Central Research Policy
Maharashtra University of Health Sciences

Preamble

Maharashtra University of Health Sciences, Nashik is a State Govt. University. The University caters academic services to the students and institutes in the state of Maharashtra. At present there are 373 health science institutes affiliated to the University. The University conducts undergraduate, postgraduate, super speciality courses, fellowship programs, Ph.D. and M.Phil. Programs and other need based academic programs for different health science faculties such as Allopathy, Ayurved, Homeopathy, Unani, Dentistry, Physiotherapy, Occupational Therapy, Audiology & Speech and Language Pathology & Nursing. The undergraduate and post graduate students, research fellows and teachers undertake various research activities as a part of curriculum and also as a professional activity. Research in health sciences has a key role in creating a scientific temper among the stake holders and providing solutions to health care related problems of the society.

The 'Central Research Policy' provides a framework for design, management and implementation of research and for development a infrastructure for research related activities in the University and its affiliated organizations. It is aimed to inculcate the culture of research and to enhance attitude of innovation, incubation, and implementation of robust research among the academic fraternity of the University.

Mission

- To cultivate and develop research scientists who create and apply knowledge to enhance the quality of health of individuals and communities.
- To create a conducive ecosystem for excellence in research amongst the academic and medical fraternity

Vision

To Pursue excellence in health care through innovative research and education contributing to implementation of affordable systems to improve and transform health care worldwide.

Values: To inculcate following values in research scholars:

- Integrity: Maintain professional, ethical, and honest practices in all research activities.
- Originality: Develop and maintain originality in research work and to prevent plagiarism.
- Excellence: Pursue the highest standards in research, teaching, and service.

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MNHS Research Policy

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- Learning: Continuously evaluate and improve research through the creation and use of rational approaches and innovative ideas.
- Inclusiveness: Respect cultural values and diversity, maintain dignity and respect for all, and build an environment as diverse as the challenges and opportunities facing health care.
- Collaboration: Establish relationships across disciplines and the various communities being served, and incorporate multiple perspectives into research, teaching, and health care.
- Equity: Equal opportunity of participation to all involved and to be open to ideas of research from any one.
- Commitment: Commitment by all to serve the needs of the entire population, regardless of differences or circumstances, and address the barriers and disparities that hinder people's ability to lead healthy lives through research, teaching, and health care.

Aims of the policy

To promote and generate globally acceptable quality scientific evidence addressing the health problems of society through active participation of all stake holders.

1. To generate conducive atmosphere for research and improve overall research experience.
    a. by developing strategies and plans ensuring open and clear communication.
    b. by providing efficient research administrative services while effectively managing risks and opportunities.
    c. by reducing administrative burden of the researcher .
2. To promote capacity building in Research
    a. by improving access to key information.
    b. by providing required guidance, training, and know how.
    c. by improving researcher productivity
3. To improve the quality of Research.
    a. by providing necessary infrastructure for research training and activity related work
    b. by providing guidelines for conduct and publication of research.
4. To promote research education
   by conducting various academic courses, programs based on research methodology, clinical research, drug research etc.
5. To integrate research and education
    a. by implementing dynamic curricula which will automatically include extraordinary research contributions.
    b. by including subjects like research methodology, innovation, design thinking etc. in the syllabus at appropriate levels.
    c. by allotting credits for participation in research activities such as paper presentations of published research papers from peer reviewed journals as a part requirement of course curriculum at UG level

