completeness. Incomplete applications are returned with deficiency letters. A researcher cannot unilaterally classify the type of review – the IEC categorizes risk level.

- The documents required for submission are the following:
  a. Study proposal with covering letter.
  b. Protocol along with compensation details and any amendments to it, Informed Consent Form (ICF), including any amendments and its translation(s) into regional language (s) with translation certificates.
  c. Written information to be provided to the subjects {e.g., Patient Information Sheets (PIS), if applicable}.
  d. Investigator's Brochure (IB).

e. Undertaking by Investigator.
f. Subject recruitment procedures (e.g., advertisements), if applicable.
g. Available safety information.
h. Information about payments and compensation available to the subjects.
i. Investigator's current Curriculum Vitae indicating qualification and experience.
j. Approval from competent regulatory authorities.
k. Copy of the Insurance Certificate.
l. DCG (l) clearance (whenever applicable).
m. Investigator's agreement with the Sponsor /CRO.
n. Health Ministry Screening Committee (HMSC) / Bhabha Atomic Research Centre (BARC) / Genetic Engineering Advisory Committee (GEAC) / Director General of Foreign Trade (DGFT) clearance wherever applicable.
o. Food and drug Administration (FDA) marketing / manufacturing license for herbal drug wherever applicable.

Prescribed Application Form for Clearance of Research Project by IEC:

a. Name of the Investigator/co-investigator with designation.
b. Name of the Department where research will be conducted.
c. Protocol of the proposed research involving human subjects /participants*:
d. Ethical issues in the study and plans to address these issues.
e. Copies of Proforma / Case Report Forms / Questionnaires / Follow-up Cards, etc.
f. Details of Informed Consent Process, including patient information sheet and the Informed Consent Form in local language /English.
g. For any drug / device trial, all relevant publications / pre-clinical data and clinical trial data from other institutions within the country / other countries, if available.
h. Curriculum Vitae of all the investigators with relevant publications during the last five years.
i. Regulatory clearances (other than IEC, MDC), if required
j. Details of Funding agency/sponsors and fund allocation for the proposed work.
k. An agreement to report only Serious Adverse Events (SAE) to IEC.
l. Statement of conflicts of interest, if any.

m. A statement specifying pecuniary risks involved and the measure(s) taken to provide compensation to the research participants, the human subjects involved as participants in research (as defined in the guidelines of various national agencies), the researchers themselves, and such other persons who may be directly or indirectly at risk in the conduct of the research.
n. Plans for publication of results – positive or negative - while maintaining the privacy and confidentiality of the study participants.
o. Agreement to comply with the relevant national guidelines for research in human genetic, transplantation etc. as and when applicable.
p. Any other information relevant to the study.

Signature of Principal Investigator (PI)

Place:

Date:

Signature of Co-investigator(s)

Place:

Date:

*The protocols should include among other things the following:

a. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
b. Subject recruitment procedures.
c. Inclusion and exclusion criteria for entry of subjects in the study.

d. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedure, if any.
e. A description of plans to withdraw or withhold standard therapies in the course of research.
f. The plans for statistical analysis of the study.
g. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research.
h. Storage and maintenance of all data collected during the trial.
i. Agreement to comply with national and international GCP protocols for clinical trials.

11. Documentation

Procedure for Document Receipt & Handling:

Receiving the Study Documents

The Member Secretary will receive the study documents and other related documents in hard copies at the Ethics Committee office, submitted by the Principal Investigator / Institution / Sponsor / CRO.

The Member Secretary will check the following:

- A Submission Letter addressing the Ethics Committee.
- Total number of copies of all documents.

Circulating the Documents

- Study documents will be circulated to the members along with a Document Circulation Log to maintain the record of the same and the template of Document Circulation Log is given below.
- The *Document Circulation Log* will be filed by the person receiving the documents.
- After the documents have been circulated, Document Circulation Log will be checked for completeness and will be archived in master log file.

IEC-MDC DOCUMENT CIRCULATION LOG

Sponsor / CRO:

Protocol No.:

Member's Name	Receiver's Name	Date	Signature

Return of the Documents

- On the meeting day, the members will bring their hard copies of the study documents to be reviewed.
- After taking the decision for the proposed study, the members return their copies at the office.
- All the returned copies will be discarded if not asked to be returned by the Investigator / Institution / Sponsor / CRO, except for two copies, one Committee reference copy and one copy to be kept with the Chairperson.
- Out of the two copies, one Committee reference copy will be archived at the Committee office and the Archival Log will be updated accordingly and the second copy will be kept with the Chairperson.
- Archival will be done as described in Archival Policy,
- In case a member is not able to attend the meeting, it will be the member's responsibility to return the documents to the Committee.

12. Review Process

Review Categories and Criteria

Elements of Review

The submitted proposal shall be reviewed both for scientific content and ethical principles. The Committee members shall review the proposal with reference to the following:

a. Scientific design of the study
b. Justification / Rational of the study
c. Selection criteria for subjects
d. Justification for use of placebo, if any
e. Potential benefits to the study subjects, predictable risks to the study subjects
f. Criteria for discontinuation / withdrawal of the subjects
g. Monitoring of serious adverse events
h. Compensation to the subjects for participating in the study
i. Subject recruitment procedures (e.g., advertisements), if applicable
j. Patient retention activities
k. Compensation for study related injury or death
l. Post trial benefits

m. Protection of privacy and confidentiality and plans for publication of results (positive or negative)
n. Statistical analysis
o. Informed consent document in English and regional languages
p. Competence of the Investigators, supporting staff and infrastructure facilities
q. Approval of regulatory authorities wherever applicable.
r. Safety Information

Adverse Event/ Serious Adverse Event reporting may be required for

a. The protection of the subject

b. Proper use of drug once it is marketed.

Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) is any untoward medical occurrence that at any dose:

- Results in death
- Is life-threatening: If subject was at substantial risk of dying at the adverse event time, or continued use of the device or other medicinal product which might have resulted in the death of the subject.
- Requires inpatient hospitalization or prolongation of existing hospitalization: If subject requires admission to the hospital or prolongation of hospitalization was a result of adverse event.
- Results in persistent or significant disability/ incapacity: If the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., significant, persistent or permanent change, impairment or damage or disruption in the person's body function/ structure/ physical activities and/or quality of life.
- Result in a Congenital Anomaly/ Birth Defect: If exposure to a medicinal product during pregnancy may have resulted in an adverse outcome in the child.
- Important medical event like allergic bronchospasm, blood disorders, seizures/ convulsions, the development of drug dependence or drug abuse.
- Required medical or surgical intervention (treatment) to prevent permanent impairment of a body function or damage to a body structure as a result of medicinal product usage.

