

MAEER MIT PUNE'S MIMER MEDICAL COLLEGE & DR. BSTR HOSPITAL TALEGAON DABHADE-410507

CODE OF ETHICS FOR RESEARCH

Amended on- 23rd May 2022

MAEER MIT PUNE's



MAHARASHTRA INSTITUTE OF MEDICAL EDUCATION AND RESEARCH MEDICAL COLLEGE (ESTD - 1995)

DR. BHAUSAHEB SARDESAI TALEGAON RURAL HOSPITAL

Accredited by NAAC with 'A' Grade

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CODE OF ETHICS FOR RESEARCH

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1. Introduction:

Medical Research is defined as the development of knowledge with the aim of understanding health challenges and trying to address them in an appropriate manner. It is a tool for the advancement and attainment of health, and it should commit to the highest standards of scientific quality and ethical integrity. The proposed research work to be done by the faculty/post-graduate students/undergraduate students will undergo a scientific review by the Department of Clinical Research and Incubation Center. It should then be forwarded to MIMER Medical College, IEC. Institutional Ethics Committee (IEC) ensures that the research involving human participants is conducted in accordance with the basic and general ethical principles. The researcher and the team will be responsible for protecting the dignity, rights, safety and well-being of the participants enrolled in the study. MIMER Medical College, IEC works in accordance with Standard Operating Procedures, which has been prepared as per National Ethical Guidelines for Biomedical and Health Research involving human participants, 2017. This committee is registered with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), Department of Health Research (DHR) provisionally as EC/NEW/INST/2020/913 dated 16th December 2020. Responsibility for ethical behavior in research rests entirely on the researcher. Researchers and collaborators should commit to the highest standards of research conduct and strive for excellence in developing, carrying out, participating in, publishing, and applying the results of their research outcome. They should apply the highest standards of scientific integrity as detailed in this Code. It is therefore essential that all students and faculty know and understand the Code and use it as

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a guide for the conduct of research activities in this institution.

Objectives:

The primary objectives of the Code of Ethics for Research for MAEER MIT Pune's MIMER Medical College & Dr. BSTR Hospital are-

- 1. To make the researchers aware of the ethical considerations involved in all aspects of research.
- 2. To motivate the faculty and students to carry out innovative and globally relevant quality research.
- 3. To encourage application of research for human welfare and dissemination of valuable knowledge.

Scope:

This Code applies to all researchers- Faculty members, Postgraduate & Undergraduate Students of MAEER MIT MIMER Medical College & Dr. BSTR Hospital.

It will also be applicable to all who collaborate with MAEER MIT PUNE'S MIMER Medical College & Dr. BSTR Hospital, Talegaon Dabhade, Pune, for conducting scientific and ethical research. This Code states key principles for conduct of research and seeks to provide guidance to researchers and collaborators, engaging in research, by clarifying the requirements of the Institute.



2. Ethical principles for research

The researchers and collaborators, should adhere to the principles of integrity, accountability, independence/impartiality, respect for persons and communities, and professionalism in their research engagements. Breaches in this Code of ethics for research may cause the institute to terminate the project or any collaboration.

The four basic ethical principles that need to be followed while conducting any research are:

- 1. Autonomy (Respect for Persons)
- 2. Beneficence
- 3. Non-Maleficence and
- 4. Justice

so as to protect the dignity, rights, safety and wellbeing of research participants.

This can be achieved by the strict compliance of the following 12 general principles:

- 1. **Principle of Essentiality:** Whereby after due consideration of all alternatives in the light of existing knowledge, the use of human participants is considered essential for the proposed research.
- 2. **Principle of Voluntariness:** Whereby 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 most important. The informed consent process ensures that the participants' rights are safeguarded.
- 3. **Principle of Non exploitation:** Whereby research participants are selected fairly and impartially so that the benefits and burdens of the research are distributed fairly and without discrimination. This should particularly be considered for the protection of the vulnerable groups.
- 4. **Principle of Social responsibility:** Whereby research is planned and conducted in a way so as to avoid creating or deepening social or historic divisions or disturb social harmony in community relationships.

