CODE OF ETHICS IN RESEARCH

INSTITUTIONAL ETHICS COMMITTEE

GOVERNMENT DENTAL COLLEGE & HOSPITAL

MUMBAI

CONTENT

INTRODUCTION

Government Dental College and Hospital Mumbai stands as a beacon of excellence in the field of dentistry, nurturing aspiring minds with the guiding principle: "Knowledge empowers, research propels." Committed to enriching the welfare of individuals and society, it strives for excellence in all its endeavors. Central to this mission is a strong focus on research, which is essential for understanding current dental care needs and advancing oral health care knowledge. Research efforts at the institution lead to the development of new treatments and improvements in patient outcomes, benefiting the community as a whole.

The institution also upholds the principle of academic freedom, allowing students and faculty to conduct and publish research without hindrance. This environment encourages innovation, critical thinking, and the ongoing pursuit of knowledge. By supporting these academic activities, Government Dental College and Hospital, Mumbai not only advances the field of dentistry but also reinforces its commitment to serving humanity through education, research, and clinical excellence.

Research at Government Dental College and Hospital, Mumbai plays a vital role in advancing knowledge, fostering creativity and innovation, enhancing teaching and learning, advancing careers, and improving patient care. The institution is dedicated to rigorous scholarly standards, ensuring that all research proposals are conducted with integrity and a commitment to knowledge and understanding. The institute has formed a strict code of ethics that protects human subjects, maintains research integrity, ensures fairness and equity, upholds professional standards, and enhances public trust. This dedication extends to all research areas, regardless of their potential implications or outcomes.

The code of ethics for researchers sets forth the principles upheld by the research community, highlighting the researcher's primary duty to follow these principles with honesty, accountability, and impartiality. It defines good practice criteria, identifies ethical violations in research conduct, and outlines procedures for addressing instances of dishonest behaviour.

This document provides details of the code of ethics for academic research observed by faculty, staff and students of Government Dental College and Hospital Mumbai.

B. SCOPE

Code of Ethics for research applies to all investigators, students, faculty and researchers involved or planning to conduct any research at Government Dental College and Hospital, Mumbai.

Code of Ethics for Research shall be updated from time to time by appropriate authorities of the College as per the changing needs of the time and the medicolegal amendments of the law.

C. GOAL

Government Dental College and Hospital, Mumbai strives to uphold the integrity, confidentiality and moral conscience to match the current standards of ethics, fairness and justice in all its affairs at all times.

Code of Ethical Conduct serves:

1. To enable the dental student, faculty or a researcher to learn the professional standard with its Medico-legal and ethical principles.
2. To aid the researcher in their work and supervise their work which is to be conducted in accordance with the research and ethical principles and following the institutional research guidelines.
3. To provide a help desk for the researcher in case of any query regarding protocol or ethical issues arising.
4. To periodically follow up with the researcher after resolution of query and/or ethical issue to ensure continued application of corrective measures.
5. To provide reporting and redressal system for any reported or known or suspected medico-legal and ethical violations.
6. To protect the interests and intent of the researcher along with the rights of the subjects involved in case of a known or suspected breach of medicolegal and/or ethical protocol.
7. To prevent and report any mishap or misconduct by the researcher to the appropriate authorities in time.
8. To recommend disciplinary action against the defaulter for illegal action.
9. To maintain a record of the conduct breach and update the ethical manifesto based on the case and its consequences.

D. ETHICAL PRINCIPLES AND VALUES IN RESEARCH WORK

The principles and values that underpin the integrity and reliability of science are fundamental and universal. They apply to all representatives of scientific disciplines without exception.

Researchers, institutions, funders, publishers, and scientific organizers, all adhere to these principles and values. They should maintain ethical conduct in their interactions with each other and in their communication with the wider community.

These universal principles include:

1) Conscientiousness in portraying the objectives and intentions of planned or ongoing research, outlining research methods and procedures, interpreting the results, and communicating information about possible threats and well-substantiated predictions regarding benefits and possible applications in terms that are comprehensible by the subjects, committees and co researchers involved.

2) Reliability in conducting research, a critical approach towards the results, meticulousness, attention to detail, and care in the presentation of research findings.

