



Royal Dental College

Affiliated to Kerala University of Health Sciences, Thrissur, Kerala
Recognised by Ministry of Health & Family Welfare, Govt. of India

Iron Hills, Chalissery, Palakkad, Kerala - 679536



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3.3.1 The Institution ensures implementation of its stated Code of Ethics for research. The Institution has a stated Code of Ethics for research, the implementation of which is ensured by the following:

- 1. There is an Institutional ethics committee which oversees the implementation of all research projects**
- 2. All the projects including student project work are subjected to the Institutional ethics committee clearance**
- 3. The Institution has plagiarism check software based on the Institutional policy**
- 4. Norms and guidelines for research ethics and publication guidelines are followed**

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CERTIFICATE OF THE HEAD OF INSTITUTION



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Dr. E. ANURADHA SUNIL, MDS, PGDHHM.,

PRINCIPAL

TO WHOMSOEVER IT MAY CONCERN

This is to certify that the Institution ensures implementation of its stated Code of Ethics for research. The Institution has a stated Code of Ethics for research, the implementation of which is ensured by the following:

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CODE OF ETHICS



CODE OF ETHICS OF RESEARCH

- The Institution Ethics Committee (IEC) must draught a constitution and standard operating procedures, as well as terms and conditions for member appointments, resignations, and quorum requirements.
- To protect the study subjects' rights, safety, and well-being, the IEC will assess the research protocol and Good Clinical Practice (GCP) guidelines.
- In the event of any undesirable incidents, the IEC will investigate and provide its view.
- It will allow Department of Health Research inspectors and officials to enter its premises to inspect any record, data, or document relevant to clinical trials, as well as respond to any questions.
- The committee must keep all clinical trial documentation for at least five years after the trial is completed.
- The registration is valid for two years. In the event that the composition of the committee changes, it must notify the relevant authorities in writing.
- If there are any problems in the registration, the licencing authority has the ability to cancel it.
- The committee shall have a minimum of 7 and a maximum of 15 members, including the chairperson, one member secretary, a basic scientist, clinician, legal expert, social scientist, and a layperson from outside the institution.
- The committee must have a quorum of at least 5 members.
- The members of the committee and the primary investigator should be well-versed in GCP rules.
- There should be no conflicts of interest in the protocol decision-making. The same declaration should be made by all members.
- The committee will invite experts to provide expert opinions on the subject. The invitees will not be involved in any decision-making.



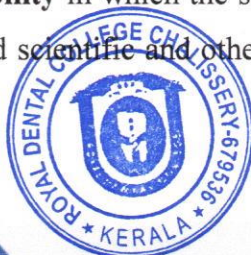

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RESPONSIBILITIES OF ETHICS COMMITTEE

- **Principle of essentiality** states that the involvement of human participants is required for the planned research after careful examination of all alternatives in light of existing knowledge.
- **Principle of voluntariness** ensures that participants' rights are protected through the informed consent procedure
- **Principle of non-exploitation** states that research volunteers should be chosen equally so that the advantages and burdens of the study are spread properly and without discrimination. There should be adequate measures in place to protect vulnerable groups.
- **Principle of social responsibility** - The research is organised and carried out in such a way that social and historic divisions are not created or deepened, and social harmony in community connections is not disturbed in any way.
- **Principle of ensuring privacy and confidentiality** states that in order to protect the privacy of potential participants, their identities and data are kept private, and access is restricted to only those authorities who need it.
- **Principle of risk minimization** states that all stakeholders should take reasonable precautions at all stages of the research to guarantee that risks are reduced and that appropriate care and compensation are provided in the event of adverse outcomes.
- **Principle of professional competence** according to which the research is organised, carried out, assessed, and supervised throughout by people who are competent and have the necessary qualifications, experience, and/or training.
- **Principle of maximization of benefit** states that all efforts should be made to design and execute research in such a way that the advantages to study participants and/or society are maximised directly or indirectly.
- **Principle of institutional arrangements** in which the institutions conducting the research have policies for adequate research governance and accept responsibility for facilitating research by providing necessary facilities, manpower, money, and training opportunities.
- **Principle of transparency and accountability** in which the study strategy and outcomes are made public through registries, reports, and scientific and other publications while respecting the participants' right to privacy.



[Signature]
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- **Principle of totality of responsibility** states that all stakeholders in a research project are responsible for their activities. All stakeholders, directly or indirectly, are bound by professional, social, and moral responsibilities in accordance with ethical norms and relevant rules.
- **Principle of environmental protection** in which researchers are responsible for ensuring environmental and resource protection throughout the study process, in accordance with existing rules and regulations.



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