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- 5. **Principle of ensuring privacy and confidentiality:** Whereby privacy of the participants is maintained and their identity and records are kept confidential and access is limited to only those authorized.
- 6. **Principle of risk minimization:** Whereby care is taken by all stakeholders 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:** Whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have appropriate and relevant qualification, experience and training.
- 8. **Principle of maximization of benefit:** Whereby due care is taken to design and conduct the research in such a way so as to maximize the benefits to the participants and society at large.
- 9. **Principle of institutional arrangements:** Whereby institutions where research is being conducted have policies for appropriate research governance and take the responsibility to facilitate research by providing required infrastructure, manpower, funds and training opportunities.
- 10. Principle of transparency and accountability: Whereby the research plan and outcomes of the research are brought into the public domain through reports and publications, while safeguarding the right to privacy of the participants. Any conflict of interest should be managed appropriately. The research should be conducted in a fair, honest, impartial and transparent manner to guarantee accountability.
- 11. **Principle of totality of responsibility:** Whereby all stakeholders involved in research are responsible for their actions.
- 12. **Principle of environmental protection:** Whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research.



3. Wrong doing in research

The non-adherence to the principles laid out in this Code will be considered wrong doing and action will be taken depending upon the seriousness of its implications on the health of the people.

Wrong doing in research includes

- Inappropriate development of research protocols;
- Failure to disclosure or take action on declared conflict of interest;
- Inadequate management of a research project;
- Fabrication, falsification and plagiarism

Plagiarism:

Plagiarism refers to use of others published and unpublished ideas. It may occur at any stage of research- planning, research, writing, or publication: applies to print and electronic versions.

All sources should be disclosed. If large amounts of other people's written or illustrative material is to be used; permission must be sought.

Plagiarism software is available in the institute. Facilities can be availed by the students and faculty.



4. Good practice in the conduct of research

Adherence to research standards:

The researchers are required to adhere to high scientific and ethical standards when engaged in research. The research proposal should be submitted in the prescribed format which includes medical, scientific, ethical, and monetary aspects of the proposed study; Biomedical & Health Research should be reviewed by the MIMER Medical College, IEC and other, non- human subjects research should be reviewed by Institutional Animal Ethics Committee (for animal research). In case of collaboration with outside institutes, the research protocol should have the appropriate and required ethical and regulatory clearances as applicable. There should be a clear definition of the respective responsibilities of the institute and partner institutions in collaborative research in advance of the start of the Research project. Researchers should recognize and accept their responsibilities as per established standards and best practices in their research field.

Research training and supervision:

The Department of Clinical Research and Incubation Centre was established at MIMER Medical College, Talegaon Dabhade on 2/12/2019 with the purpose of promoting genuine medical research and innovations. Scientific Publishing is also encouraged as it promotes recognition of our institute in the national and international circles and contributes to the existing pool of global knowledge.

Role of the Department:

- 1. To guide students and faculty in initiating research by suggesting ideas and areas to start new research.
- 2. To help the investigators with the technical aspects of planning and conducting research from the initial stages itself.
 - Development of an appropriate study design for the project
 - Development of the research protocols and statistical analysis plans for the study



- 3. To guide and supervise the ongoing research projects and maintain its records.
- 4. To provide robust statistical analysis expertise for ongoing and future research projects
- 5. Help to write research paper/papers related to the study for publication in reputed journals.
- 6. Grants
 - To identify the various funding agencies and facilitate application for grants.
 - To guide and facilitate making proposals to various funding agencies for grants for research.
- 7. Resource faculty in Research Methodology Workshop (RM) in coordination with the Medical Education Unit (MEU)
- 8. Study guidelines about MUHS related synopsis/dissertation of Post graduate students and guide and maintain communications.
- 9. To provide an 'Elective' for UG students in research methodology.
- 10. To help in In-house funding of institutional projects.

Conflict of interest

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Researchers must ensure that the documents submitted to the IEC include a disclosure of interests that may affect the research. MIMER Medical College, IEC evaluates each study in light of any disclosed interests and ensures that appropriate steps are taken.



