KMCT DENTAL COLLEGE

CODE OF ETHICS

(Revised)

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TABLE OF CONTENTS

S.NO	CONTENTS	Page. No
1	Introduction	4
2	Purpose	4
3	General principles	5
4	Responsible conduct of research	6
	i) Ethical consideration in collaborative research	7
	ii) Informed consent process	8
	iii) Vulnerable population	9
	iv) Conflict of interest	11
5	Policies for clinical trials of drugs and other interventions	12
6	Public health research & social and behavioural sciences research for health	13
7	Biological materials, bio banking and datasets	14
8	Research during humanitarian emergencies and disasters	14
9	Intellectual property	14
10	Peer review	14
11	Responsible authorship and publication of research	15
12	Plagiarism Policy	15
13	Research misconduct and policies	16
14	Training of EC members	17

INTRODUCTION

The field of research in India is witnessing an exponential growth in the last few years. The lacuna of Indian contribution to international scientific literature is probably a skewed understanding of research. Research and scientific knowledge impart a great impact on the economic and societal development. Science and innovation are being devised and promoted at the institution and forms one of the missions of our college. The primary motive of research is to produce new knowledge or find new ways of making the existing knowledge available among our research scholars.

This Code of Ethics in Research sets forth general principles of ethical conduct to guide the scholars towards the highest ideals of scholarly research. This applies to all members of the KMCT dental college and hospital, Calicut, India. The general principles and policies which are followed by the college are in accordance with National ethical guidelines for biomedical and health research involving human participant, 2017. Thus, the principles are stated broadly to be applied to faculty, PhD scholars, post graduate students and undergraduate students in various disciplines depending on the context of the researcher.

PURPOSE

The Code of Ethics for Institutional Research aims at developing the ethical principles and standards that will guide the Work of institutional researchers. All researchers are liable to follow appropriate ethical, legal, and professional frameworks under the code of conduct and ethics of KMCT Dental college.

The purpose of research carried out should be:

- Directed towards enhancing the knowledge about the human condition while maintaining sensitivity to the Indian cultural, social, and natural environment.
- Conducted under conditions such that no person or persons become mere means for the betterment of others and that human beings who are participating in any biomedical and/ or health research or scientific experimentation are dealt with in a manner conducive to and consistent with their dignity and well-being, under conditions of professional fair treatment and transparency; and
- Subjected to a regime of evaluation at all stages of the research, such as design, conduct and reporting of the results thereof.

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GENERAL PRINCIPLES

For the conduct of health research, the four basic ethical principles namely, respect for persons (autonomy), beneficence, non-maleficence and justice have been enunciated for protecting the dignity, rights, safety and well-being of research participants.

These 10 general principles described below are to be applied to all scientific research for health involving human participants, their biological material and data.

1. **Principle of essentiality**

   The need to use human participants will be duly vetted by the Ethics Committee (EC) independent of the proposed research.

2. **Principle of voluntariness**

   Respect for the right of the participant to agree or not to agree to participate in research, or to withdraw from research at any time, is assured by the informed consent process which will ensure that participants rights are safeguarded.

3. **Principle of non-exploitation**

   Research participants must be equitably selected so that the benefits and burdens of the research are distributed fairly and without arbitrariness or discrimination. Sufficient safeguards to protect vulnerable groups will be ensured.

4. **Principle of social responsibility**

   The research must be planned and conducted so as to avoid creation or deepening of social and historical divisions or in any way disturb social harmony in the community relationship.

5. **Principle of ensuring privacy and confidentiality**

   To maintain privacy of the potential participants, her/his identity and records will be kept confidential and access is limited to only those authorized as per the court of law. Privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons with the consent of ethical committee.

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6. **Principle of risk minimization**

   Due care will be taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.

7. **Principle of professional competence**

   The research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriateand relevant qualification, experience and/or training.

