ST.TERESA'S COLLEGE (AUTONOMOUS)
Affiliated to Mahatma Gandhi University, Kottayam

ST. TERESA'S COLLEGE 100 By Thy Grace 1925-2025

46th RANK IN NIRF RANKING 2024

INSTITUTIONAL RESEARCH ETHICS POLICY (IREP)

1. PREAMBLE

St. Teresa's College (Autonomous), Ernakulam is dedicated to upholding the highest ethical standards in research, ensuring the dignity, rights, and welfare of all research participants while maintaining integrity across research processes. This policy provides a framework for the ethical review and monitoring of research, aligned with institutional and regulatory standards while maintaining a balance between research development and Ethical standards.

2. SCOPE OF THE POLICY

This policy applies to all research activities involving human participants conducted by faculty, students, and affiliated researchers at the institution. The scope extends across disciplines, including but not limited to the social sciences, behavioural and health sciences, interdisciplinary, transdisciplinary and multidisciplinary studies.

3. OBJECTIVES OF IREP

- Ensuring strict adherence to the policy, direct researchers to adhere to best practices relating to the ethical development, implementation and dissemination of research.
- Effective implementation of Standard Operating Procedure (SOP).
- Promote exemplary ethical standards in research and scholarly endeavors.
- Create a conducive environment for a better research ecosystem with action plans to support research activities.
- Uphold ethical research standards by ensuring compliance with the ethical code of conduct and preventing plagiarism.

4. INSTITUTIONAL RESEARCH

Institutional Research Ethics Committee (IREC): IREC at St.Teresa's College (Autonomous),Ernakulam is a independent review board or committee comprising of medical / scientific and non-medical / non-scientific members whose responsibility is to ensure that the researchers adhere to ethical standards and guidelines. Its primary objective is to safeguard the rights, dignity, safety and well-being of research participants, including humans and the environment. It includes multidisciplinary members, including subject experts who are competent to approve research protocols and resolves ethical dilemmas.

5. ETHICAL PRINCIPLES

5.1 Informed consent

Informed consent is a critical process ensuring autonomy, comprehension, and voluntary participation in any research or activity. It includes clear, comprehensive information about the purpose, procedures, risks, and benefits, especially for vulnerable populations requiring special consideration. Investigators must ensure that legally effective informed consent is obtained before enrolling or involving participants in any activity. This process respects individual rights and guarantees ethical compliance.

5.2 Beneficence

Beneficence emphasizes the ethical principle of doing no harm while maximizing possible benefits and minimizing potential harms. It requires balancing risks and benefits to ensure the well-being of participants, reflecting an obligation for researchers to act in the best interest of individuals.

5.3 Justice

Justice ensures fairness in the distribution of benefits and burdens of research. It advocates for equal treatment of individuals, considering factors such as individual needs, effort, societal contributions, and merit to determine who receives benefits or bears burdens equitably. These principles are central to ethical decision-making and safeguarding human dignity.

5.4 Non-maleficence

Non-maleficence focuses on minimizing risks to participants, implementing continuous monitoring, and ensuring research practices avoid causing harm.

5.5 Privacy and confidentiality

Privacy and confidentiality require obtaining informed consent from participants before collecting personal data. Personal information should only be shared with authorized individuals, and identifying details such as names, contact information, or medical records must be kept private and secure. Data should be anonymized or de-identified whenever possible to safeguard participants' identities.

5.6 Inclusivity and diversity

Inclusivity and diversity emphasize equal opportunities, fair representation, and respect. They

advocate for fair treatment of all individuals while minimizing harm and promoting an environment that values diverse perspectives.

5.7 Conflict of interest

Conflict of interest requires researchers to disclose any potential conflicts to relevant authorities. When conflicts arise, researchers may need to recuse themselves from certain decisions to maintain impartiality. Independent oversight ensures that conflicts are reviewed and managed objectively.