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6. To prioritise areas of research.
    a. by assessing the health care needs of the society
    b. by assessing the strength of respective medical systems
7. To identify and adopt good research practices
8. To develop ideal Research Infrastructure & facilities as follows
    a. Central Research Facility
    b. Central Research Laboratory, Animal House, Medicinal plants garden, Museum
    c. Media laboratory/Business Lab/e-resource Studio
    d. Research/Statistical Databases/Health Informatics centre
    e. Central research library
    f. Research referral and guidance centre
    g. Biomedical engineering laboratory
    h. Clinical trial facility for all Systems in the University Hospital
    i. Research Training centre for providing training in all modalities related to research such as Research methodology, design thinking, innovation, medical statistics, Scientific writing, designing a research proposal, legal aspects of research, ethics in research and research grant writing etc.
9. Achievement of Operational excellence in Research
    a. by streamlining research processes
    b. by developing effective relationships with process partners and campus research community.
    c. by Identifying and adopting best research practices
    d. by promoting a culture of continuous process improvement in research work
    e. by motivating the teachers, faculty and students for research activities.
    f. by embracing a culture of transparency and accountability.
    g. by establishing transparent, merit-based decision-making systems for the allocation of financial and other supports for research.
    h. by developing a system of strategically analysing risk and benefits of any proposal, policy or system.
10. To encourage interdisciplinary research between different systems.
    a. by removing barriers in collaboration
    b. by encouraging inter and intra disciplinary knowledge sharing
    c. by encouraging inter and intra disciplinary interactions
11. Development of research ecosystem for attracting talented researchers from diverse fields
    a. by cultivating an environment that stimulates challenges, develops skills, knowledge and competencies through continuous learning
    b. by encouraging staff engagement and participation in research activities at all levels
    c. by ensuring development of career paths for promoting upward mobility in organisation
    d. by developing competitive work culture.

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e. by encouraging strategic initiatives, strategic research directions and policies that will have national and international impact.
f. by translating research outcomes into applicable measures for public benefit.
g. by promoting and enhancing cost effective research initiatives
h. by promoting cutting edge technologies
i. by procuring external research funds

12. To Motivate the students, teachers and practitioners to undertake and develop research activities
    a. by rewarding the best thesis / dissertations at PG and PhD levels
    b. by rewarding best publications at periodic intervals
    c. by rewarding best innovative ideas
    d. by recognising outstanding contribution in research
    e. by nominating emeritus, distinguished professors/ scientists
13. To collaborate with research organisations & institutions of high repute having mutual interests at National and International levels.

Organizational structure:

An organizational structure for monitoring various research activities in the University will be established. It will comprise of Central Research Board, University Research Steering Committee and other sub-committees.

Central Research Board:

There will be a Central Research Board, which will overall supervise the University research activities. The composition of this board will be as follows:

1. Chairman – Vice chancellor – Ex officio
2. Vice -Chairman - Pro-Vice Chancellor – Ex officio
3. Dean of Faculty - two members by rotation of faculties (Roaster of rotation between the faculties will be decided by lottery method at the time constitution of first Central Research Board)
4. Member Secretary – Registrar – Ex officio
5. De facto Members: Chairman and 2 Co-chairmen of University Research Steering Committee will be de-facto members of the board.
6. Member Secretary - University Official heading Research activities -Ex officio
7. Finance & Accounts officer ex officio
8. Expert Members: 5 (1 from each of the faculties)
   Eligibility for expert members:
   Qualification: Minimum Post-graduate degree (Excluding P.G. diploma)
   Experience: 10 years teaching/Professional with Notable research contribution in the form of publication, reviewer of indexed research journal, first or second author of original research article published in indexed journals, participant of research project as an investigator, Patent holder (Not necessary that he should be a member of any of university bodies or a teacher or officer in University or University affiliated institutes)

   The term of the Central Research body will be 5 years.

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University Research Steering Committee:

There will be a University Research Steering Committee, which will be responsible for setting the direction and monitoring of all research related activities in the University.

Composition of University Research Steering Committee will be as follows:

1. Chairman (Experts from each faculty of the University will get a chance to chair the steering committee by rotation. Roaster of rotation between the faculties will be decided by lottery method at the time constitution of first Steering committee. The term of the faculty once decided by lottery method the expert from that faculty will be nominated by the Vice-chancellor)
2. Co-chairman – 2 (The faculty represented as Chairman will not be considered for Co-chair. The remaining faculties will be decided on the basis of lottery method as applied for nomination of the chairman)
3. Member – Member Secretary University Ethics committee de-facto
4. Expert Members – 7
   5 nominated by Vice Chancellor 1 from each faculty
   2 nominated by Academic Council
5. Member Secretary - University Official Heading Research activities - ex officio