8. **Principle of maximization of benefit**

   Due care will be taken to design and conductthe research in such a way as to maximize the benefits directly or indirectly to the research participants and/or to society.

9. **Principle of transparency and accountability**

   The research will be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes has been retained for the required period for possible external scrutiny/audit.

10. **Principle of environmental protection**

    Researchers are accountable forensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

RESPONSIBLE CONDUCT OF RESEARCH

All researchers should obtain approval from Institutional Scientific Review Committee (SRC), Institutional Ethics Committee (IEC), before initiating any research as per the norms. Registration with Clinical Trial Registry-India (CTRi) is mandatory for clinical trials.

Research will be carried out by qualified, competent persons, having relevant experience/training to collect reliable data, undertake accurate analysis, interpretation and publication and should be aware of and comply with the scientific medical ethical legal and social requirements of the research proposal.

The following must be established prior to conducting the research:

- Conflict of Interest policies
- Safeguards for data acquisition, management, sharing and ownership
- Policies for handling research misconduct including fabrication, falsification and plagiarism

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-Researchers should undertake only meaningful and quality research, be accountable to outcomes and take needful steps to protect participants from risks, respecting the autonomy of participants.

-Researchers, guides and EC must declare COI (Conflict of Interest) if any.

-Researchers should ensure that gender racial or other types of discrimination should not impact on the scientific process in which the research is conducted.

-Maintain appropriate standards of accuracy, reliability, credit, and confidentiality in all research and scholarship activities.

-Researchers should use the knowledge and skills, health equity and social justice according to the highest ethical standards.

-Researcher should conduct the research with objectivity and communicate with honest and responsible manner.

-All raw data should be securely stored by the investigator. Confidentiality should be maintained at all levels of research. The research records should be maintained for 3 years in case of biomedical and health research and 5 years for clinical trials as per regulatory requirements.

-Investigations should be carried out with due process and in fairness to all parties. With maintaining proper transparency and uniformity.

-The researcher must obtain informed consent from the participant/legally acceptable/ authorized representative (LAR) in writing.

ETHICAL CONSIDERATION IN COLLABORATIVE RESEARCH

As KMCT Dental College is having many collaborations with renowned institutes in India, the ethical consideration for smooth conduct of research should be specified in the memorandums of understanding (MoUs) and material transfer agreements (MTA)

-Collaborating institution will function as partners with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and IPR as appropriate. There will be free flow of knowledge and capacity at bilateral/multilateral levels.

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-Careful consideration will be given to protect the dignity, rights, safety, and well-being of the participants in cases where the social contexts of the proposed research can create foreseeable conditions for their exploitation or increase their vulnerability to harm.

-The nature, magnitude and probability of all foreseeable harm resulting from participation in a collaborative research program has to be specified in the research protocol and well explained to the participants.

-If there is exchange of biological material involved between collaborating sites, the EC may require appropriate MoU and/or MTA to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.

-In multicentre research, common ethics review by the designated EC can help to reduce time for getting ethical approvals from across the sites and improve coordination among participating sites. However, the local EC should look at site specific concerns and monitor research.

INFORMED CONSENT PROCESS

-The informed consent documents (participant information sheet and informed consent form) should carry the specified elements in simple, layman's language. -These documents should be approved by the EC.

-In case of research involving children, in addition to parental consent, verbal (7-12 years) or simplified written (>12 – 18 years) assent should also be taken from the participant.

-The LAR's consent is required in case a participant is incompetent (medically or legally).

-Electronic/online consent may be obtained for research involving sensitive topics while safeguarding information and data and if required for regulatory clinical trials.

-Oral consent/waiver of consent/re-consent may be obtained under certain conditions, after due approval by the EC.

-Researcher(s) should safeguard the privacy and confidentiality of participants and research-related data from unauthorized access.

-The ethical committee will follow up the research to protect the interest of researchers and the proper conduct of the research.

