



INSTITUTIONAL CODE OF ETHICS



ST. GREGORIOS DENTAL COLLEGE

UNDER THE MANAGEMENT OF MJSCE TRUST, PUTHENCRUZ
CHELAD, KOTHAMANGALAM, ERNAKULAM DIST, KERALA- 686681
(AFFILIATED TO KERALA UNIVERSITY OF HEALTH SCIENCES)

INTRODUCTION

St Gregorios Dental College, Kothamangalam, Ernakulam Dist, India (SGDC) is, established for the purpose of Dental education, research, and patient care especially in the state of Kerala. The college caters to UG courses, PG courses and patient care. One of the primary objectives of the Institute is to cater to research in various aspects of Dental sciences involving human subjects by ensuring ethical practices by the researchers.

THE CODE OF ETHICS

All research principles are guided by the declaration of Helsinki, on the basis of Good Clinical Research Practices (GCP) adopted by the International Conference on Harmonization (ICH) and The Indian Council of Medical Research (ICMR) issued ethical guidelines for research on human subjects. This also forms a part of GCP guidelines issued by the Central Drug Standard Control Organization (CDSCO) of the Ministry of Health, Government of India.

The conduct of Human research needs to strictly adhere to the four ethical principles of Justice, Confidentiality, To do no harm and Truthfulness. This code is strictly adhered to by all researchers and research activities within the institution.

SCOPE

The institutional ethics committee ensures:

1. To protect the right, safety and well-being of the research subject and assist in welfare and benefit the society.
2. To review the qualifications of all investigators participating in the proposed research study.
3. To keep all information submitted to them confidential especially, the proprietary information.
4. To review all research proposals submitted to the committee within the specified time limits.
5. To review the progress of each research project at appropriate and specified intervals and review the summary of the final report of the study.



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CONSTITUTION AND COMPOSITION OF INSTITUTIONAL ETHICS COMMITTEE

IEC should be constituted in the following pattern and shall be multidisciplinary and multi-sectoral in composition.

- i). A Chairperson
- ii). A Member Secretary,
- iii). 6- 8 members from different Departments /Specialties/ disciplines or areas

- iv) The external members shall be in majority to ensure the independence of the committee
- v) The Chairman should necessarily be from an outside Institute. Member Secretary should be from the Institute and willing to work as an Ethics Committee Member.
- vi) The period of Membership will be three years, or until they cease to be members either at their own request or by a decision of the other Committee members.
- vii) At the end of 3 years, the committee is to be reconstituted, and 50% of the members will be replaced
- viii) Members should maintain confidentiality of all discussions during the meeting and sign a confidentiality agreement at the start of their term.

MEMBERSHIP REQUIREMENTS

All members should fulfill the eligibility criteria as mentioned in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants-2017 and COSCO guidelines

I). Chairperson/ Vice Chairperson - Non-affiliated member

A well-respected person from any background with prior experience of having served/ serving in an EC.

ii). Member Secretary/ Alternate Member Secretary-Affiliated member,

Should be a staff member of the institution and have knowledge and experience in clinical research and ethics, be motivated and have good communication skills. He should be able to devote adequate time for this activity under protection of the institution/ college.

iii). Basic Medical Scientist(s) - Non-affiliated/ Affiliated member

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Non-medical or medical person with qualifications in basic medical sciences preferably be a pharmacist

iv) Clinician(s) - Non-affiliated/ Affiliated member

An individual/s with recognized medical/dental qualification, expertise, and training

v) Legal expert/s - Non-affiliated member

Should have a basic degree in Law from a recognized university, with experience, if possible, have training in medical law.

vi) social scientist/ philosopher/ ethicist/theologian - Non-affiliated/ Affiliated member

An individual with social/ behavioral science/ philosophy/religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities

vii) Lay person(s)/Educated person from Community-

Literate person from the public or community and not pursued a medical science or health related career in the last Seven years. May be a representative of the community from which the participants are to be drawn and aware of the local language, cultural and moral values of the community. involvement in social and community welfare activities is desirable.

Submission of the Research Proposals

1. All communications with the Committee will be in writing (Physical or electronic)
2. Before receiving the review materials, it is advisable to obtain COI (conflict of interest) declaration and CA (Confidentiality Agreement) from the Member Secretary, Chairperson & Members.
3. 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
 - c) Written information to be provided to the subjects, if applicable
 - d) Investigator's Brochure (IB).
 - e) Undertaking by Investigator.
 - f) Subject recruitment procedures, if applicable.



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- g) Available safety information.
- h) Investigator's current Curriculum Vitae indicating qualification and experience.
- i) Approval from competent regulatory authorities.