Eligibility for nomination as chairman, co-chairman and member in the committee
Qualification: Minimum Post graduate degree (Excluding P.G. diploma)
Experience: 15 years teaching/Professional with Notable research contribution in the form of publication, Peer or reviewer of peer reviewed research journal, having Impact Factor, first or second author of original research article published in indexed journals, participant of research project as an investigator, Patent holder (Not necessary that he should be a member of any of university bodies or a teacher or officer in University or University affiliated institutes)

The term of the Steering committee will be five years

Subcommittees

On recommendation of University Research Steering Committee, the Central Research Board will constitute sub-committees to take forward the research work in a systematic manner. The committees will be as follows:

1. Committee on Research methodology & training
2. Institutional Ethics committee (Registered) with DCGI
3. Committee on Publication guidelines
5. Research collaboration and networking committee
6. Research Grants Committee
7. Research Conference & Competition Committee
8. Research Data Management Committee
9. Faculty wise Project Evaluation committee.

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In addition to the above committees the Central Research Body will constitute any other sub-committee as and when required on recommendation of University Research Steering Committee.

The members of the sub-committees will be nominated by the Vice Chancellor

No committee will have minimum five members and not more than 7 members.

Operative guidelines for Research Activities in the University:

The university research activities are broadly categorized as under

1. Intra-mural Research
2. Extra-mural Research
3. Training in Research
4. Research Publications
5. Reward & recognition of research contributions
6. Translation of Research outcomes into applicable measures for Public benefits
7. Capacity building of stakeholders
8. Identification of thrust areas for research
9. Intellectual property Rights support
10. Post-doctoral research

1.Intra Mural Research Projects:

University will take up research projects in its own Research Institute or department or in collaboration of University affiliated organizations.

The modus operandi of these projects will be as follows:

- Subject for the research project will be identified and selected by the Central Steering Committee considering the priority areas.
- The steering committee will see that the project will be of integrative nature, which will require experts from various systems of medicine.
- All such experts will be identified by the committee from the University Research dept/institute or from affiliated organizations.
- Concerned expert working in the University Research department will function as a Principal Investigator of this project. If such an expert is not available in University dept., expert from organizations affiliated to the University will be identified and will be invited to function as Principal investigator of the project.
- Principal Investigator will draft the project and submit it to the University Research Steering Committee.
- University Research Steering Committee will screen and approve the project along with required funds.
- Such approved project will be placed in the Central Research Board for final approval.
- Following approval of the project by the Central Research Board the Principal Investigator will start his work.

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- The project work will be monitored by the Central Steering Committee.

2. Extra-mural research (EMR):

Extramural Research activities are broadly divided into following two categories:

A. Research under University assisted Extra-mural Research Schemes (EMR)
B. Post-graduate, Doctoral and Post-doctoral Research

A. Research under University assisted Extra-mural Research Schemes (EMR)

University will provide financial assistance to teachers, students, practitioners and other stakeholders for research projects under Major and Minor Research schemes. The schemes will be designed and updated and modified periodically considering the existing requirements.

The EMR scheme shall be executed to provide funding to potential research scholars like practising doctors / professionals willing to take up research projects. However, every investigator may be compelled to involve PG/Ph. D. Scholars/teachers/adjunct faculties as research assistants from University affiliated institutions in the projects funded by the University.

Researchers receiving funding for major research projects will be asked to take graduate and post-graduate students as per the necessity of the project from the university affiliated institutes preferably from local institutes as research fellows, associates or assistants as required. These fellows, associates and assistants will be entitled to receive stipend as admissible in the scheme. A provision in this regard will be made in the scheme.

B. Post-graduate, Doctoral and Post-Doctoral Research:

PG, Ph.D. students are the principal source of future research scholars. The PG. Ph.D. study period needs to be considered as incubation period of research scholars. The students need to be groomed and their affinity for impulsive research, which needs to be harboured and groomed. Attempts will be made for improving the quality of post graduate and doctoral research. Steps will be taken to imbibe research attitude in the PG and PHD students.

Following steps will be adopted:

Thrust areas for taking up the research projects will be identified. The institutes will be encouraged to select specific research areas considering their geographical area and societal needs. The departments will be asked to maintain the continuity of research studies even though the students are replaced at regular intervals due to completion of their study period, with an objective to achieve expertise in that subject. Every institute will be asked to communicate University department wise selection of identified research topics/subjects setting ten year objectives.

