



MAEER MIT PUNE'S
MAHARASHTRA INSTITUTE OF MEDICAL EDUCATION AND RESEARCH,
MEDICAL COLLEGE (ESTD – 1995)
DR. BHAUSAHEB SARDESAI TALEGAON RURAL HOSPITAL

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).

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

Objectives:

The primary objectives of the Code of Ethics for Research for Maharashtra Institute of Medical Education & Research 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 MIMER Medical College, Talegaon (D).

It will also be applicable to all who collaborate with Maharashtra Institute of Medical Education & Research, 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.

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. Wrongdoing in research

The non-adherence to the principles laid out in this Code will be considered wrongdoing 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. The researchers are instructed to check the content plagiarisms by using various tools to detect plagiarism.

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

1. To guide and supervise the ongoing research projects and maintain its records.
2. To provide robust statistical analysis expertise for ongoing and future research projects
3. Help to write paper/papers related to the study for publication in reputed journals.
4. Grants
 - To identify the various funding agencies and facilitate application for grants.
 - To guide and facilitate making impressive proposals to various funding agencies for grants for research.
5. Resource faculty in Research Methodology Workshop (RM) in coordination with the Medical Education Technology Cell.
6. Study guidelines about MUHS related to synopsis/dissertation of Post graduate students and guide and maintain communications.
7. To provide an 'Elective' for UG students in research methodology. Every UG student must be allotted a Research Project, in second years, which will be under direct guidance and supervision of the Department of Clinical Research & Incubation Center (DCR & IC).
8. To help in In-house funding of institutional projects.

▪ **Conflict of interest**

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**

1. Researcher should have a clear understanding of intellectual property ownership and its use within the research projects as well as collaborative research projects.
2. Researchers should collaborate with colleagues who have the expertise and/or resources needed to carry out particular research. This could be inter-departmental/ inter-institutional or international and also multicentre involving public and/or private research centers and agencies.
3. Researchers 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. Obtain the appropriate permissions before making use of pre-existing intellectual property in research.
5. Acknowledge the use of pre-existing intellectual property when reporting and publishing research.
6. Consult 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).
7. After leaving the Institute, the researcher is required to obtain the written permission from the concerned authority 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 Dept. 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 Dept. of Clinical Research and Incubation Center.

B) Postgraduate Research Projects

JR1 students who are admitted to MIMER Medical College, Talegaon Dabhade, Pune and require funding for their Dissertation/Thesis projects are eligible.

Application for funding of Dissertation/Thesis research projects should be submitted to research@mitmimer.com

A separate sheet mentioning sample size, investigations/procedures for which funding is required, whether investigations/ procedures are available in house or needs to be outsourced need to be clearly mentioned. Xerox copy of IEC clearance certificate also needs to be submitted.

Financial Support:

- For investigations / Procedures that are a part of the treatment protocol, the cost of the same will be borne by the patient.

- For investigations/ Procedures that are not a part of the treatment protocol and that are done as a part of the thesis/ dissertation project-

A) If the facilities are available in house, the student will bear the cost of the same. At the end of the period of data collection, the student can submit the bills in the said format and will be reimbursed 80% of the amount spent. Remaining 20% of the amount will be reimbursed after submitting the Published copy of the project in indexed journals.

B) If the facilities are not available in house and the investigation/Procedures are outsourced, the student will bear the cost of the same. The charges for the same will be according to the rack rate fixed for the institution. At the end of the period of data collection, the student can submit the bills in the said format and will be reimbursed 80% of the amount spent. Remaining 20% of the amount will be reimbursed after submitting the Published copy of the project in indexed journals.

✓ It is mandatory that all investigations / Procedures need to be done in the institution, if facilities are available or in case of Outsourcing, the institutional protocol for the same is to be followed.

✓ The number of investigations/ Procedures permitted per project will be according to the sample size decided in the synopsis of the project. Additional 20 investigations/ procedures will be permitted in case of any unexpected outcomes. It is desirable that the concerned department Head be informed about the same.

Utilization of funds: Funding is only meant for test/procedure costs. Funding for purchase of equipment, stationary etc is not allowed.

Review of research work: The postgraduate student has to inform the Department of Clinical Research and Incubation Centre about the progress of the project every year by submitting a progress record to research@mitmimer.com

The post graduate student is required to publish at least one paper in International /National peer reviewed indexed journal from this project

C) Faculty Research Projects

All faculty research projects applying for institutional funding should have IEC clearance. The project needs to be submitted to the Research Committee for review along with the budgetary requirements for review. The funds allotted for faculty projects are Rs 20,000/department/year. A maximum of 5 departments / year will be allotted funds. Faculty presenting Oral papers/ posters in National and International conferences will also be awarded Rs.2500/- for poster and Rs.5000/- for Oral paper presentation. In order to promote publication of the research projects carried out in the institute, financial support of Rs. 7500/-, Rs. 5000/- and Rs.3000/- will be provided depending upon the Impact factor of the journal.

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 (DRDI) , Ministry of Health and Family Welfare (MHFW) 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 MIMER Medical College, 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 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.
- d. Before applying for any IPR the Researchers and Faculty in MIMER should take the approval of the concerned authority/committee.
- e. All Intellectual Property rights (IPR) 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 MIMER.
- e. Where IP arises out of research funded by an external Sponsor e.g government agency 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.
- f. MIMER can protect and/or commercialize such IP with its own mechanism or using a third party service provider.
- g. 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 MIMER Medical College, Talegaon Dabhade 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.
- Researchers are advised to submit their articles to journals with Impact factor 2 and above.
- 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 journal published 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.

6. Conclusion:

This Code supports the commitment of MIMER Medical College, Talegaon Dabhade, to scientific and ethical conduct of health research. Researchers must follow the principles of ethical behaviour 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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