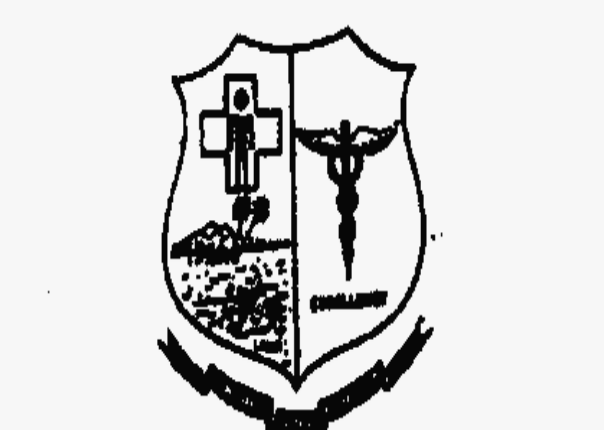
FMIEC POLICIES



POLICIES

Father Muller

Institutional Ethics Committee,

Father Muller Charitable Institutions,

Father Muller Road, Kankanady,

MANGALORE-575002.

Copy No :

Issued to :

FMIEC POLICIES

FMIEC : POLICIES

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Chairperson, FMIEC.

FMIEC POLICIES

Distribution List

Following are the Authorized Holders of Controlled Printed Version No. 2 of FMIEC POLICIES.

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1	Dr. Shalini Shenoy	Chairperson
2	Dr. Shivashankara A.R.	Member Secretary
3	Mrs. Anuradha Shetty	Member – Social Scientist and Vice Chairperson
4	Dr. Devina F.Rodrigues	Member – Nursing Expert; Joint Secretary
5	Dr. K.Shreedhara Avabratha	Member- Clinician
6	Dr. Nicole Pereira	Member- Basic Medical Scientist
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8	Fr. Roque Victor D'Sa	Member- Theologian/Ethicist
9	Mr. Sushanth F.Sequeira	Member – Legal Expert
10	Dr. Kurian PJ	Member – Homeopathy Expert
11	Dr. Vivek Sakthidharan	Member – Homeopathy Expert
12	Dr. Santhosh Kumar	Member – Speech and Hearing Expert

- Soft copy of the FMIEC POLICIES (PDF) is made available in website of Father Muller Charitable Institutions.
- FMIEC POLICIES copy (PDF) is issued to Principal investigators of Clinical Trials.
- Member Secretary of FMIEC is the custodian of the soft copy (MS word) and office copy (hard copy) of the FMIEC POLICIES.

FMIEC POLICIES

Amendment Record

Sl. No.	Date	Details of Amendment Done	Page No.	Reason for Amendment

FMIEC POLICIES

Table of Contents

F. Introduction to FMIEC

Father Muller Institutional Ethics Committee (FMIEC) reviews all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and wellbeing of all research participants before approving the research proposals. The FMIEC is primarily appointed to review and approve research protocols from Father Muller Homeopathic Medical College, Father Muller College of Nursing, Father Muller School of Nursing and Father Muller College of Speech and Hearing.

The FMIEC will ascertain whether all cardinal principles of research ethics viz. autonomy, beneficence, non-maleficence and justice are taken care in the research involving human participants. The FMIEC reviews all research projects to be conducted at the institution irrespective of whether the research project is funded or non-funded, and irrespective of funding agency.

The FMIEC adheres to existing applicable rules and regulations for its formation and functioning. The IEC follows ICMR guidelines of 2017, guidelines of Ministry of AYUSH and Indian GCP.

G. Goals and Objectives of FMIEC

Goals of FMIEC :

1) To ensure the safety of participants of research studies
2) To protect the rights, privacy and confidentiality of participants of research studies
3) To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs

Objectives of FMIEC:

1) To review the research proposals in an unbiased manner, without compromising the scientific quality, and ethical principles in conduct of biomedical, experimental and behavioral research
2) To advice and educate the researchers on ethical guidelines in conducting research involving human participants
3) To be updated with the relevant guidelines and regulations on research, research ethics and good clinical practice
4) To monitor the progress of approved research proposals with regard to compliance of protocol and ethical principles

FMIEC POLICIES

1. Policies and SOPs of FMIEC

The policies of FMIEC are defined in this document. The FMIEC has and follows written SOPs for its different functions as per applicable rules and regulations.