Activities like interchange of teaching faculties and post graduate students between nearby institutes will be introduced. The institutes will be encouraged to invite expert and eminent speakers having expertise in related subjects as visiting professors.

To create the research and study ambience student will be asked to set his own term wise targets based on his research subjects. So that he will be kept engaged and research oriented. The University will notify the minimum number of each such activity to be taken up for every term.

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The students will be asked to complete specific set work objectives related to their research work at the end of every six months term of study period. Every student will prepare a completion report of the allotted work and submit it to University at the end of this period.

The examiners appointed for taking Post graduate examinations will be asked to evaluate the work done by non-appearing but undergoing PG Ph D study in the department in the concerned department in addition to taking examination of examinee. They will be asked to submit their evaluation, specifying whether the research work allotted to the student in the related period is completed or not. They may recommend extension of study period of the student who does not complete the expected task. Period specific targets may be given by the student himself in his synopsis. The target needs to be practical oriented, theoretical targets such as review or study of literature, collection of references may not be considered.

3. Training in Research

   Training is a very important part in every activity. Usually the research is conducted in the medical field as an activity in addition to the regular profession teaching or clinical practice. However, there is a dire need to produce experts specialized in Research. Research needs to be developed as a carrier opportunity. These experts will choose research in medicine as their carrier. This will boost the research activities in University as a whole. Programs based on Research methodology, Clinical research, Drug research, Public health, Biomedical research, Medicinal plants, Mineral and metal drugs, Literary research, History of Medicine etc. will be conducted in the University.

4. **Research Publications:**

An independent publication cell or department will be established under the University Research Department for all publication related work. Publication is the basic need of any research activity and it is mandatory for every institution to have an ecosystem of documentation and publication of research work undertaken in the institution and elsewhere. Developing a peer reviewed research journal with high impact factor is therefore extremely essential. Such journal not only serves as source of publication, but it is also used as source of reference and acts as a guiding light for further researches. Good research journal is a show case of the quality outcome of the research projects. The quality of published research work demonstrates the research acumen of research scientists and it also helps to evolve the research acumen of aspiring scientists

It will function as an independent activity under following standard under will invite original research articles, review articles, articles and other material from all over the globe and strive to maintain the quality of published work. Apart from publication for research journal the department will undertake publication of other research and academic material also such as books, information brochures etc.

A scheme for publication of text books and other academic publication for teachers and researchers will be developed and launched for encouraging quality writing.

5. **Reward and recognition of Research work**

   Appreciation of research work whether it is at graduate, post-graduate, doctoral or post-doctoral levels, is essential to keep up the motivation for research and attract the talent towards research. MUHS will create a rewards and recognition programme to systematically enhance the pool of motivated passionate researchers contributing to the society.

   MUHS will identify the research acumen and reward it with best award for:

   a. best compilation or survey at UG levels

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b. best thesis at PG level
c. best research work at PhD levels
d. best publications at periodic intervals
e. best innovative idea
f. by recognising outstanding contribution in research
g. rewarding research stalwarts of the fraternity with honours like, adjunct / emeritus/ distinguished professor, emeritus scientist or recognise with titles of Ph. D. (Hon.) or D. Litt.

6. Translation of Research outcomes into applicable measures for the Public benefit

Research work utilizes huge amount of financial resources, human resources and intellectual resources but if we look at the translation of the research outcomes in terms of benefits to the society the conversion ratio is extremely poor. Special efforts need to be undertaken to develop a system which will help in translating the outcomes of research in terms of direct benefits to the society i.e. health of people, development of new drugs, improvement in teaching methodologies, improvement in the curriculum etc. In an ideal situation research outcome should drive development of guidelines and protocols of preventive, promotive and protective health, treatment protocols, research protocols, etc.

Research Data management committee will study the high-quality outcome researches published in various peer reviewed journals and prepare guidelines for its implementations. These guidelines may be submitted to the steering committee which will decide the further course of action.