Timeline for reporting of SAE as per 122 DAC of Schedule-Y Responsibility of Investigator:

To	Within 24 hours of identifying the event	Within 14 days of Occurrence of SAE	Within 21 days	Within 30 days
Sponsor	Notification	-	-	-
DCGI Office	Notification	Report of Death+ other SAE	-	-
Ethics Committee	Notification	Report of Death+ other SAE	-	-
Head of Institution	-	Report of Death+ other SAE	-	-
Chairman of Expert committee at CDSCO Office	-	Report of Death Only	-	-

Responsibility of Sponsor:

To	Within 24 hours of identifying the event	Within 14 days of Occurrence of SAE	Within 21 days	Within 30 days
DCGI Office	Notification	Report of Death+ other SAE	-	The sponsor shall pay the compensation in case of clinical trial related injury or death
Ethics Committee	Notification	Report of Death+ other SAE	-	
Head of Institution	-	Report of Death+ other SAE	-	

Chairman of Expert Committee at CDSCO Office	-	Report of Death Only	-	within 30 days of receiving the order from Licensing Authority DCGI

Note:

- In case if the sponsor fails to provide medical management/ financial compensation to the subject, the Licensing Authority (DCGI) may after giving an opportunity to show cause why such order should not be passed and/or may suspend or cancel the clinical trial and/or restrict sponsor to conduct any further clinical trials in the country.
- For SAE other than Death, trial subject will get the compensation.
- For Death, nominee of the subject will get the compensation.

Responsibility of Ethics Committee:

Shall forward its report after due analysis on SAE with its opinion on the financial compensation (if any) to be paid by the sponsor to:

To	**Within 24 hours of identifying the event**	**Within 14 days of Occurrence of SAE**	**Within 21 days**	**Within 30 days**
DCGI Office	Notification	Report of Death+ other SAE	-	-
Chairman of Expert committee-at CDSCO Office	-	Report of Death Only	-	-

Responsibility of Expert Committee (CDSCO Office) & Licensing Authority (DCGI Office):

- The Expert Committee shall examine the report of death and gives its recommendations (including quantum of compensation) to the Licensing Authority within 30 calendar days of receiving the report from the Ethics Committee.
- After considering the recommendations of the expert committee, the Licensing Authority shall decide the quantum of compensation and issue an order (shall be paid by Sponsor) within 3 months of receiving the report of SAE.
- All SAE should be submitted as per the format of Appendix XI of Schedule Y and Ethics Committee should analyze and forward its opinion as per procedures specified in Appendix XII of Schedule Y.

Criteria for the Approval of Research

In order to approve the research proposal, the Committee shall determine that all of the following requirements are satisfied:

- Risks to subjects, if any, are reasonable in relation to anticipated benefits. In evaluating risks and benefits, the Committee should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
- Selection of subject is equitable. In making this assessment, the Committee should take into account the purposes of the research and the setting, in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children prisoners, pregnant women, mentally disabled persons, or economically or educationally or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the Legally Authorized Representative of the subject.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- In case, in which the documentation requirement is waived, the Committee may require the Investigator to provide subjects with a written statement regarding the research.
- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
- The Committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the Committee's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reason /s for the Committee's action and shall be reported promptly to the Investigator, appropriate institutional officials, the department or agency head.

Meetings

- The Committee will hold regular meeting, depending on the number of research proposals for review. However the committee will meet at least once every 1-2months.
- A maximum of 5 proposals can reviewed at each meeting if the proposals are of the different molecules and different study designs; however, if proposals require urgent review, the same can be done irrespective of number of protocol. In case, the proposals are with the similar molecule and/or similar study design they can be reviewed in the same meeting.
- The Member Secretary will check the availability of the members for the meeting and shall invite the members for the same accordingly.
- Primary reviewer could be assigned by the chairperson to conduct a detailed review of a research protocol and provide a report at the meeting
- All regular members will receive notification of meeting schedules at least five(5) days in advance. In case of molecule/ combination of molecules which has already been discussed earlier by the Committee and / or the molecule/ active ingredient that have been in case for considerable period of time, review meeting for such protocols / studies can be scheduled well within five(5) days or short notice as per availability of members. Towards the same, a list of molecules reviewed will be updated on regular basis for ready reference.

- The proposal may be sent to a subject expert for his/ her assessment and opinion of the research proposal. The subject expert may be invited for the meeting if deemed necessary by the Committee.
- The Investigator and / or Co- Investigator may be invited to the meeting to provide clarifications on the study protocol if deemed necessary by the Committee.

- Specific patient group representatives may also be invited for the meeting based on the requirement of the research area if deemed necessary. e.g. Subjects with HIV/AIDS or genetic disorders etc.
- Meeting will be held only if quorum is met. A quorum will be defined as a minimum of 5 (five) members including one basic scientist (preferably a pharmacologist), one clinician, one legal expert, one social worker/ representative of a non – governmental organization / theologian or a similar person, one lay from the community.

Minutes

- The proceeding of the meeting will be recorded in English and in the form of minutes. The Members Secretary will be responsible for coordination, recording and circulation of the meeting minutes.

Decision Making

- Decision for each proposal / study shall be individual voting.
- All members present at the meeting will vote on the research proposal.
- The decision will not be declared until the consensus is reached amongst all the members regarding the opinion to the proposal/ study under consideration.
- The queries, comments or suggestions from the member(s) not in favour of the approval, shall be forwarded to the Sponsor / CRO/ Principal Investigator and reply received from their end will be discussed with members. After all the members(s), are satisfied with the reply, the chairperson shall take the final decision regarding further action on the protocol depending on the opinion / decision which is favoured by majority of the quorum members present at the meeting.

- Absent members will not have a right to vote. However, if absent members has been a part of the entire discussion via any electronic media from (e .g. telecom, webcam etc.). They will be eligible to vote.
- Member(s) of the Committee who is/ are listed as investigator(s) on a research proposal will opt out from all deliberations on the proposal and will not vote on the proposal.
- An investigator or study team member invited for the meeting will vote or participate in the decision making procedures of the Committee.
- The Committee shall reserve the right to withhold favorable opinion/approval on a research proposal when the Committee does not have reasonable assurance about the qualification of the Investigator(s), the site facilities, the Sponsor/CRO or the research protocol itself.
- The Committee shall notify the Investigation/ Sponsor / CRO in writing of its decision to approve or disapprove the proposed research activity. If the Committee decides to disapprove a research activity, it shall include in its written notification, a statement of the reasons for its decision and give the Investigator / Institution / Sponsor /CRO an opportunity to respond in person or in writing.

Review Outcome

The Committee will document its view as the following:

- Approval – Unconditional or Conditional
- Request for Modification or Information
- Disapproval
- Termination/ Suspension of the research proposal / ongoing study

Notification of Review Outcome

- The outcome of the Committee review will be recorded and conveyed to the Investigator / CRO/Sponsor within 7 (seven) Working day from the date review.
- Approval Period
- All projects will be given approval for a period of 1 (one) year from the date on which the project was approved and for the projects continuing for longer than one year annual renewal will be mandatory.

Procedures for Appeal after Protocol Rejection

- For research proposals rejected by the Committee, the applicant may appeal for a repeat review in writing, within Twelve (12) weeks of the receipt of the Committee's decision. While doing so, the applicant shall give justification relevant to the issues / objections raised by the Committee.
- Amendments to the Approved Research Proposal and Informed Consent Documents
- All amendments to the approved research proposal shall be submitted to the Committee immediately for its review.
- No changes in the protocol and/ or Informed Consent Documents shall be initiated without prior written approval from the Committee, except when necessary to eliminate immediate hazards to the subjects, or when the change(s) involve only logistical or administrative aspects of the trial [e.g. change of monitor (s), telephone numbe(s)].