3) Objectivity: interpretations and conclusions must be based exclusively on facts, verifiable reasoning, and data that can be confirmed by others and reproduced.

4) Independence from external influences over the conduct of research, with respect to both those who commission studies or expert opinions, and to political, ideological, religious, or economic pressure groups.

5) Publication of one's research to contribute to the accumulation of knowledge and communication of authentic information to the public.

6) Discussion of one's own research with other researchers, which is one of the key conditions for advances in science and willingness to accept and acknowledge constructive criticism and additional insights regarding the same.

7) Transparency in documenting research, ensuring data availability after the research results are published.

8) Responsibility towards the subjects of research; studies involving human or animal subjects can only be carried out when this is necessary and with respect for human dignity and animal rights, on the basis of approval issued by the relevant ethics committees, including bioethics committees.

9) Consensual involvement of human subjects only after providing authentic information regarding the research process and expected outcomes and impact.

10) Researchers' responsibility for the socioeconomic and environmental consequences of the conclusions being formulated.

11) Fairness and integrity in evaluating the merits and ethical aspects of the work of other researchers and in reviewing and recognizing the scientific achievements of those to whom such recognition is truly due, by properly citing sources and honestly recognizing their contributions to scientific achievements.

12) Refraining from invoking one's scientific authority when speaking out on topics outside one's own area of expertise.

13) Courage to oppose views contrary to scientific knowledge and practices incompatible with the principles of research integrity;

14) Concern for future generations of researchers, manifested not only in respect for co workers, their fair treatment, and support for their scientific development, but also in the communication of binding standards and ethical norms.

E. PRINCIPLES OF ETHICS FOR DENTAL RESEARCH

Ethical guidelines for dental research are a set of principles and standards that guide the conduct
of research involving human subjects in the field of dentistry. These guidelines aim to ensure that research is conducted in an ethical and responsible manner and that the rights and welfare of research participants are protected.

Principles of voluntariness, informed consent, and community agreement

Consent is the most important principle of any research involving humans. Research participants should be completely apprised of the research and the associated risks and benefits.

The participants should be informed of the right to abstain from the research or withdraw consent at any time. Where research entails treating any community, the principles of voluntariness and informed consent apply to the community as a whole and to each individual member. In case a person is incapable of giving consent, a legally acceptable guardian should give the informed consent.

Principles of non-exploitation

The participants should be fully apprised of all the possible dangers that may arise during the research so that they can appreciate all the physical and psychological risks. Each research should include an in-built mechanism for compensation for the human participants either through insurance cover or by any other appropriate means to cover foreseeable and unforeseeable risks, and provide remedial action and comprehensive aftercare.

Principles of privacy and confidentiality

The identity and records of the participants are as far as possible kept confidential (except when required for legal reasons). This is to avoid any form of hardship, discrimination or stigmatization as a consequence of having participated in the research.

Principles of precaution and risk minimization

Due care and caution should be taken at all stages of the research and experiment to ensure that the research participant and those affected by it including the community are put to the minimum risk, suffer from no known irreversible adverse effects, and generally, benefit from the research or experiment. There should be a plan for interim reviews to detect whether any intervention arm (active or control) is associated with increased risks, so that undue harms are avoided by stopping the research.

Principles of professional competence

Research should be conducted by competent and qualified persons who act with total integrity and impartiality and who have been made aware of the ethical considerations to be borne in mind in respect of such research or experiment.

Principles of accountability and transparency

The research or experiment should be conducted in a fair, honest, impartial, and transparent manner after full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research, and any conflict of interest that may exist. Full and complete records of the research should be retained for such reasonable period as may be prescribed or considered necessary for the purposes of post-research monitoring, evaluation of the research, conducting further research, and scrutiny by the appropriate legal and administrative authority, if necessary.

Principles of the maximization of the public interest and of distributive justice

The research or experiment and its subsequent application should be conducted and used to benefit all human kind (and not just those who are socially better off), in particular, the research participants themselves and or the community from which they are drawn.

Principles of public domain

The research findings should be brought into the public domain so that its results are generally made known through scientific and other publications. This would help in consolidating the scientific knowledge base of the field being studied and would prevent the undue replication of studies which pose risks to some subjects.