7. Capacity building of stakeholders in research

The stake holders i.e. students, teachers, Research scientists form the backbone on Research in any institution, the quality of outcome of the research is directly dependant on the capacity of the stake holders. Capacity building initiatives and training programmes and organization of Workshops, seminars etc. should be undertaken continuously in systematic and sustained manner. Following activities will become the part of mandatory research activities as capacity building initiatives.

A. Capacity building in research methodology, research ethics etc

Indicator for monitoring the outcome:

Number of Workshops/seminars conducted (at Institutional / University level) on

i. Research methodology,
ii. Good clinical Practice,
iii. Laboratory, Pharmacy and Collection practices,
iv. Research Grant writing,
v. Intellectual Property Rights (IPR),

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vi. Computer Assisted Data Management Techniques etc.

B. Institutional Capacity Building – The quality of the research work of University lies in the quality of stake holders in the institutes within its campus and in the affiliated institutions, with the later forming a major part. The affiliated institutions will be motivated to undertake capacity building measures in alignment with MUHS.

Indicators for monitoring of University affiliated institutes will be as follows:

Establishment and functioning of Institutional Research Cell/ Society, Institutional Ethics Committee, number of teachers trained in basic and advanced research methodology workshops etc. number of University approved resource persons for research methodology trainings.

C. Research Collaboration and networking

Indicators for monitoring

Number of research collaborations

Number of collaborative research projects undergoing / completed with National / International Research / Academic / Health Institutes

Grants received through research collaborations

D. Promotion and mobilization for research

No. of scientists awarded research grants

No. of scientists completed University funded research projects

No. of completed Ph. D. researches

E. Development of appropriate ecosystem

No. of Research Competitions / conferences organized

No. of Research Publications / Journals / Modules

F. Extramural research

On high priority health related issues identified by inviting the thrust areas from Directorates and Research/ Academic Institutes and implementation through multi centric design.

Indicators for monitoring

Number of extramural projects undertaken / completed.

G. Generation of Research Data base at Institutional/ University level

No. of institutes having complete research data base of last 5 years.

Percentage upload of faculty research data base on university website of last five years.

H. Promotion of Interdisciplinary research

No. of interdisciplinary research projects undergoing/completed in affiliated institutes.

No. of interdisciplinary research projects undergoing/completed at University level.

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8. **Identification of thrust areas for research and development of database of research problems**

Well directed research which addresses the needs of the society is essential to contribute to the development of the science and to be useful and relevant to the society.

The identification of the thrust areas can be achieved by constituting a research think tank of experienced researchers from across all faculties which will identify the most needed areas in health sector. The parameters to decide the thrust areas for research can be:

a. Those diseases / conditions which have limitations with respect to treatments e.g. Psoriasis, Cancer, HIV etc
b. Those diseases / conditions which affect larger group of the society e.g. diabetes, ischemic heart diseases
c. Those diseases / conditions for which treatments are very costly
d. Those diseases /conditions which have the potential to damage the health of society to a great extent e.g. Alcoholic liver diseases, psychological conditions

The research problems thus identified from this source and from other sources will be stored in database and will prove as a major resource for future researchers it can be made accessible to all researchers.

The think tank can add various additional parameters and the data collected by this group can be forwarded to steering committee for further action.

A system and subject specific problem bank for providing research questions and problems to students and researchers will be developed and maintained. It will be updated from time to time.

9. **Patenting and Intellectual Property Rights support**

The steering committee will have a sub committee which can assess the progress of research projects undertaken under various schemes of MUHS like EMR, IMR etc. and those projects having promising outcome that can positively affect the society can be taken up for providing support for IPR with the help of legal cell of the MUHS.

Separate database of patents applied for and patents granted can be maintained and made accessible to everyone.

10. **Post-doctoral research**

University will establish a state-of-the-art centre for conducting post-doctoral research. This centre will have facilities for conducting experiments and clinical trials specially for post-doctoral research fellows. Facilities like accommodation for long

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stay for study and other project related activities will be provided. University will award post-doctoral fellowships and other degrees like D.Lit., and other similar qualifications.

Inter faculty, inter disciplinary within the system and across the system Post doctor research will be encouraged by the University.

Review of Research Policy

The research policy will be reviewed periodically at the interval of five years or as required from time to time.