Review categories

The IEC follows a **three-tier review** system per ICMR 2017: **Exempt, Expedited, or Full** (Table below. The Member Secretary/Secretariat categorises each proposal based on risk and vulnerability:

- **Exempt Review:** Non-human or minimal-risk studies without identifiers (e.g. public-domain data analysis, educational surveys, program evaluations). Exempt projects are noted but still require IEC registration; informed consent may be waived only by EC decision.
- **Expedited Review:** Minimal-risk studies (e.g. use of existing anonymous specimens/ data, minor protocol amendments, routine progress reports). An expedited subcommittee (Chair + ≥1 member) reviews and grants provisional approval, which is later ratified by full committee.
- **Full Committee Review:** All other research (more than minimal risk or involving vulnerable groups, novel interventions, deception, major changes, etc.). These are discussed at a convened meeting with quorum. All decisions (approve, request modifications, defer or reject) are determined by majority vote.

Table 1: Types of Review (ICMR 2017)

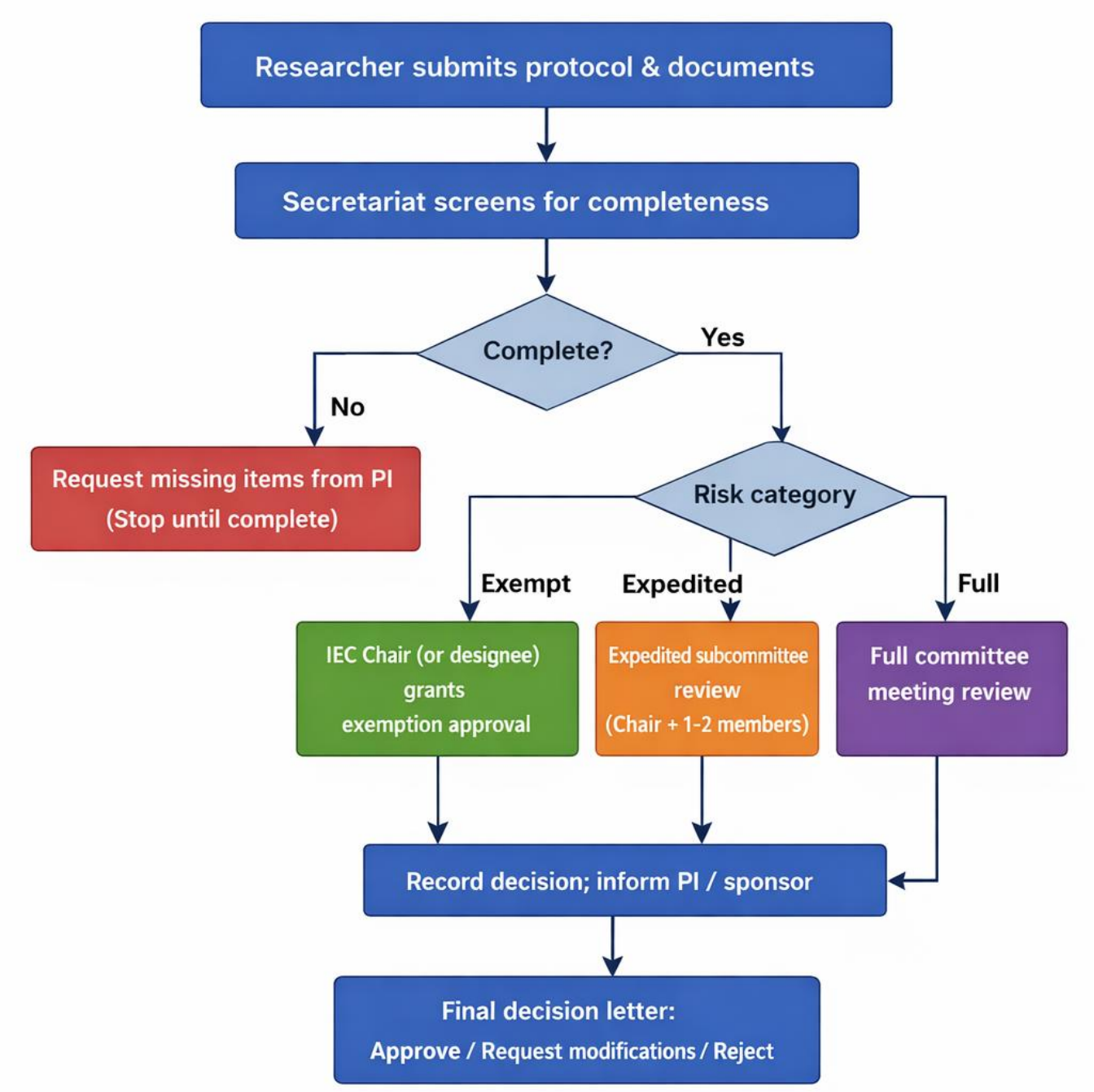
Review Type	Examples / Criteria
Exempt	- Research using non-identifiable data or publicly available datasets - Observational studies in public settings without collection of identifiers - Educational research, quality assurance studies, or institutional audits - Government programme evaluations without individual-level identifiers
Expedited	- Research using non-identifiable leftover biological specimens, medical records, or charts - Studies involving anonymous or anonymized survey/questionnaire data - Minor amendments or administrative corrections to approved protocols - Renewal applications or progress reports with no additional risk - Single-site ethical review for multicentric studies - Research conducted in emergency situations as per applicable guidelines
Full Committee	- All research involving more than minimal risk - Studies involving vulnerable populations, even if risk is minimal - Research involving deception in socio-behavioural studies - Major amendments or protocol deviations affecting participant safety or study integrity - Research involving new drugs, medical devices, or interventions without prior approval - Any study not qualifying for Exempt or Expedited review

Procedures:

- All proposals must go through IEC. Investigators submit to the Secretariat, which screens documents.
- The IEC then determines the review type.
- The Chair/Member Secretary plus 1–2 members may do expedited review, with decisions ratified at the next full meeting.
- Full reviews are scheduled in regular meetings (held at least monthly or as per SOP) and generally completed within ~4–6 weeks. (*If no formal timeline in ICMR, the IEC should state its target turnaround in its SOP*)

Review Workflow

The review workflow can be summarized as follows:



- *Secretariat Check:* Within 1–2 weeks of submission, Secretariat verifies documents against the checklist. Incomplete files trigger an immediate notice to the researcher for revision.
- *Categorisation:* The Member Secretary presents complete protocols to the IEC for initial category assignment (Exempt/Expedited/Full). Researchers may provide justification if they believe a proposal qualifies as exempt or expedited, but final assignment is by the IEC.

- *Meeting Notices:* For full reviews, investigators receive notice of meeting date ~2 weeks in advance with copies of reviewers' comments. All EC members should receive proposal materials at least 1 week before the meeting.
- *Decision and Communication:* The IEC records decisions in minutes. The Member Secretary issues an official decision letter to the PI (and sponsor/funder if applicable), detailing approval conditions or reasons for deferral/rejection.