The Policy document is reviewed every year, and if necessary revisions are done. The Member Secretary is responsible for the review and updating of the Policy Document. Two or three members from the IEC will be in the Policy Review Team. Inputs from Head of the institution, the Chairperson of IEC and members will be taken. The Chairperson of IEC will verify the Policy document and is the Approving authority for the Policy Document.

The FMIEC members are trained on the policies and SOPs of FMIEC during their induction, and with every revision of these documents.

There is a SOP for the preparation and review of SOPs of FMIEC. (Refer to FMIEC SOP document; SOP-1).

2. Constitution of FMIEC

2.1. Appointment : The Director of Father Muller Charitable Institutions appoints the members of FMIEC including the Chairperson and Member Secretary based on their competence, experience and integrity. The members need to sign the consent letter and confidentiality agreement.

2.2. Administrative Support and Independence for Functioning : The management of Father Muller Charitable Institutions provides support to the ethics committee activities including infrastructure, secretariat staff, financial resources and training. The management does not interfere in the functioning of FMIEC including review, decision making and monitoring. No undue influence is exerted by the management of FMCI on the FMIEC. The FMIEC does not have the institutional head or any official of the institution holding administrative post in the management (Dean, Principal, Administrator, Vice Principal, Vice Dean) as its member.

2.3. Composition: The FMIEC will have 7 to 15 members, and is multidisciplinary and multisectorial. . The chairperson is from outside the institution and non-affiliated. Any current or retired employee of FMCI will not be the Chairperson of FMIEC. The Member

Secretary is from the Institution. The FMIEC will have one of the members as joint secretary. The members include at least two clinicians, one basic medical scientist, one legal expert , one social scientist, one lay person and one philosopher/theologian/ethicist. One of the members is selected as the Vice Chairperson. There is adequate gender representation. The Social Scientist, Philosopher/Theologian, Legal Expert and Lay Person will be non-affiliated to the institution.

2.4. Tenure : The members have tenure of two years. After the tenure, at least 1/3rd of the members retire and are replaced by members of the same category. The Chairperson, Member secretary and members could get maximum two consecutive terms. Any member showing professional misconduct and members with continuous absence from meeting s of FMIEC are terminated as and when such cases are found.

2.5. Subject Experts : Subject experts and representatives of vulnerable subjects are invited as required with prior invitation. This is to ensure that the scientific review is appropriate, approval of the research protocol meets the regulatory requirements and vulnerable population is protected from undue risk.

(For the detailed procedure of constitution of FMIEC refer to FMIEC SOP ; SOP-2)

3. Conflict of Interest and Confidentiality

3.1. The FMIEC members are informed about the conflict of interest policy during their appointment . In the consent letter for appointment, the members declare that they will disclose any conflict of interest, and will exempt himself / herself from the review process and decision making. During the meetings of FMIEC, the chairperson asks the members to declare conflict of interest if any, and reassesses the quorum when any member withdraws from the decision making. The declaration of conflict of interest is recorded in the minutes of the meetings. The FMIEC members are trained on the conflict of interest policy. (For detailed procedure of handling conflict of interest, refer to FMIEC SOP; SOP-3).

3.2. The members are informed about the need for maintaining confidentiality of all documents, discussions and deliberations during their appointment. The members and secretariat staff sign the confidentiality agreement. (Confidentiality agreement formats are given in FMIEC SOP; SOP-2).

4. Selection of Independent Consultants/Subject Experts

4.1. The Head of the Institution appoints independent consultants/subject experts. The subject experts sign the confidentiality agreement.