Managing collaboration in research

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- Researcher should have a clear understanding of intellectual property ownership and its use within the research projects as well as collaborative research projects.
- 2. Collaboration should be with colleagues who have the expertise and/or resources needed to carry out particular research. This could be interdepartmental/ inter-institutional or international and also multicenter involving public and/or private research centers and agencies.
- 3. They should familiarize themselves with all aspects including local, national and international requirements for research collaboration including necessary approvals, memorandums of understanding (MOU) and material transfer agreements (MTA) and also IEC approvals of collaborating institutes as well as MIMER Medical College, IEC.
- 4. Appropriate permissions should be obtained before making use of pre-existing intellectual property in research.
- 5. Acknowledgement of the use of pre-existing intellectual property when reporting and publishing research should be done.
- 6. Consultation with collaborative partners prior to the disclosure of research or the findings of research (always subject to the protection of confidential information and proprietary rights) is necessary.
- 7. After leaving the Institute, the researcher is required to obtain the written permission from the Head of the Institute for the use of any intellectual property and/or information that belongs to the Institute or parties collaborating with the institute and may have become known to him/her during their association with the organization.



The financial management of research

Institutional Funding of Research Projects

A. Undergraduate Student Research Projects

As an initiative to promote research activities among undergraduate students, the Management of MIMER Medical College has sanctioned funds (Maximum amount 1Lakh/year) for undergraduate student research projects. UG students wishing to apply for these grants should submit their research proposal to the Department of Clinical Research and Incubation Centre. These projects will be scrutinized by the Research Grants Committee and grants will be sanctioned for the selected projects. Investigators will have to submit their completed project report and publications related to work done to the Department of Clinical Research and Incubation Centre.

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B. Postgraduate & Faculty Research Initiatives:

Grants and incentives to promote research activities amongst Postgraduate and faculty members.

The details are as follows:

Research Grants for Institutional Projects To promote research activities in the institute

- 1) Every department will be granted a Research fund of **Rs.20,000**/- to carry out research activities to encourage research. However, every year only five departments will be sanctioned this amount on first come first serve basis.
- 2) In each case, however, a detailed project report including the tentative expenses and IEC clearance certificate should be submitted to the committee.
- 3) The committee will scrutinize the project report and submit it for sanction to the Management.
- 4) This fund will be provided by the Management.
- 5) For project with one year duration: The principal investigator has to complete the project and submit the completion report along with the balance sheet (including receipts of expenses done) at the end of first year to research committee.
- 6) For project with more than one year duration: The principal investigator has to complete the project and submit the completion report along with the balance sheet (including receipts of expenses done) at the end of first year to research committee.
 - On satisfactory submission of required documents, the department will be entitled for next installment in next year.
- 7) At the end of completion of research project, if at all, the expenses incurred are less than the amount received by the principal investigator; the balance amount is to be returned to Research Committee and the account needs to be closed.
- 8) No project is to be funded by two funding agencies.



I- Incentive for Presentation in Conference:

- 1) Any faculty/PG student who will have an Oral presentation of Original research work in any discipline specific national/international (venue within India) conference will be sanctioned lump sum amount of **Rs. 5000**/-
- 2) Any faculty/PG student who will have an Oral presentation of original research work in any discipline specific state conference will be sanctioned lump sum amount of Rs. 3000/-
- 3) Any faculty/PG student who will have a Poster presentation of original research work in any discipline specific national/international (venue within India) conference will be sanctioned lump sum amount of **Rs. 3000**/-
- 4) Any faculty/PG student who will have a Poster presentation of original research work in any discipline specific state conference will be sanctioned lump sum amount of Rs. 2000/-
- 5) These incentives will be sanctioned after production of valid documents only.
- 6) One faculty/PG student will be entitled for the incentive for presenting a paper/poster in only one conference per year.
- 7) The incentive will be given for either an oral presentation or poster in case the faculty has presented both- the research paper and poster.
- 8) Presentation in Online Conference-Paper and Poster- Incentives will be given similar to the physical conference presentation guidelines mentioned above.

Point to be noted: No incentive will be given for chairing a session/attending the conference and no TA/DA will be given in any circumstances.