F. GOOD PRACTICE IN ACADEMIC RESEARCH

1. ACADEMIC FREEDOM, INTEGRITY AND RESPONSIBILITY

Academic freedom is the freedom to teach, study and pursue knowledge and research without unreasonable interference or restriction from law, institutional regulations or public pressure. Its basic elements include the freedom of scholars to inquire into any subject that evokes intellectual concern, to present findings, to publish data and conclusions without control or censorship and to teach in the manner they consider professionally appropriate.

At the same time, integrity, accountability and responsibility in conducting academic research form the cornerstone of any academic enterprise and violations of widely-recognized academic research standards represent serious offences to the entire Institute and are considered injurious for its credibility and authority as an institution that promotes excellence in academic research.

Academic integrity requires that academic research follows elevated professional standards, including appropriate research design and frameworks, adheres to high levels of

research ethics and abides by the requirements set out by professional and regulatory research guidance and research ethics frameworks issued in appropriate areas.

Principles and Values of Academic Integrity Academic integrity is defined in terms of the commitment to the values of honesty, trust, fairness, respect, responsibility, legality and dissemination.

Accountability: A researcher should be well versed with subject of research and the medicolegal and ethical protocols related to it to ensure accountability for all the aspects and steps involved in the research.

Fairness: A researcher should seek to ensure fairness in institutional standards, practices and procedures as well as fairness in interactions between members of the community.

Honesty: A researcher should advance the quest for truth, knowledge, scholarship and understanding by requiring intellectual and personal honesty in learning, teaching and research.

Communication: A researcher should seek to make the results of its research as widely and as freely available as possible.

Legality: A researcher should observe valid legal norms related to the conduct and publication of research particularly in relations to copyright, the intellectual property rights of third parties, the terms and conditions regulating access to research resources and the laws of libel.

Respect: A researcher should promote respect among students, staff and faculty: respect for self, for others, for scholarship and research, for the educational process and intellectual heritage.

Responsibility: A researcher should uphold high standards of conduct in learning, teaching and research by requiring shared responsibility for promoting academic integrity among all members of the community.

Trust: An academic community should foster a climate of mutual trust to encourage the free exchange of ideas and enable all to reach their highest potential.

2. INSTITUTIONAL RESPONSIBILITIES

The responsibility of promoting a transparent and ethical academic environment for research rests with the researchers, ethics committee, and faculty of the institution. The Dean, Heads of Departments, Librarian, & teaching staff must endorse and model high professional and ethical standards for academic research. The research guides are expected to create and maintain an atmosphere of mutual cooperation that fosters the open exchange of ideas and the

development of research skills. Additionally, they are responsible for providing suitable supervision and guidance to researchers in alignment with the specific academic discipline and research methodology.

It is the responsibility of all the Heads of the Department to create and sustain a climate of mutual co-operation that facilitates the open exchange of ideas and the development of academic research skills. They are also expected to ensure the provision of appropriate supervision and direction for researchers, in accordance with the nature of the individual academic discipline and associated mode of research.

3. TRAINING

The Institute's Research Departments will provide comprehensive training to researchers in research design, methodology, regulatory compliance, and ethical standards. This includes obtaining necessary approvals and consents, proper use of equipment, confidentiality, data management, record keeping, data protection, publication, and adherence to licensing agreements and third-party intellectual property rights. By providing appropriate training, the Institute's Research Departments ensure that researchers are equipped with the necessary knowledge and skills to conduct research with integrity and in accordance with best practices. The mentor or guide of the researcher will ensure that the researcher has proper knowledge, training and institute ethical approval before start of the research.

Academicians and guides should be required to be well versed with latest developments in technology and their subject of expertise to ensure that the researcher receives best in class knowledge and amenities to carry out research which is on par with the developing times.