Timelines

While ICMR does not mandate specific timelines, common practice (and CDSCO guidance for clinical trials) is:

- **Expedited reviews** are completed in ~7–14 days, and
- **Full reviews** in ~4–6 weeks from complete submission. These should be specified in the IEC SOP.

Review of On-going Studies

- The Committee will conduct continuing review of each on-going Study at intervals appropriate to the degree of risk to the human subjects, but not less than once a year, and can also have authority to observe or have a third party observe the research activities.
- The investigator should promptly report the following to the Committee:
- Deviations from or changes to the protocol to avoid immediate hazards to the trial subjects.
- Deviations / changes that increase the risk to subjects and / or affect significantly the conduct of the trial.
- All serious and/ or Unexpected Adverse Events should be reported to the Committee by the Investigator within 24 hours of their occurrence as per applicable regulatory guidelines. The report of the serious adverse event of that or severe adverse event other than that after due analysis should be submitted within 10 (ten) calendar days of occurrence.
- New information that may affect adversely the safety of the subjects or the conduct of the trial.
- In addition, the Investigator should submit the progress report of the study at intervals appropriate to the degree risk to the human subjects or as directed by the Committee.
- In case of serious adverse event of death or other serious adverse events, the Committee will meet as and when required, in the view of recent amendment by CDSCO. The Committee may also invite an expert for his / her opinion on the same. The Committee will generate the report

after due analysis and submit the same to the applicable authority within timelines specified in the applicable regulatory guidelines.

13. Informed Consent Procedures

- **Voluntariness and Capacity:** Participation must be voluntary, without coercion or undue inducement. Investigators must assess capacity – only participants who understand the study and its implications may consent. If a participant lacks capacity (e.g. minor child, cognitively impaired), consent must be obtained from a **Legally Authorized Representative** (LAR) (such as a parent/guardian).
- **Assent (for minors):** In addition to parental/LAR consent, **assent** should be sought from children aged roughly **7–18 years**. Children 7–12 years provide oral/verbal assent (documented in presence of parents), and those 12–18 provide written assent (signed by child and parent). The assent language must be age-appropriate and explained clearly. Children under 7 are not required to assent. Any indication that a child does **not** wish to participate must be respected (their refusal overrides parental consent).
- **Information and Language:** Before requesting consent, the researcher must explain the study in the participant's understandable language. Consent forms (Information Sheet + Consent Form) must be in simple, non-technical language, culturally sensitive, and in all relevant local languages, with back-translations where needed. The participant information sheet should cover study purpose, procedures, duration, risks, benefits, confidentiality, compensation (if any), voluntary nature of participation, withdrawal rights, and contacts for questions.
- **Documentation:** Written informed consent (ICF) must be obtained *prior* to any study procedures. The ICF should be signed and dated by the participant (or LAR) and the person obtaining consent (PI or trained designee). A copy of the signed ICF is given to the participant. Electronic or audio-visual recording of consent may be used if permitted by EC and applicable law (e.g. CDSCO requirement for some trials). The process of obtaining consent (including Q&A and comprehension) should be documented in the research records.
- **Special Populations:** For vulnerable groups (e.g. illiterate persons), impartial witnesses must observe the consent process. For non-literate participants, consent may be thumb-imprinted with a witness signature. Translations must be linguistically validated. If the research is

conducted among a population with group/community leaders, their permission or engagement should be sought in addition to individual consent (but not in place of it).

- **Consent Form Content:** At minimum, the consent form should include (Box 5.1, ICMR 2017): study purpose; procedures; duration and contacts; risks; expected benefits; alternative treatments (if any); confidentiality provisions; compensation/injury management; costs/incentives; the right to withdraw; and identification of investigators (Table below). Additional elements for specific studies (e.g. genetic data storage, insurance, incidental findings, future use of samples, publication plans) should be included as needed.

Consent Form Section	Description
Purpose & Procedures	Explains the study purpose in lay terms and outlines what procedures will be done and their duration.
Risks & Discomforts	Describes any foreseeable risks (medical, psychological, social) from participation.
Potential Benefits	Describes direct benefits (if any) to participant, and possible societal benefits.
Confidentiality	Explains how data/samples will be stored, who will have access, and measures to protect privacy.
Compensation/Injury Management	Details free care for study-related injury and compensation (per institutional policy/regulations).
Voluntariness & Withdrawal	States participation is voluntary and withdrawal is allowed anytime without penalty.
Alternative Treatments (if any)	For clinical trials, mentions available alternative procedures/therapies outside the study.
Costs & Reimbursements	Outlines any payments, reimbursements for expenses (travel, time) or costs to participant.
Contact Information	Names, addresses, phone numbers of PI and EC (for questions or complaints).
Community/Group Permission (if applicable)	Note any community engagement or approvals obtained (without replacing individual consent).

Sample text headings above are illustrative; the actual consent form should adapt these to the study context. See ICMR Box 5.1 for detailed elements.

14. Risk–Benefit Assessment

The IEC must ensure that the **anticipated benefits justify the risks**. The PI should provide a risk–benefit analysis in the protocol. The committee examines all study risks (physical, social, economic, legal, etc.) and planned mitigations. For higher-risk or vulnerable studies (e.g. involving children, pregnant women), the IEC applies extra safeguards. For example, in pediatric research, the EC evaluates whether risk is no more than minimal or justified by potential benefit. The IEC may require safety monitoring (e.g. Data Safety Monitoring Board) or interim reviews if appropriate. Overall, research is permissible only if risk is minimised and justified by benefits (to participants or knowledge).

15. Participant Recruitment and Selection

Recruitment must be **fair and transparent**. Inclusion/exclusion criteria should be scientifically justified and applied consistently. Selection should avoid overrepresentation of any vulnerable or disadvantaged group, and no group should bear the burden of research without reasonable benefit. Advertisements or invitations should be factual and non-coercive. Enrollment should be voluntary (no force or undue influence) and participants must be free to decline or withdraw at any time without penalty or loss of benefits. If incentives are provided (e.g. travel reimbursement), they must not be so large as to cloud judgment. Vulnerable individuals may be recruited only with special justification (e.g. the research addresses their health needs.

16. Data Management and Confidentiality

The IEC must ensure that data are handled securely and confidentially at all stages:

- **Data Security:** Participant data (paper and electronic) should be stored in locked files or encrypted databases. Access is limited to authorised staff only.
- **De-identification:** Wherever possible, data and biospecimens should be coded or anonymized. Codes/keys linking identities to data must be kept separately under strict controls. Personal identifiers should not be shared with unauthorized parties.
- **Confidentiality Measures:** All research team members must be instructed on privacy procedures. Research records must be filed separately from routine hospital records.

Publications must not reveal identifiable information; any case reports/photos require explicit consent.

- **Data Sharing:** Any sharing of data or samples (within or outside the institution) must comply with consent provisions and be reviewed by the IEC. Material Transfer Agreements (MTAs) must be in place for any biospecimen transfer. International shipment of human materials requires government clearances and export permits.
- **Confidentiality Limits:** The IEC will ensure participants are informed if confidentiality must be broken (e.g. legal orders, public health threats, mandated SAE reporting).
- **Record Retention:** All study documents (including source data) must be kept for the retention period specified by regulations (typically 3–5 years post-study). Secure archiving procedures should be followed.