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छत्रपती शाहू महाराज शिक्षण संस्थेचे
दंत महाविद्यालय व रुग्णालय, औरंगाबाद
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Date: 01/01/2021

34. College Ethical Committee

Sr. No.	Name of Teacher	Designation
1)	Dr. S.G.Deshmukh	Chairman
2)	Dr. S.C.Bhoyar	Member
3)	Dr. Lata Kale	Member
4)	Dr.Jeevan Khatri	Member
5)	Dr.Suchita Daokar	Member
6)	Dr.Babita Yeshwante	Member
7)	Dr. S.G.Daokar	Member
8)	Dr. Maya Mhaske	Member
9)	Dr. Uma Mahindra	Member
10)	Dr. Sanjay Sarode	Member
11)	Dr. Mayuri Kwasadikar	Student Member
12)	Dr. Shubham Nandkhedkar	Student Member

Dr. Lata Kale
Acting Dean
DEAN
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Dr. S.C. Bhoyar
Director
DIRECTOR
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Kanchanwadi, Aurangabad.

Chhatrapati Shahu Maharaj Shikshan Sanstha's
DENTAL COLLEGE & HOSPITAL
(An ISO 9001: 2008 Certified)
KANCHANWADI, PAITHAN ROAD, AURANGABAD - 431 011. (M.S.)
(Recognized by Dental Council of India Under Maharashtra University of Health Science,Nashik)

INSTITUTIONAL CODE OF ETHICS FOR RESEARCH

THE INDIAN PERSPECTIVE

The Indian Council of Medical Research (ICMR), in February 1980, released a 'Policy Statement on Ethical Considerations involved in Research on Human Subjects'. This was the first policy statement giving official guidelines for establishment of ethics committees (ECs) in all medical colleges and research centres. But as with other nations of the world, these guidelines were not respected by many researchers and India was not free of controversial research works.

In 1970s and 1980s researchers at the Institute for Cytology and Preventive Oncology in New Delhi, carried out a study on 1158 women patients of different stages of cervical dysplasia or precancerous lesions of the cervix . These patients were left untreated to see how many lesions progressed to cancer and how many regressed. By the end of the study seventy one women had developed malignancies and lesions in nine of them had progressed to invasive cancer. Sixty-two women were treated only after they developed localised cancer. After the controversy about the study became public in 1997, the ICMR started developing 'Ethical Guidelines for Biomedical Research on Human Subjects' and finalised them in the year 2000. These are a set of guidelines which every researcher in India should follow while conducting research on human subjects. Although not a law, these guidelines have been put into force through Schedule Y. With the changing scenario in the research field and development of modern techniques, the guidelines were revised in 2006.

These guidelines have elaborated the three basic ethical principles: **A. Respect for person, B. Beneficence and C .Justice** by inducting **twelve** general principles as follows:

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1. PRINCIPLE OF ESSENTIALITY

The research being carried out should be essential for the advancement of knowledge that benefits patients, doctors and all others in aspects of health care and also for the ecological and environmental well being of the planet.

2. PRINCIPLES OF VOLUNTARINESS, INFORMED CONSENT AND COMMUNITY AGREEMENT

The research participant should be aware of the nature of research and the probable consequences of the experiments and then should make a independent choice without the influence of the treating doctor, whether to take part in the research or not. When the research treats any community or group of persons as a research participant, these principles of voluntariness and informed consent should apply to the community as a whole and also to each individual member who is the participant of the research or experiment.

3. PRINCIPLE OF NON-EXPLOITATION

Research participants should be remunerated for their involvement in the research or experiment. The participants should be made aware of all the risks involved irrespective of their social and economic condition or educational levels attained. Each research protocol should include provisions of compensation for the human participants either through insurance cover or any other appropriate means to cover all foreseeable and hidden risks.

4. PRINCIPLE OF PRIVACY AND CONFIDENTIALITY

All the data acquired for research purpose should be kept confidential to prevent disclosure of identity of the involved participant and should not be disclosed without valid legal and/or scientific reasons.