4. PUBLICATION PRACTICE AND AUTHORSHIP, NOTIFICATION, ARCHIVING AND DEPOSITING COPIES OF RESEARCH PUBLICATIONS WITH THE INSTITUTIONAL REPOSITORY (IR)

The Institute encourages the publication and dissemination of results of high-quality research. It also expects that researchers will engage in the process of publishing following **CODE of ETHICS for MEDICAL RESEARCH PUBLICATION ISMPP** issued by international society for medical publication professionals. The **2019 ISMPP Code of Ethics** details the shared global values and ethical benchmarks for all medical publication professionals, regardless of ISMPP membership.

1. Researchers should publish the results of their research, and their interpretations should be reliable, transparent, and accurate and research methodology should be described in a manner that allows it to be replicated by other researchers.
2. The authorship of a scientific publication must be based on the fulfilment of at least one of the following conditions: a creative and significant contribution to the research, which means a significant contribution to creating scientific ideas, formulating concepts, and designing research, an unquestionable active involvement in the acquisition of data, in the analysis and interpretation of the findings, as well as a substantive and reliable contribution to preparing and critically drafting the article from the point of view of the applicable scientific criteria.
3. Obtaining funding, providing access to equipment and related training, collecting data, or exercising general administrative supervision of a research group do not give anyone the right to claim co-authorship. The head of a research unit may not be listed automatically as a co author of articles published by his or her subordinates.
4. All authors are fully responsible for the content of the publication unless otherwise specified (for example, that they are responsible only for a specific portion of the research in their area of expertise). When the affiliations of authors are listed, it is recommended that the nature of their contribution be specified.
5. A co-authored publication intended as a basis for the application for an academic degree or title should contain a separate, self-authored section or be edited in such a manner as to allow the evaluation of the precisely identified contribution of each co-author to the publication.
6. Names of the authors of a publication should be listed in the order that is customary in a given scientific discipline and should be accepted by all co-authors at the initial stage of drafting the publication. Intellectual contributions of other individuals who have a significant impact on the published research should be appropriately acknowledged.
7. Financial support and other types of assistance should be appropriately acknowledged.
8. Republication of the same work (or significant portions thereof) may be accepted only with the permission of the editors, and it should always include a reference to the first publication. Such studies that are related to one another in significant portions and in significant scope should be included in the list of the author’s achievements as a single item. Artificially inflating the list of publications by multiple mentions of the same scientific achievement under different titles is a reprehensible practice.

9. References to publications of other authors must always follow the rules of proper citation. Authors should avoid unjustified self-citations or citations of works substantially different from the content of their publication with the intention to increase the citation rate or other scientific indicators for themselves or for others.
10. Contact with the general public and the media is subject to the same standards of honesty and precision as the publication of the results of work. Exaggerating the importance of research results and their practical applicability is a reprehensible practice.
11. Science is universal, but it is also a component of national cultures. Researchers should therefore strive to popularize the scientific achievements of their home countries; in doing so, however, they should be guided primarily by the merits of such achievements and the need to maintain proper proportions in this regard.

G. THE INSTITUTIONAL ETHICS COMMITTEE

APPOINTMENT OF THE ETHICS COMMITTEE an ethical committee will be constituted by the institute according to ICMR. The committee will be constitution following:

1. Chairperson
2. Member secretory
3. Basic medical scientist
4. Clinician
5. Statistician
6. Epidemiologist
7. Pharmacologist
8. Legal expert
9. Philosopher/ representative of non government agencies NGO
10. Social scientist
11. Lay person from community.

This committee will be responsible for monitoring the researches conducted in the institute.

TASKS OF THE ETHICS COMMITTEE

1. Identifying the code of Conduct for the following stakeholders

 Students

 Teachers

 Administrators

 Other staff

2. Incorporating the code of Conduct for the various researchers on campus in the form of dedicated Handbooks.

3. Reviewing the Codes at specific intervals and reprinting the Handbooks whenever necessary.

4. Monitor adherence to the Code of Conduct by periodic announcements to the stakeholders in the form of notices, circulars etc.

5. Assist the Disciplinary Committee in undertaking appropriate disciplinary actions in instances of violations of the specified code of Conduct.

6. Plan and organize in coordination with the IQAC professional ethics programmes for students, teachers, administrators and other staff.

7. Conduct periodic interactive sessions with researchers to gain feedback on research practices and problems arising pertaining to the same.