Annual Progress Report

- For the study continuing for longer than the period of one year, the first report shall be submitted within thirty (30) days of completion of one year following the date of the first approval.
- Subsequent report shall be submitted at one year intervals following the first report.
- The Committee can recommend termination of ongoing clinical trials for the reasons like patient's safety, breach of any condition of approval, non-compliance on part of the Investigator, goal of the study achieved midway, complaint from the subject tetc.

Annual Renewal Process

- For studies, whose duration is more than one year, an extension of approval shall be given, after the status report and all other relevant reports mentioned are reviewed and approved by the Committee by the Annual Renewal Process.
- The approval for extension for study will be given for a period of one year.

Reports to the Relevant Regulatory Authorities.

- The Committee will make a yearly activity report for submission to the Relevant Regulatory Authorities upon request, which would include the following elements;
- A quantitative evaluation of the activities of the Committee and list of proposals reviewed.
- Status of each study proposal.

- Statements of significant new findings provided to subjects.

Handling of Subject Queries

- The subjects can call on the Committee Office number which is given in the Informed Consent Document.
- Subject's queries shall be documented by the Member Secretary and the same shall be conveyed to the Chairperson. The reply of the Chairperson will be conveyed back to the concerned subject.
- In case the subjects want to talk directly to the Chairperson, the Chairperson's number shall be provided from the Committee Office.
- Investigators are encouraged to submit at least 1–2 months before planned study start.

17. Biospecimen Handling

For research involving biological samples (blood, tissue, DNA etc.):

- **Consent for Samples:** The consent form must specify if samples will be stored for future research, including any tiered consent options (e.g. use for any research, or only specific diseases). Tiered (multi-layered) consent options are recommended.
- **Storage:** Samples should be stored securely (temperature controlled, access-restricted). They should be labelled with codes, not names. ICMR advises storing the least identifiable (coded) forms of data.
- **Biospecimen Code:** The linkage between samples and personal identifiers must be protected. If anonymized completely, re-contact is impossible. If coded (reversible), the custodian must maintain confidentiality and re-consent capabilities.
- **Transfer:** Transfer of samples to collaborators requires an approved Material Transfer Agreement. For shipping human biological material outside India, regulatory approvals (e.g. DGFT licence) are mandatory. The IEC must approve all intra- or inter-institutional sharing of samples.
- **Secondary Use:** Any use of stored samples for purposes beyond the original consent (secondary research) must be reviewed by the IEC. The EC will decide on a case-by-case basis whether additional consent is needed. If re-contacting donors is impractical and data can be anonymized, a waiver may be considered (depending on risk and feasibility).

- **Benefit Sharing:** If research on samples leads to new products/ commercialization, participants should be informed of any potential benefits (see Community Engagement and Benefit Sharing).

18. Safety Monitoring and Adverse Events Reporting

- **Adverse Events (AE/SAE) Reporting:** Investigators must promptly report all serious adverse events (SAEs) occurring in studies (especially clinical trials) to the IEC and appropriate regulators. ICMR mandates that the investigator report any SAE within 24 hours of awareness. SAE reports must detail the event and any relation to the research intervention.
- **IEC Review of AEs:** The IEC will review each SAE to assess causality and recommend necessary actions. If needed, an expedited review subcommittee (or separate SAE subcommittee) may be convened for urgent SAE evaluation. The EC must ensure that the investigator is complying with regulatory timelines and that participant care is assured.
- **Medical Management:** Participants suffering study-related injuries or illnesses must receive appropriate medical care at no cost. The IEC should verify that a plan for free treatment (for as long as needed) is in place.
- **Compensation:** If a participant is harmed by the research (and the harm is related to the study), the IEC should recommend compensation to the participant or family. Compensation arrangements (e.g. insurance policies) should be documented in the protocol or grant.
- **Monitoring Plans:** High-risk studies (e.g. clinical trials of new interventions) should include a Data Safety Monitoring Board (DSMB) or equivalent oversight. The IEC may mandate interim safety analyses or additional monitoring visits if indicated. Reports from sponsor monitoring and DSMB should be shared with the IEC.
- **Protocol Deviations:** All deviations/violations from the approved protocol must be reported to the IEC. The EC will review corrective actions; for serious or repeated non-compliance, it may suspend or terminate the study and notify institutional/government authorities as appropriate. The IEC should document reasons for any approval withdrawal.

19. Standard operating procedure followed by the committee for vulnerable population

The committee will give special consideration to the proposals involving vulnerable population for protecting the right and welfare of vulnerable subjects. Potentially vulnerable groups may include.

- Medical, pharmacy, dental and nursing student, subordinate hospital and laboratory personnel, employees of the pharmaceutical company.
- Members of the armed forces and persons kept in detention
- Unemployed or impoverished person
- Patients with in curable diseases
- Patients in emergency situation
- Ethnic or racial minority groups
- Homeless persons, nomads, refugee
- Pregnant women, foetus and neonates
- Decisionally in capacitated

- The committee will include representation in selected vulnerable population if additional expertise is needed in reviewing and approving the proposed research that involves vulnerable subjects. The committee may work with these participants, to be part of the review process. The documentation for the same will be maintained.
- The committee will follow the applicable regulation and guidelines in reviewing the research that involves vulnerable population as research subjects.
- The Committee will ensure that adequate justification for the involvement of vulnerable subject is provided in the protocol and other pertaining document wherever applicable.
- The new study submission including vulnerable groups as potential research participants will be reviewed by the full board meeting and cannot be reviewing under expedited procedures.
- Subsequent review of amendment and continuing review applications involving vulnerable group as potential research participants can be reviewed by expedited review procedures.

20. Policy to monitor and prevent the conflict of interest

- During the appointment of members, one of the conditions is “To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any at appropriate time”.
- The member will be signing the consent letter after going through the terms and conditions in the appointment letter.
- The conflict of interest policy of the MDC-IEC will be explained to the members on induction. It will be a part of the trainings imparted to the members

Types of Conflict of Interest (COI):

Personal COI:

If the investigator of a research proposal has close and immediate family relationship with the member of MDC-IEC (spouse, son/daughter, parents, sibling, dependent) ; If the MDC-IEC member is a collaborator, Principal investigator, co-investigator, financer, research staff, consultant for a research proposal which has come for review in MDC-IEC.

If a research proposal is submitted by a departmental colleague with whom the member has conflict of interest (dispute, bias, any benefits, etc.) if applicable and if the member feels there is a conflict of interest.

Professional COI:

If the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor of the funding agency sponsoring the research.