II- Incentive for presentation in International conference (venue outside India)

Any faculty/PG student who will have an Oral presentation of original research work/poster presentation in an International Conference (venue outside India) conference can be sanctioned an incentive in the form of reimbursement of registration fee. Reimbursement of registration fee for Online presentations in International Conference will also be considered. However, the funds to be sanctioned will be solely decided by and given by the Management and will depend upon production of relevant documents.

III- Incentive for Publication of original research work for faculty/PG students

- 1) If a manuscript is published in a journal indexed by PubMed/Web of science/ Scopus and if the impact factor of the journal (Clarivate Analytics, 2021) is **more than 4.0**; then an incentive of **Rs. 7500**/- can be given to the first author of the article.
- 2) If a manuscript is published in a journal indexed by PubMed/ Web of science/ Scopus and if the impact factor of the journal (Clarivate Analytics, 2021) is **more than 2.0**; then an incentive of **Rs. 5000/-** can be given to the first author of the article.
- 3) If a manuscript is published in a journal indexed by PubMed/Web of science/ Scopus and if the impact factor of the journal (Clarivate Analytics, 2021) is **less than 2.0**; then an incentive of **Rs. 4000/-** can be given to the first author of the article.
- 4) If a manuscript is published in a journal published by a society/ single subject/Indian citation index/UGC listed; then an incentive of **Rs. 3000**/- can be given to the first author of the article.
- 5) The faculty/PG student will submit the valid application to Research Committee for the incentive through the Head of Department and Principal office.
- 6) These applications will be scrutinized by the Scrutiny Committee and it will decide the amount of incentive to be sanctioned.
- 7) This incentive will be given by Management.

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IV- Incentives for Book/Book chapter Publication

- 1. If the author/authors from MIMER have published a book with reputed international publisher such as Springer, Wiley, Elsevier, Taylor and Francis, etc., then an incentive of **Rs. 20,000/-** will be given to the author/authors.
- 2. If the author/authors from MIMER have published a book with reputed Indian publisher such as Tata McGraw Hill, BPB, New Age, etc., then an incentive of Rs. 15,000/- will be given to the author/authors.
- 3. If the author/authors from MIMER have published a book chapter in a book published with reputed international publisher such as Springer, Wiley, Elsevier, Taylor and Francis, etc., then an incentive of **Rs. 10,000/-** will be given to the author/authors.
- 4. If the author/authors from MIMER have published a book chapter in a book published with reputed Indian publisher such as Tata McGraw Hill, BPB, New Age, etc., then an incentive of **Rs. 5,000/-** will be given to the author/authors.
- 5. If faculty from MIMER has edited a book published with reputed international publisher such as Springer, Wiley, Elsevier, Taylor and Francis, etc., then an incentive of **Rs. 10,000/-** will be given to the faculty.

V- <u>Incentive for Patent- to be given by Management.</u>

Any faculty who gets national/international patent shall be awarded a lumpsum amount of Rs.25000/- as incentive.

VI- Any other Research Work

Any other research work getting special recognition at international/national level will be awarded by Management.



VII- Prizes for Best Oral and Poster Presentation

- 1) A cash prize of **Rs.5000**/- for best oral presentation (first prize) in international conference.
- 2) A cash prize of **Rs.3000**/- for best oral presentation (first prize) in Discipline specific State/ National conference.
- 3) A cash prize of Rs.1000/- for best poster presentation (first prize) in Discipline specific State/ National conference.

Funding of Research projects by other agencies

The students and faculty of MIMER Medical College are informed about funding available for research projects by various government funding agencies e.g. Maharashtra University of Health Sciences (MUHS), Indian Council of Medical Research (ICMR), Department of Bio-Technology (DBT), Department of Science and Technology (DST), Council of Scientific and Industrial Research (CSIR), Defense Research and Development Organization (DRDO), Ministry of Health and Family Welfare (MOHFW) etc. as well as Non-Government funding agencies by the Department of Clinical Research and Incubation Center.



Quality Practices in Research.

In order to inculcate a good research culture at MAEER MIT PUNE'S MIMER Medical College & Dr. BSTR Hospital, Talegaon Dabhade, various Workshops are conducted by the Department of Clinical Research and Incubation Centre regularly.