8. Appoint experienced academicians to bridge the gap between professional scientific research and the participation of younger students in it by familiarizing students with research in layman terms.

9. Conduct seminars of alumni to present their research and give on ground feedback regarding the process to promote participation and a healthy competition among peers.

9. Monitor the implementation of the Induction week for students, Inviting of Alumni for student interaction programmes, Departmental grooming sessions, Placement Orientations and conducting of Exit Interviews.

H. MISCONDUCT IN ACADEMIC RESEARCH

1. FFP Misconduct

Fabrication, falsification, and plagiarism are the unethical research practices that seriously harm research integrity:

Fabrication and falsification of research results are egregious forms of research misconduct that involve the creation or manipulation of data to present false or misleading findings. Fabrication involves completely making up data, while falsification involves manipulating or omitting data to fit a desired outcome. Both of these practices are a clear violation of the fundamental principles of scientific inquiry.

Plagiarism is another form of research misconduct that involves using someone else's ideas, research findings, or written work without giving proper credit. This violates intellectual property rights and undermines the principles of academic integrity.

These types of misconduct can occur at any stage of the research process, from the proposal stage to publication and dissemination of findings. They can occur in research conducted by individuals, teams, or organizations. The consequences of such misconduct can be severe and may lead to the disqualification of the researcher or the retraction of published work. Any instances of these unethical research practices will be thoroughly investigated and appropriate disciplinary actions will be taken. It is crucial to maintain the integrity of research and ensure that the scientific community can trust the validity of research findings

2. Review and citation violating research integrity

Reviews and citations violating research integrity refer to unethical practices that involve manipulating or falsifying the peer review process or misusing citations to misrepresent the validity of research findings. These practices are serious violations of research integrity and can undermine the credibility and reliability of scientific research.

Citation manipulation is another violation of research integrity that involves misusing or fabricating citations to falsely boost the impact or significance of one's own research or to undermine the validity of other research. This can include citing one's own work excessively, citing irrelevant or unrelated sources, or omitting relevant citations that would contradict one's claims.

These types of violations can have serious consequences for the research community, including the spread of misinformation, damage to reputations, and a lack of trust in the peer review process. It is important to maintain the integrity of the review and citation process by promoting transparency, ethical practices, and accountability for those who violate research integrity.

3. Other misconducts

Part from above misconducts few minor misconducts may occur because of inexperience or lack of knowledge of the principles of academic integrity and are often characterised by the absence of dishonest intent on the part of the person committing the violation.

They may result from either weak procedures and methods which may jeopardise the integrity of the research but are not undertaken deliberately or recklessly or mistakes which present no major risks to either subjects or policies which they may influence On the whole, these misconducts can be seen as failings which may reflect only poor, rather than unacceptable

practices and therefore mainly require further training and development rather than any formal disciplinary action.

Examples of minor violations include:

 Minor plagiarism defined as a small amount of paraphrasing, quotation or use of diagrams, charts etc. without adequate citation. Minor plagiarism may result from poor scholarship (i.e., when a student, through inexperience or carelessness, fails to reference appropriately or adequately identify the source of the material which they use).

 Inaccurate claims to experience, qualifications or contributions in a context where the person committing the violation cannot expect major benefits (such as winning a competition for a prize or job)

 Lack of diligence in declaring relevant conflicts of interest.

4. Principles for Approaching and Addressing Identified Violations of Research Integrity

The Ethics Committee will conduct an investigation about the misconduct found or reported during or after research.

All allegations of research misconduct will need to be properly examined, and if the allegations are confirmed, the facts and circumstances surrounding the misconduct should be investigated in detail to take relevant corrective and disciplinary steps in accordance with applicable laws.

Individuals with relevant experience in the relevant scientific field will be involved in the investigation to ensure accuracy and fairness.

The following principles need to be incorporated into any investigation process.

Integrity

 Investigations should be fair, comprehensive and conducted expediently, without compromising accuracy, objectivity or thoroughness.

 The parties involved in the procedure must have declared any conflict of interest that may arise during the investigation.

 Measures should take to ensure that Investigations are carried through to a conclusion.

 Procedures are conducted confidentially in order to protect those involved in the investigation.