5. PRINCIPLE OF PRECAUTION AND RISK MINIMISATION

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Due care and caution should be taken at all stages of the research and experiment (from its beginning as a research idea, formulation of research design/ protocol, conduct of the research or experiment and its subsequent applicative use) to prevent research participant from any harm and adverse events. EC has to play an active role in risk minimization.

6. PRINCIPLE OF PROFESSIONAL COMPETENCE

Clinical research should be carried out only by competent and qualified persons in their respective fields.

7. PRINCIPLE OF ACCOUNTABILITY AND TRANSPARENCY

The researcher should conduct experiments in fair, honest, impartial and transparent manner after full disclosure of his/her interests in research. They should also retain the research data, subject to the principles of privacy and confidentiality, for a minimum period of 5 years, to be scrutinized by the appropriate legal and administrative authority, if necessary.

8. PRINCIPLE OF THE MAXIMISATION OF THE PUBLIC INTEREST AND OF DISTRIBUTIVE JUSTICE

The results of the research should be used for benefit of all humans, especially the research participants themselves and/or the community from which they are drawn and not only to those who are socially better off.

9. PRINCIPLE OF INSTITUTIONAL ARRANGEMENTS

It is required that all institutional arrangements required to be made in respect of the research and its subsequent use or applications should be duly made in transparent manner.

10. PRINCIPLE OF PUBLIC DOMAIN

The results of any research work done should be made public through publications or other means. Even before publication, the detailed information

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of clinical trials should be made public before starts of recruitment via clinical trial registry systems that allow free online access like: www.ctri.in/; www.actr.org.au/; www.clinicaltrials.gov/ or www.isrctn.org/.

11. PRINCIPLE OF TOTALITY OF RESPONSIBILITY

All those directly or indirectly connected with the research should take the professional and moral responsibility, for the due observance of all the principles, guidelines or prescriptions laid down in respect of the research.

12. PRINCIPLE OF COMPLIANCE

All those associated with the research work should comply by the guidelines pertaining to the specific area of the research.

For research to be conducted ethically we need to follow these twelve general principles laid down by the ICMR. In order to follow these principles we should be aware about the informed consent process, vulnerable population, therapeutic misconception, post trial access and structure and role of ethics committees. These concepts hold special importance in developing countries like ours, as most of the research participants are uneducated and economically backwards, hence we discuss them here.

INFORMED CONSENT

A well-documented informed consent is the hallmark of any ethical research work. It is the responsibility of the investigator/researcher to obtain the informed consent of the prospective participant or in the case of an individual who is not capable of giving informed consent, the consent of a legal guardian. Informed consent respects individual's autonomy to participate or not to participate in research. Adequate information about the research is given in a simple and easily understandable vernacular language in a document known as the 'Participant/Patient Information Sheet' attached along with the 'Informed Consent Form (ICF)'.

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The patient information sheet should include: A statement that the study involves research; an explanation of the purpose of the research and the expected duration of the subject's participation; a description of the procedures to be followed and identification of any procedures which are experimental; a description of any reasonably foreseeable risks or discomforts to the subjects; a description of any benefits to the subjects or to others which may reasonably be expected from the research; trial treatment schedule(s) and the probability for random assignment to each treatment (especially in randomized placebo controlled trials); a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subjects;

A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained; for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, and where further information may be obtained; an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subjects; a statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subjects are otherwise entitled, also the subjects may discontinue participation at any time without penalty or loss of benefits.

The ICF should specify that the participant has read and understood the patient information sheet; no further permission is required to look into his health records for study purpose until his identity is not revealed; the results arising from the study can be used only for scientific purposes and he voluntarily agrees to take part in the study. The ICF should have space for signature/thumb print of the participant, the principal investigator, a witness and a legally acceptable representative when required.

The ICF with participant/patient information sheet should be approved by the EC before use. The ICF should have the sign or thumb impression of the prospective participant before start of the experiment. If the participant is

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illiterate, the document should have the signature of a witness, who has seen that the contents of the patient information sheet were adequately explained to the participant. If the participant is a minor or not capable of giving consent, a verbal assent should be taken from him and the consent form should be signed by his legally acceptable representative. If the treating physician of a prospective participant is also the investigator, the informed consent should be taken by any other neutral physician to prevent biased decision of the participant. Informed consent if properly taken protects the rights of prospective participants and thus forms the basis of ethical research work.