- Workshop on Research Methodology
- Ethical practices in Research
- Academic Integrity and Ethical practices in research and publications
- Good Clinical Practice
- Good Clinical Laboratory Practice
- Intellectual Property Rights (IPR)

For projects involving diagnostic investigations, the students and faculty are provided facilities available in house at the Central Clinical Laboratory. Central Clinical Laboratory encompasses 3 sections- Pathology, Biochemistry and Microbiology. Each section is equipped with the latest automated instruments. Quality Control (QC) program's-both internal QC and External Quality Assurance Services (EQAS) are performed regularly to assess the quality and performance of the laboratory. Annual Maintenance Contract (AMC) of the instruments are regularly done and monitored. This ensures obtaining accurate data for the various studies.

Various parameters are also studied to understand the quality of publications done after the completion of the various research projects. These include

- Impact factor of Journal
- Society/Publication House of Journal
- Citations
- H-index of faculty



Managing and monitoring research data review:

- a. Researchers and Faculty should maintain a Standard Operating Procedure (SOP) & laboratory notebook while performing research that has the potential to be commercialized and should ensure that it is regularly signed and dated by a senior colleague wherever applicable. This may be required to be produced as evidence in a court of law in case of any dispute. The Researchers and Faculty should hand over the laboratory notebook and all the relevant documents to the higher concerned authority.
- b. Activities carried out jointly with other departments, institutions or agencies or under a sponsorship by an agency should be initiated after the governing terms are agreed upon mutually.
- c. Researchers and Faculty should take approval from concerned authority/Committee before starting/submitting a project to the internal/external grant agencies.



Intellectual Property Rights (IPR):

All Intellectual Property rights of research work carried out by Faculty / Scientists / Students / Project Staff / Supporting Staff / visitors of MIMER with or without intramural support shall vest in and be the absolute property of the.

a. Where Intellectual Property (IP) arises out of research funded by an external Sponsor e.g., governmentagency or other agency/institution/private company but the work/research is conducted at MIMER, the IPR of inventions arising out of such research projects in the absence a written arrangement shall be owned by MIMER.MIMER will meet the entire cost of filing and protection of IPR.

b. MIMER can protect and/or commercialize such IP with its own mechanism or using a third-party service provider.

c. At the time of appointment, the faculty is required to sign a document stating:

"The employee hereby agrees to strictly adhere to the Research and IPR policies of MIMER Medical College, failing which may lead to termination of employment



5. Publication and dissemination of research findings:

The Institute promotes publication and dissemination of research and its outcomes in indexed journals.

- All research projects carried out at MAEER MIT PUNE'S MIMER Medical College & Dr. BSTR Hospital, Talegaon Dabhade, Pune should be submitted for publication in indexed journals. A copy of submission of the same should be sent to Department of Clinical Research and Incubation Centre for their records.
- NMC advocates publication of research articles in journals indexed with Medline, PubMed Central, Science Citation Index, Science Citation Index Expanded, Embase, Scopus and Directory of Open Access Journals (DOAJ).
- The MIMER Medical Journal (MMJ) is a multidisciplinary, open access journalpublished biannually. MMJ is a peer reviewed official journal of MIMER Medical College, Talegaon Dabhade, Pune. It aims at disseminating novel biomedical research, clinical/ surgical methodologies, treatment reports and observational case reports freely to promote research and exploration in the medical fraternity and beyond. The students and faculty are also encouraged to publish their research papers in this journal.

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6. Conclusion:

This Code supports the commitment of MAEER MIT PUNE'S MIMER Medical College & Dr. BSTR Hospital, Talegaon Dabhade, Pune to scientific and ethical conduct of health research. Researchers must follow the principles of ethical behavior and standards of conduct that should guide their decisions and actions. All faculty members/ researchers are required to follow this Code in all research-related settings. The Department of Clinical Research and Incubation Centre, MIMER Medical College, IEC and Institutional Animal Ethics Committee (for animal research) ensures maintenance of an environment of transparency, honesty, integrity and responsibility in the conduct of research.

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Talegaon Dabhade