Financial COI:

If the IEC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g., consulting fees or honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

Procedure for Declaring COI:

- The IEC member should identify the COI whenever a research proposal is assigned to him/her for the review. The COI should be declared in the format provided in SOP of MDC-IEC, and submitted to the member secretary.
- The IEC members should not participate in discussing, or decision making on research proposals‟ applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC.
- If an IEC member has a COI for review outside a meeting (e.g., the expedited procedure/ amendments), he or she should notify the IEC Member Secretary and return the documents.
- If an IEC member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the IEC Member Secretary so that the review is reassigned to other members.
- If an IEC member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IEC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed
- The IEC member who declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence.
- If an IEC member finds that he/she has a COI during the conduct of a research project approved by IEC, he/she shall report the conflict to the IEC at the next IEC meeting.
- At the beginning of each meeting, the MDC-IEC Chairperson asks the members to disclose any COI concerning any of the items on the agenda.
- During the meeting, IEC member having conflict discloses the existence of the conflict just before the review of the relevant item begins.

- If the Chairperson has a conflict of interest for a particular project, this should be so declared and handled like any other member‟s conflict is handled. An acting Chairperson should be appointed for discussion on such a project.
- When determination regarding existence of COI is uncertain, more information is gathered from relevant sources and determination is done by the IEC member with the help of the IEC Chairperson / Member Secretary or by IEC Chairperson / Member Secretary (as applicable)
- The IEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection. The IEC shall not approve a research study proposal where a COI is not managed or eliminated
- The declaration and management of COI should be recorded in the proceedings of the MDC-IEC meetings.

DECLARATION OF CONFLICT OF INTEREST FORM

Investigator/Sponsor / CRO

Protocol No.:

Protocol Title:

Sl No.	**Member's Name**	**Designation**	**Conflict of Interest declared**		**Signature and Date**
			Yes	**No**	

21. Commitments of ethical committee

- The Committee shall review and accord its approval to a clinical trial and also carry ongoing review of the trial at appropriate intervals, as specified in Schedule Y and Good Clinical Practice Guidelines for Clinical Trials in India and other applicable regulatory requirements for the safeguarding the rights, safety and well- being of the trial subjects.

- In case of any SAE occurring to the clinical trial subjects during the clinical trial, the Committee shall analyse and forward its opinion as per procedures specified under APPENDIX XII of Schedule Y
- The Committee shall allow inspectors or officials authorized by the Central Drugs Standard Control Organization (CDSCO) to enter its premises to inspect any record, data or any document related to clinical trial and provide adequate replies to any query by such inspectors or officials, as the case may be, in relation to the conduct of clinical trial.
- The Committee shall agree to maintain adequate and accurate record after the completion or termination of the study for not less than five years from the date of completion or termination of the trial (both in hard and softcopies).

22. Compensation and Insurance

As per ICMR and national rules, the IEC will ensure that all interventional studies have insurance or indemnity covering participants. The compensation policy must comply with New Drugs & Clinical Trials Rules (2019) and ICMR guidelines. The SOP should specify the mechanism and formula for calculating compensation (as per government guidelines). For non-trial biomedical research, an institutional fund or insurance may be arranged to compensate study-related injuries as decided by the IEC. Participants and LARs must be informed of compensation provisions during consent.

23. Training and Capacity Building

All IEC members and staff should receive **initial and ongoing training** in ethics and SOPs. The institution should facilitate workshops or courses on research ethics, GCP, and IEC procedures. Investigators and research staff should also be trained in ethical conduct, informed consent processes, and privacy protections. Records of all such training (member induction, continuing education) should be maintained. The IEC should review its own performance and update practices regularly.

Policy regarding training of new and existing members

- The Chairperson will identify the training requirements of the Committee members.
- The Chairperson and the Member Secretary will organize at least one workshop or training program for the Committee member's every year.

- The type of programs, areas for training and mentors for these workshops / training programs will be decided by the Chairperson in consultation with the Committee members.

24. Record-Keeping and Archiving

According to ICMR SOPs, the IEC must maintain comprehensive records of all activities: agendas, minutes, attendance, correspondence, decisions (approval letters, annual reports), and documentation of member qualifications and COI forms (Table 4.4 in ICMR shows examples). Specific rules:

- **Documentation:** Every document (letter, memo, decision) is dated and filed. Confidentiality is maintained in storage and retrieval by authorised personnel only.
- **Archiving:** Active (open) and inactive (closed) files should be clearly labelled and archived separately. Hard and electronic copies may be kept. The minimum retention is **3 years after study completion** (5 years for regulated clinical trials). Archives should be secure and accessible for audits. The IEC SOP must detail archiving/retrieval processes.
- **Accessibility:** IEC records should be made available to institutional or regulatory inspectors upon request (e.g. ICMR monitors, CDSCO auditors). Investigators must also maintain their study records (source data, consent forms, logs) for the same duration as the IEC records.
- **Data Retention:** Raw research data should be retained as per institutional and legal requirements (typically minimum 3–5 years). The SOP should indicate a schedule for periodic cleanup if allowed.

Records Retention

- The Committee will retain the following records;
- Standard Operating Procedures (SOPs) in effect at the time of review and the previous SOPs.
- Membership list at the time of review and the previous membership records.
- Occupation/ affiliations of the members at the time of review with CVs and training records of the members as well as CV of guest expert members.
- Invitation Letter, Consent Letter and CDA signed by members and guest expert members and Resignation Letters of the members who have resigned.
- Agenda of meetings, minutes of meetings and all correspondence with the Principal Investigator.

- Copies of all research proposals reviewed, scientific evaluation, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by the Investigators, reports of injuries to the subjects etc.
- Applicable regulatory guidelines.
- Registration details of the Ethics Committee.

Archival Policy

- The Committee reference study documents and other related documents will be archived for 5 (five) years after the completion of the study. And after 5 (five) years, the respective Principal Investigator / Sponsor/ CRO will be informed about the end of archival period and the documents will be returned or discarded as instructed by the respective authority.
- The Archival Log will be updated accordingly.
- The documents will be archived within a secure place in a locked cupboard with restricted access.
- The documents of the completed study can be archived at a separate facility and the details for the same will be maintained in the archive allog.

25. Monitoring, Audits and Non-Compliance Actions

The IEC will proactively oversee approved studies:

- **Continuing Review:** At least annually (more often if needed), the IEC reviews ongoing studies. Investigators must submit progress reports, safety reports, and final reports as required by IEC policy.
- **Site Monitoring:** The IEC may conduct site visits or request monitoring reports to verify compliance. Triggers for "for-cause" monitoring include: high protocol deviations, high SAE rates, participant complaints, non-compliance with IEC directives, or any media/adverse information.
- **Audits:** The institution may establish an independent audit mechanism. Non-compliance (e.g. data fabrication, consent violations) may lead to study suspension, investigator suspension, or notification of funding bodies/authorities.
- **Corrective Actions:** Minor protocol deviations should be corrected promptly by the researcher and reported. Serious violations should be reported to the IEC immediately. The IEC can impose sanctions (e.g. require retraining, halt recruitment, terminate the study) and

will document any actions taken. Persistent non-compliance can be referred to regulatory authorities (e.g. CDSCO, ICMR).

26. Review & request for revision of the existing SOP

- Any member of IEC or Investigator of MDC who notices any inconsistency or has any suggestion on how to improve a procedure should communicate through the Member Secretary/Chairman of the IEC.
- If IEC agree with the request then appropriate team will be designated by the Director MDC and Chairman of IEC, MDC to proceed with the revision process. If Committee does not agree the Member Secretary will inform the person who made the request for the decision.
- The Member Secretary will regularly prepare the amendment or addendum (if any) to the existing SOP to the approved discussion points in the IEC meetings.
- The Member Secretary will review the SOP at least every two years and incorporate the addendum and record the date of review in the SOP master file.