6. ETHICAL CLEARANCE

Ethics Committees across the country reviewing Biomedical and Health research needs to abide by the “New Drugs and Clinical Trials Rules 2019” and be registered with DHR. According to Chapter IV, it is also mandatory to follow the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 for conduct and review of Biomedical and Health Research.

Post graduate research topics should be screened at Department level by the HOD and the concerned project guides for IREC clearance, if any aspect of research requires ethical clearance. If the topic has biomedical aspects, drug testing or animal studies, the PG students/research scholars should be directed to obtain clearance from a DHR/CDSCO/Veterinary University registered Institutional Ethics Committee (IEC)and the copy of the certificate should be submitted to the IREC of St.Teresa’s College(Autonomous) for documentation.

7. COMPLIANCE WITH REGULATORY STANDARDS

This Institutional Research Ethics Policy (IREP)strictly adheres to:

ICMR's Ethical Guidelines for Biomedical Research 2017 , New Drugs and Clinical Trials Rules 2019, UGC's Academic Integrity and Plagiarism Regulations, APA guideline of Social Sciences, Central Drug Standard Control Organisation, ICMR Dietary guidelines for Indians 2024 , Ethical guidelines for application of Artificial Intelligence in Biomedical Research and Healthcare 2023,Hazardous waste management rules 2016 , Belmont report -Ethical Principles and Guidelines for the Protection of Human Subjects of Research , WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Participants , International council for harmonisation of technical requirements for pharmaceuticals for human use (ICH) , Guidelines for the Safety Assessment of Foods Derived from Genetically Engineered Plants – 2008 , Guidelines and SOPs for CFT of Regulated GE Plants – 2008 , Protocols for Food and Feed Safety Assessment of GE crops – 2008 , ,Guidelines on Similar Biologics, 2016 ,Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017 ,Guidelines of CPCSEA for Reuse/ Rehabilitation of Large Animals post experimentation 2020.

8. RESEARCH MISCONDUCT

Research misconduct involves fabrication, falsification and plagiarism of data, which are serious issues both nationally and internationally. Research misconduct, if suspected, needs to be investigated. IREC must investigate all allegations of misconduct as present or future participants' lives may be endangered if facts are not presented accurately. Such investigations must be done in a timely, fair and transparent manner and the results should be made available in the public domain.

8.1 Types of research misconduct

Falsification: Falsification is manipulating research materials, equipment or processes, or changing or omitting/ suppressing data or results without scientific or statistical justification, such that the research is not accurately represented in the research record.

Plagiarism: Plagiarism is the "wrongful appropriation" and "stealing and publication" of another paper or another author's "language, thoughts, ideas, or expressions" and the representation of them as one's own original work or duplicating one's own publication (self-plagiarism).

Cheating: Cheating is the use or attempt to use of any unauthorized assistance in any academic exercise. Impeding fair and equal access to the educational and research process including tampering with, damaging and impeding access to academic resources.

Misrepresentation: Misrepresentation includes falsifying, misusing, or tampering with information such as test scores, transcripts, letters of recommendation or other materials required for admission to and continued enrolment and access in the University's programs or facilities.

9. ROLES AND RESPONSIBILITIES OF IREC

The basic responsibility of Institutional Research Ethics Committee (IREC) is to ensure a competent review of all ethical aspects of the project proposals received by it in an objective manner. IREC will provide advice to the researchers on all aspects of the welfare and safety of the research participants after ensuring the scientific soundness of the proposed research . The scientific evaluation will ensure technical appropriateness of the proposed study.

- The IREC will hold annual meeting to review research proposals, ensuring adherence to research ethics guidelines and approving the ethical aspects of researchers' work.
- To protect the dignity, rights and well-being of the potential research participants.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To assist in the development and the education of a research community responsive to local health care requirements.
- Researchers must submit progress reports to the IREC upon request. IREC may conduct audits or inspections for compliance.

10. COMPOSITION OF IREC

IREC is a multi-disciplinary and multi-sectoral committee.