4.2. The FMIEC has the procedures in place for involving the subject experts as reviewers of research proposals. The subject experts will not have voting rights. For the research proposals categorized for expedited review, the subject expert does the review and submits the report to the FMIEC Member Secretary. For the proposals categorised under full review, the subject does the review and attends the meeting of full board of IEC.

4.3. The FMIEC has a subject expert panel including both affiliated and non-affiliated.

4.4. Representatives of vulnerable groups are invited for review in the research protocols involving vulnerable populations .

(Refer to FMIEC SOP; SOP-4).

5. Allowing Observers or Guests

The FMIEC has a mechanism to allow observers or guests to its office and meetings .The observers need to take prior permission, and sign an agreement of confidentiality (Refer to FMIEC SOP-5)

6. Submission of Documents for Review

The FMIEC has a documented procedure for guiding the investigators on submission of , documents to FMIEC for review. The submitted documents are scrutinized and categorized for review. The research protocol should be accompanied by protocol submission form, budget proposal, informed consent documents, permission from regulatory authorities and other documents as applicable. The investigator needs to submit the protocols at least ten days prior to the scheduled meeting of FMIEC (Refer to FMIEC SOP; SOP-6 for details).

7. Review Procedures

7.1. The FMIEC follows documented procedures for initial review of the research protocols and related documents. The proposals are reviewed as per applicable rules and regulations.

7.2. The proposals are categorized for review as : exempted from review, expedited review and full review. Research protocols with less than minimal risk are categorized as : exempted

from review. Research protocols with minimal risk are categorized for expedited review . Research protocols with more than minimal risk are categorized for full review.

7.3. The proposals and attached documents are sent to the members and subject experts at least once week before the scheduled meeting of FMIEC. Review forms are used to assess scientific validity and ethical issues, along with checklists for reviewing informed consent documents, clinical trial contract, budget, insurance agreement, and risk-benefit assessment. (Refer to FMIEC SOP ; SOP-7).

8. Meetings of FMIEC and Decision Making

8.1. The FMIEC meets once in a month once in two months on a fourth Saturday of the month. Additional meetings and emergency meetings are held if required.

8.2. The Member Secretary prepares the agenda for the meetings of FMIEC and circulated to all members at least one week prior to the scheduled IEC meeting.

8.3. The meetings are conducted by the Chairperson who ensures quorum. The FMIEC has well-defined criteria for quorum ; no decision is taken without the quorum. For review of each protocol the quorum of IEC should be atleast 5 members with basic medical scientist, clinician, legal expert, social scientist/philosopher and lay person. The chairperson or his/her designee should be present during the meeting.

8.4. The decision in FMIEC is based on risk assessment, scientific validity and adherence to ethical principles. Decisions are taken by consensus, as: approved, approved with suggestions, resubmit with revision or rejected. The decision of FMIEC is communicated to the principal investigator in writing.

8.5. Deliberations and decisions made during the meetings are documented, circulated to all IEC members, approved by the chairperson and maintained as minutes of meeting.
(Refer to FMIEC SOP ; SOP-8).

9. Continuing Review

The FMIEC does continuing review of research protocols to periodically monitor the progress of the study, to ensure continuous protection of the rights and welfare of research participants. Based on the reports submitted by the investigator and the discussions in the full

board meeting, FMIEC decides for continuation of the study, recommend for modifications, or discontinuation of the study. (Refer to FMIEC SOP ; SOP-9).

10. Review of Protocol Amendments and Resubmitted Documents

10.1. The FMMIEC reviews protocol amendments and resubmitted documents. Protocol amendments are categorized for expedited or full review. The resubmissions are categorized as exempted from review, expedited review or full review.

10.2. Review of amendments to the originally approved protocol, consent forms and investigator's brochure are done in formal meetings to evaluate the risk to trial subjects. The IEC evaluates all amendments to the approved protocol and assesses if there is an alteration in the risk benefit ratio. (Refer to FMIEC SOP ; SOP-10).