27. Community Engagement and Benefit Sharing

Consistent with ICMR guidance, community involvement and benefit-sharing are integral:

- **Engagement:** Researchers should engage relevant communities (or community advisory boards) before and during research to ensure cultural sensitivity and address community needs. Community members may be included as IEC invitees or members, but community permission *does not replace* individual consent.
- **Communication:** Study results and health benefits should be communicated back to the participant community as feasible. For example, at study end or via periodic updates, a lay summary of findings should be shared.
- **Benefit Sharing:** Participants and communities should receive appropriate benefits from the research outcomes. This may include access to interventions post-study, improvements in local healthcare (e.g. clinics, training), or broader health education. The research protocol must describe any post-trial access or benefits for participants (including controls). An a priori plan for post-trial provisions (drugs, care, infrastructure) should be made and approved by the IEC. In institutional projects with limited resources (e.g. student projects), efforts should still be made to minimise harm and support participants.

28. Implementation & distribution of SOP

The approved SOP will be implemented from the effective data and will be available in the Mamata Dental College website: https://mamatadentalcollege.com/ .

29. References to ICMR 2017 and Regulations

This SOP adheres to **ICMR (2017)** National Ethical Guidelines. Key clauses cited include:

- Chapter 4 (Ethical Review Procedures) for IEC composition, review, and record-keeping;
- Chapter 5 (Informed Consent) for consent requirements;
- Chapter 2 (General Issues) for confidentiality, community engagement and benefit sharing; and
- Chapter 7 (Clinical Trials) for SAE reporting and compensation.

Relevant Indian regulations are also complied with:

- **Drugs & Cosmetics Act (1940) and Rules (1945)** (Schedule Y) requirements for clinical trials. Note that per Rule 122DD of the Drugs Rules, any ethics committee reviewing clinical trial protocols must be registered with the CDSCO (DCGI) prior to review.
- WHO Operational guidelines for Ethical Review Committee that Review Biomedical Research (Geneva 2000) Available at: https://www.who.int/tdr/publications/documents/ethics.pdf
- International Conference on Harmonization, guidances on good clinical practice (ICHGCP) (1996). Available at https://www.ich.org/LOB/media!MEDIA482.pdf
- ICMR Ethical Guidelines for Biomedical Research on Human participants, ICMR (2018) Available at: https://ethics.ncdirindia.org/asset/pdf/Handbook_on_ICMR_Ethical_Guidelines.pd

ANNEXURES

APPOINTMENT PROPOSAL LETTER

Dr/Mr/Mrs……

Address: ……...

Sub: Constitution of MDC-IEC

Dear Sir /Madam,

As a part of the constitution of MDC-IEC, I am pleased to appoint you as the Chairperson/Member Secretary/member of MDC-IEC for the next 3 years, effective from ……..

A detailed appointment letter will be issued once I receive acceptance letter from you. I request you to submit your recently updated, signed CV along with certificates of training on GCP, Bioethics and guidelines on biomedical and health science research.

With Regards

Principal,

MDC.

ACCEPTANCE OF APPOINTMENT AS A MEMBER OF MDC-IEC

To
The Principal,
MDC, Khammam

Dear Sir/Madam,

Sub : Acceptance of Appointment as a Member of MDC-IEC

Ref : Your Proposal Letter No. , Dated. …….

I am thankful to you for appointing me as a member of MDC-IEC with effects from……I here with accept my appointment.
I am ready to undergo regular training on good clinical practice, ethical guidelines on biomedical and health science research and bioethics as required. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain the entire research project related information confidential. I shall sign the confidentiality agreement, and shall declare conflict of interest if any as and when applicable
I am submitting my recently updated, signed CV and certificates of training as requested by you. Thanking You,
Yours Sincerely,

Signature :
Name :
Designation and Department/Affiliations:
Date :
Place :

APPOINTMENT LETTER : MEMBER

To :

Sub : Appointment as member of MDC-IEC.

Category : Basic Medical Scientist/Clinician/Theologian/Social Scientist/Lay Person/ Legal Expert Dear Sir/ Madam, I am pleased to select you as a member of MDC-IEC with effect from ----------as a member of the committee, you will have tenure of 3 years.

You will be receiving an honorarium of Rs------- per sitting for the services rendered by you.

I request you to kindly extend your co operation to the Chairperson and Member Secretary of MDC- IEC, in effective and efficient functioning of MDC-IEC

Please find the enclosed terms and conditions of your appointment, roles and responsibilities.

You will be issued a copy of the policies and standard operating procedures of MDC-IEC once you sign the consent letter and confidentiality agreement.

Congratulations and all the best.

With Regards,

Principal,

MDC.

Terms and Conditions of appointment, and Roles and Responsibilities of Member, MDC-IEC

1. You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the MDC-IEC
2. You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain
3. Be willing to sign a confidentiality agreement , and to maintain confidentiality of the documents and deliberations of ethics committee meetings
4. To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and initial review and final review of research proposals .
5. As a member of MDC-IEC you need to do initial review, final review of research proposals and evaluate progress reports and final reports . You need to participate in onsite monitoring visits and review of serious adverse events as and when required. You are required to attend regular as well as emergency meetings of MDC-IEC. You are expected to participate actively in all discussions and deliberations of MDC-IEC.
6. You shall not keep any literature or study related documents with you after the discussion and final review
7. Willing to undergo training or update programs on relevant guidelines and regulations, research ethics, and good clinical practice during the tenure as ethics committee member
8. As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.
9. One month notice on either side will be necessary prior to resignation/termination of appointment.

The Details of the roles and responsibilities of a member of MDC-IEC are mentioned in the policies and standard operating procedures of MDC-IEC.

APPOINTMENT LETTER: CHAIRPERSON

To :

Sir/Madam,

I am pleased to appoint you as the Chairperson of MDC-IEC with effect from ------- You will have tenure of 3 years from the date of appointment.

As head of the institution, I assure you that MDC-IEC will be provided with all required infrastructure and facilities required for its effective functioning. The ethics committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution.

You will be receiving an honorarium of Rs. ----- per sitting for the services rendered by you.

Please find the enclosed terms and conditions of your appointment, roles and responsibilities. I request your services in the effective and efficient functioning of MDC-IEC

Congratulations and all the best

With Regards,

Principal,

MDC.