 Institutions protect the rights of 'whistle- blowers' during investigations and ensure that their career prospects are not endangered.

 General procedures for dealing with violations of good research practice are publicly available and accessible to ensure their transparency and uniformity.

Transparency.

 Investigations should carry out with due process and in fairness to all parties.

 Persons accused of research misconduct should be given complete details of the allegation(s) and allowed fair process for responding to allegations and presenting evidence.

 Action is taken against persons for whom an allegation of misconduct is upheld, which is proportionate to the severity of the violation.

 Appropriate restorative action should be taken when researchers are exonerated of an allegation of misconduct.

 Anyone accused of research misconduct is presumed innocent until proven otherwise.

Reactions to behaviour incompatible with ethics in research will depend on the gravity of the misconduct, the intent, its consequences, and other aggravating or mitigating circumstances

CONCLUSION

The institute will provide and promote research friendly environment. All the researchers conducting researches in the institute will strictly adhere to the code of ethics, defined under the handbook. The ethical committee will be responsible to monitor and investigate the researches. Appropriate action will be taken against those who violate the code of ethics in research.

During Development of this code of ethics following documents were referred.

European University Institute (2022) CODE OF ETHICS IN ACADEMIC RESEARCH

University of Exeter. (2002). Code of Good Practice in the Conduct of Research. Research Committee.

Avasthi A, Ghosh A, Sarkar S, Grover S. Ethics in medical research: General principles with special reference to psychiatry research. Indian J Psychiatry. 2013 Jan;55(1):86-91. doi: 10.4103/0019-5545.105525. PMID: 23440168; PMCID: PMC3574464.

CODE of ETHICS for MEDICAL RESEARCH PUBLICATION ISMPP Code of Ethics Jan. 29, 2019

Annexure

GOVERNMENT DENTAL COLLEGE & HOSPITAL MUMBAI

Template for applying to ethical committee

The researcher has to mandatorily get approval from the institutional ethical committee before start of any research. When applying to the ethical committee following documents have to be submitted.

Cover page

Letter to the institutional committee for approval

Synopsis

Consent form

Template for cover page

Title of research

Name of Principal Investigator

Guided by HOD

Template For Letter To The Institutional Committee For Approval

To,

The institutional Ethical Committee,

Government Dental College and Hospital,

MUMBAI

Subject - Request to issue Ethical Clearance for Research Survey.

Respected Sir/Madam,

I **name, designation, department**, Government Dental College MUMBAI, wants to conduct a research **title of study**. I am hereby humbly requesting to please issue the ethical Clearance. Synopsis for the research is duly attached.

Regards

GOVERNMENT DENTAL COLLEGE & HOSPITAL MUMBAI

Template for consent form

Please note that this is a template to assist the Principal Investigator in the design of their informed consent forms (ICF). It is important that Principal Investigators adapt their own ICFs to the outline and requirements of their particular study. The informed consent form consists of two parts: the information sheet and the consent certificate.

Part 1

RESEARCHER:

TITLE OF PROJECT:

I am asking for your voluntary participation in my science fair project. Please read the following information about the project. If you would like to participate, please sign in the appropriate box below.

PURPOSE OF THE PROJECT:

IF YOU PARTICIPATE, YOU WILL BE ASKED TO:

TIME REQUIRED FOR PARTICIPATION:

RISKS:

BENEFITS:

HOW CONFIDENTIALITY WILL BE MAINTAINED:

If you have any questions about this study, feel free to contact:

Investigator: _____

Phone/email: _____

Part 2

VOLUNTARY PARTICIPATION: Participation in this study is completely voluntary. If you decide not to participate there will not be any negative consequences. Please be aware that if you decide to participate, you may stop participating at any time and you may decide not to answer any specific question.

By signing this form, I am attesting that I have read and understand the information above and I freely give my consent/assent to participate or permission for my child to participate.

ADULT INFORMED CONSENT OR MINOR ASSENT

Printed Name of Research Subject: _____

Signature: _____

Parental/Guardian Permission (if applicable)

Parent/Guardian Printed Name: _____

Signature: _____

Date Reviewed & Signed: _____