11. Monitoring the Research Protocols

11.1. The FMIEC has procedures in place for regular monitoring of all the proposals approved at the site . This is done by on-site monitoring, and review of source documents, the informed consent process, visit details, investigational product storage, case records of SAE management, monitoring reports from the sponsor, interview with investigator /site staff. The monitoring plan to oversight assures safety of subjects and compliance to applicable rules and regulations.

11.2. The on-site monitoring is done by a team of FMIEC members headed by the Chairperson. A checklist is used to record the observations.

11.3. The FMIEC has the authority to communicate and verify with the trial subjects.

11.4. For-cause assessments are conducted following non-compliance and/or complaints for the trials approved by FMIEC.

11.5. The FMIEC suggests any areas that need to be improved based on the findings of monitoring reports.

(Refer to FMIEC SOP; SOP-11).

12. Review of Protocol Deviations and Violations

12.1. The FMIEC reviews the protocol deviations and violations, evaluates them and takes appropriate actions as per rules and regulations.

12.2. The action on protocol deviations and violation is based on the nature and seriousness, frequency of deviations and violations in the study in the past, and frequency of deviation/ violation in previous studies conducted by the same PI/ Co-PI or in the same department.

12.3. Protocol deviations and violations are reviewed in the full board meeting of IEC. The decision could be : allowing the study to be continued , allowing the study with modifications and discontinuation of the ethical approval issued. (Refer to FMIEC SOP-12)

13. Review of Study Completion or Final Reports

The study completion report is expected from the investigator within 1 month of completion of the study at the site. The report is discussed in the full board meeting of IEC . The decision of IEC could be : a) noted / approved b) request for additional information / clarification .(Refer to FMIEC SOP-13).

14. Training of FMIEC Members

14.1. The members of FMIEC are trained with the SOP of FMIEC during the first one month of their induction. The members will get voting rights only after the completion of this induction training on SOP, GCP and relevant guidelines.

14.2. The FMIEC has the training schedule, and every member undergoes annual training on GCP, bioethics and guidelines for conduct of research on human participants. (Refer to FMIEC SOP-14).

15. Review of Serious Adverse Events

Serious adverse events are addressed, adequate medical care is provided and an appropriate reporting mechanism is followed as per applicable rules and regulations. The SAE subcommittee initially analyzes the SAE, prepares a report which is presented and discussed in the full board meeting of FMIEC. (Refer to FMIEC SOP-15).

16. Waiver of Consent

The FMIEC grants waiver of consent if the research cannot practically be carried out without the waiver and the waiver is scientifically justified; for retrospective studies, where the participants are de-identified or cannot be contacted; research on anonymized biological

samples/data; certain types of public health studies/surveillance programmes /programme evaluation studies; research on data available in the public domain; or research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.(Refer to FMIEC SOP-16).

17. Management of Premature Termination or Suspension of A Study :

The FMIEC reviews the reports of premature termination or suspension of a study, and communicates to the PI, after the meeting acknowledging the approval of termination/ letter seeking clarifications/information regarding the premature termination.(Refer to FMIEC SOP-17)

18. Review of Research Involving Vulnerable Populations

18.1. Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests and providing valid informed consent. They are the individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate.

18.2. The FMIEC allows research on vulnerable population .While reviewing the research proposals involving vulnerable populations, the FMIEC evaluates following aspects in addition to the aspects reviewed routinely. The protocol should be reviewed to assess if the following points are addressed: can the research be performed in any other non-vulnerable participants? ; Is there justification to use vulnerable population? ; Do the benefits justify the risks ; Are the participants selected equitably ; and Have the measures to protect Autonomy of the vulnerable population been described.