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-Participants should not be made to pay for research-related expenses incurred beyond routine clinical care.

VULNERABLE POPULATION

Individuals may be vulnerable if they are:

• Socially, economically, or politically disadvantaged and therefore susceptible to being exploited.

• Incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled.

•Able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or

•Unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

Principles of research among vulnerable populations

-As the vulnerable populations have an equal right to be included in research, the benefits accruing from the research apply to them as well.

-Special care must be taken to ensure participant's privacy and confidentiality.

-When vulnerable populations are included in the research, all stakeholders must ensure that additional protections such as to avoid exploitation/retaliation /reward/credits, etc are in place to safeguard the dignity, rights, safety and well-being of these individuals.

-Researchers must justify the inclusion/exclusion criteria of the vulnerable population in the manuscript and the full research proposal should undergo reviewing in committee meeting.

-The informed consent process should be well documented for all the vulnerable groups. Additional measures such as recording of assent and reconsent, when applicable, should be ensured.

- The benefit–risk assessment should be carried out before proceeding the study among vulnerable group and examine risk minimization strategies.

a) Women in special situations

-Women have equal rights to participate in research and should not be deprived arbitrarily of the opportunity to benefit from research.

-Researchers must provide proper justification for inclusion of pregnant and nursing women in clinical trials designed to address the health needs of such women or their foetuses or nursing infants before the EC.

-A woman who becomes pregnant must not automatically be removed from the study when there is no evidence showing potential harm to the foetus. The matter should be carefully reviewed, and she must be offered the option to withdraw or continue.

b) Children

-Children are considered vulnerable because their autonomy is compromised as they do not have the cognitive ability to fully understand the minute details of the study and make decisions.

-The EC should do the benefit–risk assessment to determine whether there is a need to put into place additional safeguards/protections for the conduct of research in children.

c) Research among tribal population

-Research on tribal populations should be conducted only if it is of a specific therapeutic, diagnostic and preventive nature with appropriate benefits to the tribal population.

-Informed consent should be taken in consultation with community elders and persons who know the local language/dialect of the tribal population and in the presence of appropriate witnesses.

-Benefit sharing with the tribal group should be ensured for any research done using tribal knowledge that may have potential for commercialization.

d) Research involving individuals with mental illness or cognitively impaired /affected Individuals

-According to the World Health Organization, mental disorders comprise a broad range of problems, with different symptoms. They are generally characterized by some combination of abnormal thoughts, emotions, behaviour and relationships with others.

-Cognitively affected or impaired: Conscious mental activities such as thinking, understanding, learning and remembering are defined as cognition. Those in whom these activities are not fully functional are regarded as cognitively impaired.

Patients who are terminally ill

-Terminally ill patients or patients who are in search of new interventions having exhausted all available therapies are vulnerable as they are ready to give consent for any intervention that can give them a ray of hope.

-Since therapeutic misconception is high there should be appropriate consent procedures and it will be reviewed by EC.

-Additional monitoring should be done to detect any adverse event at the earliest.

-The EC will carefully review post-trial access to the medication, especially if it is beneficial to the participant.

e) Other vulnerable groups

-Other vulnerable groups include the economically and socially disadvantaged, homeless, refugees, migrants, persons or populations in conflict zones, riot areas or disaster situations.

-As the autonomy of such individuals is already compromised and researchers have to justify their inclusion.

CONFLICT OF INTEREST (COI)

Conflict of interest (COI) is a set of conditions where professional judgment concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic, or political).

KMCT Dental College has policies and procedures to identify, mitigate conflicts of interest and educate their staff about such conflicts which is in accordance with the ICMR guidelines 2017.

-Researchers must ensure that the documents submitted to the EC include a disclosure of interests for the approval of manuscript.

-ECs will evaluate each study considering any disclosed interests and ensure that appropriate means of mitigation are taken.

-COI will be in followed in standard Operating procedures (SOPs) of that EC.

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