Terms and Conditions of appointment, and Roles and Responsibilities of Chairperson, MDC-IEC

1. As Chairperson of MDC-IEC you are required to finalise the revision of SOP of MDC-IEC in coordination with the Member Secretary, and you will be final approval authority for SOPs.
2. You shall maintain high ethical standards and should not be unduly influenced during while performing assigned roles in the MDC-IEC
3. You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain
4. Be willing to sign a confidentiality agreement , and to maintain confidentiality of the documents and deliberations of ethics committee meetings
5. To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and initial review and final review of research proposals .
6. As Chairperson of MDC-IEC, you shall conduct the meetings of MDC-IEC and ensure active participation of all members in the discussions and deliberations.
7. You shall seek conflict of interest from members and ensure quorum and fair decision making
8. You are the authorized and responsible for handling of complaints against investigators, IEC members, conflict of interest issues and requests for use of IEC data
9. You are the authority and responsible for ratifying the minutes of meetings, to review serious adverse events with causality assessment.
10. You are the authority of MDC-IEC to discuss with members and recommend to the Secretary, MDC the disqualification of members (if required) before the completion of their term.
11. You need to do initial review, final review of research proposals and evaluate progress reports and final reports. You need to lead the IEC team for onsite monitoring visits
12. You shall not keep any literature or study related documents with you after the discussion and final review
13. Willing to undergo training or update programmes on relevant guidelines and regulations, research ethics ,and good clinical practice during your tenure in the MDC-IEC
14. As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.

15. One-month notice on either side will be necessary prior to resignation/termination of appointment.

The Details of the roles and responsibilities of Chairperson and members of MDC- IEC are mentioned in the policies and standard operating procedures of MDC-IEC.

APPOINTMENT LETTER: VICE CHAIRPERSON

To :

Sub : Appointment as Vice Chairperson of MDC-IEC

Dear Sir/Madam,

I am pleased to appoint you as the Vice Chairperson of MDC-IEC with effect from ----------You will have tenure of 3 years from the date of appointment.

As Vice Chairperson, you will be handling the roles and responsibilities of the Chairperson in his/her absence.

You are requested to refer to the policies and standard operating procedures of MDC-IEC.
I request your services in the effective and efficient functioning of MDC-IEC
Congratulations and all the best.

With Regards,

Principal,

MDC.

APPOINTMENT LETTER: MEMBER SECRETARY

To :

Sub : Appointment as Member Secretary of MDC-IEC

Dear Sir/Madam,

I am pleased to appoint you as the Member Secretary of MDC-IEC with effect from----------You will have a tenure of two years from the date of appointment.

As head of the institution, I assure you that MDC-IEC will be provided with all required infrastructure and facilities required for its effective functioning. The ethics committee will be independent in its functioning and decision making, without any undue influence from anybody including the authorities of the institution.

You will be receiving an honorarium of Rs. ----------per sitting for the services rendered by you.

Please find the enclosed terms and conditions of your appointment, roles and responsibilities. I request your services in the effective and efficient functioning of MDC-IEC.

Congratulations and all the best

With Regards,

Principal,

MDC.

Terms and Conditions of appointment, and Roles and Responsibilities of Member Secretary, MDC-IEC

1. As Member Secretary of MDC-IEC, you are required to do the needful for the revision of SOP of MDC-IEC in coordination with the Chairperson.
2. You shall maintain high ethical standards and should not be unduly influenced while performing assigned roles in the MDC-IEC
3. You should be willing to place your full name, profession and affiliation to the ethics committee in the public domain
4. Be willing to sign a confidentiality agreement , and to maintain confidentiality of the documents and deliberations of ethics committee meetings
5. To read, understand, accept and follow the conflict of interest policy of ethics committee, and declare conflict of interest if any during your appointment, and initial review and final review of research proposals .
6. As Member Secretary, you are required to organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review
7. To schedule IEC meetings, prepare the agenda and minutes
8. To organize IEC documentation, communication and archival
9. To arrange for training of IEC secretariat and members
10. To ensure that SOPs are updated as and when required
11. To ensure adherence of IEC functioning as per SOPs
12. To prepare for and respond to audits and inspections
13. To Ensure completeness of documentation at the time of receipt of protocols , and timely inclusion in the agenda for IEC review
14. To assess the need for exemption from review, expedited review or full review
15. You will be responsible for making communications on behalf of MDC-IEC, to investigators, members of MDC-IEC and sponsors.
16. You need to do initial review, final review of research proposals and evaluate progress reports and final reports. You need to lead the IEC team for onsite monitoring visits
17. You shall not keep any literature or study related documents with you after the discussion and final review

18. Willing to undergo training or update programmes on relevant guidelines and regulations, research ethics ,and good clinical practice during your tenure in the MDC-IEC
19. As per the policy of the committee, any member not attending three consecutive meetings will be replaced by another person of the same category in IEC. Any member showing any kind of professional misconduct will be terminated from membership.
20. One month notice on either side will be necessary prior to resignation/termination of appointment.

The Details of the roles and responsibilities of Member Secretary of MDC-IEC are mentioned in the policies and standard operating procedures of MDC-IEC

Consent Letter from Appointed Members

To:

Principal, MDC,

Khammam.

Sub : Consent to be the Chairperson/Vice Chairperson/Member Secretary/Member of MDC-IEC

Ref : Your letter No.....; Dated ..

Dear Sir/Madam,

In response to your letter, I give my consent to be the Chairperson/Vice Chairperson/Member Secretary/Member of MDC-IEC. I shall execute my roles and responsibilities as per the policies and standard operating procedures of MDC-IEC, and as mentioned in my appointment order. I shall maintain high ethical standards, and will not be unduly influenced in discharging my assigned work.

I will sign the confidentiality agreement during my induction. I am aware of the conflict of interest policy of MDC-IEC, and I will declare conflict of interest (if any) during my induction as a member, review of research proposals and decision making in MDC-IEC

Thanking You,

Yours Sincerely,

Signature:

Name :

Designation and Department/Affiliations:

Date :

Place :

Annexure- Confidentiality Agreement to be Signed By Member of MDC-IEC

In recognition of the fact, that I, Dr. B. Anuradha, Chairperson Institutional Ethics Committee, Mamata Dental College, Khammam.

((Member's name,)----------his/her position ----------on MDC-IEC and affiliation) herein referred to as the "undersigned", have been appointed as a member of the MDC-IEC and have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines.

The appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative neither of a home province, territory or community nor as a delegate of any organization.

The IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants and the undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This agreement encompasses any information deemed Confidential provided to the Undersigned in conjunction with the duties as a member of the MDC-IEC. All Confidential information (and any copies and notes thereof) shall remain the sole property of the MDC-IEC. The undersigned agrees to hold all confidential information in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review shall not be copied or retained.

I, ---------- (name of the IEC member) have read and accept the aforementioned conditions as explained in this Agreement.

Chairperson's Signature and Date

[The original (signed and dated Agreement) will be kept on file in the custody of the MDC-IEC. *A copy will be given to the Undersigned.]*

I acknowledge that I have received a copy of this Agreement signed by the MDC-IEC

Chairperson

Signature

Date

Annexure: Conflict of Interest Declaration Form

To:

Chairperson

MDC-IEC,

Dear Sir,

I am aware of the COI policy of MDC-IEC

I herewith declare my conflict of interest with regard to the following research proposal submitted to MDC-IEC for review.

Protocol No.

Study Title:

Name of Principal Investigator:

Type of COI (Personal/ Professional/Financial) and the Reason:

Hence, I stay away from reviewing this research proposal, any deliberations/discussions on this study, and refrain from any decision making.

Name and Signature of Member

Date :

Name and Signature of Chairperson:

Date :