VULNERABLE POPULATION

Persons who are relatively or absolutely incapable of protecting their own interests are termed as vulnerable research population. The very poor, illiterate patients, children, individuals with questionable capacity to give consent (including psychiatric patients), prisoners, foetuses, pregnant women, terminally ill patients, students, employees, comatose patients, tribals and the elderly are examples of vulnerable population. Declaration of Helsinki. states that 'Medical research involving a underprivileged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of that population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.' It is the responsibility of the EC to see whether the inclusion of vulnerable populations in the study is justifiable or the population is just being exploited to generate clinical data. To prevent even minor exploitation the EC should consult the representative of vulnerable population that is to be researched upon while reviewing the protocol.

THERAPEUTIC MISCONCEPTION

The therapeutic misconception (TM) is a vexing ethical issue for obtaining valid informed consent. A patient coming to a physician may misinterpret and enrol in a research study thinking it to be routine medical care without understanding the experimental nature of the treatment given. He may misinterpret the

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information given about the research, such that he believes that aspects of the research will directly benefit him.

Thus, it is important that investigators should make efforts to dispel the TM in order to promote ethical and valid informed consent. ICFs should clarify the salient features of research: The purpose of randomized controlled trials (RCTs), random selection of treatment, masking of treatment, meaning and rationale of placebo, restrictions on treatment flexibility and how treatment decision making differs in RCTs compared with routine medical care. Thus to safeguard the ethical rights of the participants therapeutic misconception needs to be taken care of.

Post-Trial Access

The concept of post trial access holds special importance for clinical research works in the less developed countries. Pharmaceutical companies from developed countries collect the clinical data for their new and experimental drugs from the population in less developed countries.

Most of these drugs would never be used by the communities from where the experimental data are collected and here comes the importance of post trial access for safeguarding the rights of such communities. The Helsinki Declaration of WMA, 2000 states that at the end of the trial, every participant should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.

The Declaration of the WMA in 2004 reaffirmed its position that "it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care.

Post-trial access arrangements or other care must be described in the study protocol so that ethical review committee may consider such arrangements during its review."

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Therefore, whenever possible EC should consider such an arrangement in the a priori agreement. Sometimes more than the benefit to the participant, the community may be given benefit in indirect way through improving their living conditions, establishing counselling centres, clinics or schools and giving education on maintaining good health practices.

ETHICS COMMITTEE

The first appearance of need of ethics committee (EC) was made in Declaration of Helsinki in 1964, while in India it appeared in 1980 in the ICMR Policy Statement. EC also called as the Institutional Review Board or the Ethics Review Board stands as the bridge between the researcher and the ethical guidelines of the country.

The establishment of EC requires 5-15 members with at least one basic medical scientist (preferably one pharmacologist), one clinician, a legal expert, a social scientist / representative of NGO / philosopher or theologian and a lay person from the community. Every institute, where research is going on should have its own EC with its head preferably from outside the institute.

Individuals carrying out research can approach to independent ECs. The decisions of EC should be taken only after quorum formation with a minimum of five members having at least one basic medical scientist, one clinician and one legal expert or retired judge. The ECs should have independence from political, institutional, professional, and market influences, in their composition, procedures, and decision-making. As there are no laws governing the registration, formation or working of ethics committees in India, each ethics committee should have their own standard operating procedures for proper functioning.

ECs are responsible for carrying out the review of proposed research before the commencement of the research. The basic responsibility of EC is to ensure an

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independent, competent and timely review of all ethical aspects of the project proposals received in order to safeguard the dignity, rights, safety and wellbeing of all actual or potential research participants. The scientific design and conduct of the study should also be reviewed at the outset as poor science is poor ethics. The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation) and the potential for reaching sound conclusions with the smallest number of research participants should be assessed. The EC should also look into matters like informed consent process, qualifications of principal investigator and supporting staff, adequacy of infrastructure and facilities, risk benefit ratio, plans to maintain confidentiality and plans for post trial access and compensations. They also need to ensure that there is regular evaluation of the ongoing studies that have received a positive decision. EC is the most important check point for promoting ethical research in the country.

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