- There should be adequate representation of age and gender.
- Preferably 50% of the members should be non-affiliated or from outside the institution.

- The number of members in an EC should preferably be between seven and fifteen and a minimum of five members should be present to meet the quorum requirements.
- The IREC should have a balance between medical and non-medical members/technical and non-technical members, depending upon the needs of the institution.

The composition of IREC will be as follows: -

- Chairperson
- Vice chairperson
- One - two persons from basic medical science area (Subject experts)
- One - two clinicians from various Institutes (Subject experts)
- One legal expert
- One social scientist / representative of non-governmental voluntary agency
- One representative from the local community
- Principal
- IQAC (Institutional Quality Assurance Cell) Coordinator.
- TRACC(Teresian Research and Consultancy Cell) Coordinator
- Member Secretary /Alternate Member Secretary

11. DECISION MAKING PROCESS

- The decision must be taken by a broad consensus after the quorum requirements are fulfilled to recommend / reject / suggest modification for a repeat review or advice appropriate steps. The Member Secretary should communicate the decision in writing to the Principal Investigator (PI).
- If a member has conflict-of-interest (COI) involving a project then s/he should submit this in writing to the chairperson before the review meeting, and it should also be recorded in the minutes.
- If one of the members has her/his own proposal for review or has any COI then s/he should withdraw from the IREC while the project is being discussed.
- A negative decision should always be supported by clearly defined reason.

- The discontinuation of a trial should be ordered if the IEC finds that the goals of the trial have been compromised, are no longer achievable, or if the risks outweigh the potential benefits to the participants
- In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.

12. TRAINING

The IREC members should be encouraged to keep abreast of all national and international developments in ethics through orientation courses on related topics by its own members or regular training organized by constituted bodies so that they become aware of their role and responsibilities.

13. GRIEVANCE REDRESSAL COMMITTEE

The Principal shall set up a committee to address any grievances against the functioning or decisions of the IREC. The committee shall consist of Dean of Research and one other member, who may be an external member, if required, appointed by the Principal, who has experience of conducting research, administering projects and/or being part of juries of research committees.

ADDITIONAL GUIDELINES

1. Training in Research Ethics for Research Guides, Faculty,Research Scholars and PG students: Training sessions on research ethics will be conducted (Plagiarism/ethical guidelines).

2. Policy Updates: The IREC will periodically review and update the policy to reflect evolving ethical standards and regulatory changes.

14. STANDARD OPERATING PROCEDURES (SOP) FOR THE INSTITUTIONAL RESEARCH ETHICS COMMITTEE (IREC)

14.1 Roles and responsibilities of individual members in IREC

Role	Responsibilities
Chairperson	Conduct IREC meetings, ensure quorum, and oversee decision-making..
Vice Chairperson	Handle complaints and ensure impartial reviews
Subject Experts	Evaluate scientific design, benefit-risk analysis, and overall ethical soundness of the proposal.
Legal Expert	Ensure compliance with regulatory and legal requirements, including informed consent and contracts.
Social Scientist/Philosopher	Assess cultural, societal, and ethical implications of the proposed research.
Community Representative	Provide participant perspectives and ensure risks and benefits are clearly communicated.
Member Secretary/Alternate Member Secretary	Organize proposal reviews, document management, training, and ensure adherence to SOPs.

Application procedures:

1. All proposals should be submitted on any working day 2 weeks in advance of scheduled meeting in the prescribed application form.

2.All relevant documents should be enclosed with application form.

3.Required number of copies of the proposal along with the application and documents in prescribed format duly signed by student, research scholar, Guide & HOD. In the case of projects the Principal Investigator (PI) and Co-investigators shall be guided to the Chairperson of IREC

4.Every application will be allotted an IEC registration number to be used for all future correspondence and reference. The date of IREC meeting will be intimated to the applicant to make a brief presentation of the proposal and to clarify the points raised by the members.

5.The decision of the committee on the proposal will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

6.All research proposals will be charged an administrative fee/ processing fee as specified by IREC.