18.3. In addition to all members of the IEC, the Chairperson and Member Secretary include one or two experts who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. A representative of the vulnerable population also will be included. (Refer to FMIEC SOP-18)

19. Grievance Redressal Process :

The FMIEC has a grievance redressal mechanism in place. The FMIEC readily accepts complaints/grievances from participants, or gets the inputs from interviews with patients during the site monitoring. The patient information sheet has the contact numbers of Member Secretary and Chairperson of FMIEC, who could be contacted through e mail, telephone or direct walk-in meet . The complaints and concerns of participants are addressed and managed appropriately. (Refer to FMIEC SOP-19)

20. Record Keeping and Archival :

The FMIEC has a documented procedure for record keeping archival. Security, confidentiality and integrity of all proposals and associated documents is reviewed from time to time and administrative communication is maintained. Documentation is dated, filed and archived as per the SOP. Confidentiality is maintained during the archival and retrieval. The document storage has restricted access with pest-control and fire safety. (Refer to FMIEC SOP-20)

21. Financial Transparency :

There is financial transparency of the FMIEC activities and functioning. The FMIEC maintains financial records of honorarium payment to each of the members, and other expenses incurred. The Accounts Department maintains the records of these transactions. (Refer to FMIEC SOP-21)

22. Communications :

The FMIEC has a process for communication with all stake holders. The communication modes could be printed letters, e mail, or telephonic calls. The Chairperson does the communications to Head of the Institution and Regulatory authorities. He/she is also responsible for communicating to members in case of any queries on disciplinary grounds. The Member Secretary does most of the communications. He/she is responsible for communications to members of IEC and principal investigators. The effective communications within and by FMIEC assure co ordination between all research stake holders and with the regulatory authority. (Refer to FMIEC SOP-22)

FMIEC POLICIES

I. Rights and Responsibilities of Study Subjects (Research Participants)

Rights :

1. To be treated with respect and courtesy
2. To get adequate information on the research protocol : purpose, about the drug or device used in the study, risks, benefits, compensation for participating, compensation for any adverse events, and any other details of the study
3. To ask any questions on the research protocol
4. To get enough time to decide whether or not to participate in the research study, and to make that decision without any pressure from the people who are conducting the research
5. To be told about the other non-research treatment options available
6. To refuse to participate in the study or to stop participating in the study at any time once he/she starts participating
7. To get the necessary medical care even after withdrawing from the study
8. To be told who will have the access to the information or data collected from the participant, and confidentiality of the information/data
9. To be told about whom to contact for any information or queries about the research study
10. To be told about whom to contact in case of any complaint or grievance
11. To receive a copy of the informed consent form signed by him/her

Responsibilities:

1. To Respect investigators, research staff and other participants.
2. Completely read the patient information sheet and consent form, and ask the principal investigator any questions he/she may have. The subject should understand what will happen to him/her during the study before agreeing to participate.
3. Carefully weigh the risks and benefits when deciding whether to participate in the study.
4. Refrain from signing the consent document until he/she believes that he/she understands its content and feel comfortable with the decision to participate.
5. Follow directions for proper use, dosing and storage of self-administered study medications, providing biological samples, and preparing for tests, procedures or examinations.
6. Follow directions for abstaining from non-study-related medications, or other contraindicated medications or procedures.
7. Know when the study begins and ends. This is particularly important for an intervention trial that has a follow-up period after the intervention is completed.
8. Show up at scheduled appointments on time, and inform the staff within a reasonable time if he/she needs to reschedule an appointment.
9. Provide truthful answers to questions asked during screening/enrolment and during the study.
10. Inform staff if other medical care is needed while on the study.
11. Inform the staff if there are questions he/she would rather not answer.
12. Report pain, discomfort, nausea, dizziness and other problems and symptoms he/she experiences during the study.
13. Keep information about the study confidential, if asked to do so.
14. Keep staff informed when contact information (eg, phone number, address) changes.
15. If he/she decides to withdraw from the study, inform the staff and follow the procedures for withdrawal

References :

1. ICMR. National Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Indian Council of Medical Research: New Delhi; 2017.
2. FERCI. Standard Operating Procedures. Forum for Ethics Review Committees in India.