KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH, BELAGAVI

(Deemed-to-be-University)
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KLE
EMPOWERING PROFESSIONALS

CODE OF ETHICS

kledeemeduniversity.edu.in

The University

The KLE ACADEMY OF HIGHER EDUCATION & RESEARCH (KAHER) was established on 13th April, 2006 as per the Ministry of Human Resource Development, Government of India under the recommendation of University Grants Commission. The sponsoring society "The KLE Society" celebrating its centenary was established on 13th of November 1916 by "Seven Dedicated Teachers —The Saptarishis" and has under its wing 250 institutions spread across Karnataka, Maharashtra, Goa, Delhi etc.

In a short span of time the University has firmly established itself as a centre of excellence in terms of medical education, research and health care services at the national and international level. The University offers various undergraduate, postgraduate, post-doctoral, fellowship and certificate programs in the faculties of Medicine, Dentistry, Pharmacy, Ayurveda, Physiotherapy and Nursing.

In terms of infrastructure the University has excellent teaching facility, state of the art teaching hospital and medical research centre having 2400 beds, basic science research centre spread over an area of 10,000sq.ft., Wi-Fi facility all over the campus, digital library and other facilities on par with premier institutes of national and international repute. Facilities like bank, post-office, pharmacy, gym, swimming pool, indoor stadium, cafe, department store, travel booking, etc. are provided in the campus itself. Calendar of events delineating the date of examination schedule and other important curricular events are provided to every student at the beginning of academic session thus enabling the students to plan and pace their studies well in advance.

The Department of Allied Courses was established in 2007. There is expected to be a tremendous demand for allied health professionals in the years to come because of the phenomenal growth in the healthcare industry. In view of this, KAHER offers a range of allied courses in the form of undergraduate, postgraduate, fellowship, diploma, postgraduate diploma and certificate courses.

Code of Ethics
KLE Academy of Higher Education and Research
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Contents

Code of Ethics
KLE Academy of Higher Education and Research (Deemed-to-be University)

1. Preamble:

The KLE Academy of Higher Education and Research (KAHER)is committed to promote and support quality research in an intellectually stimulating and inspirational environment to address the scientific challenges of today and the future.

This Code of Ethics aims to encourage and support research for acquiring, investigating and developing knowledge for the good of society, and to confirm that, all research is conducted in accordance with ethical principles.

The enduring excellence in research that KAHER aspires for, is dependent on several attributes that include creativity, rigor, curiosity, persistence as well as on honesty, responsibility and ability for good communication and collaboration. Thus, intellect and integrity have to go together to maintain the credibility and reputation of the University's Research and repute of individual researchers. Hence it is there sponsibility of every staff member and student to uphold the good reputation of the University and, consequently, it is expected that they will conduct research with integrity.

2. Definition of Research:

All investigations undertaken in order to acquire new knowledge and understanding will be defined as Research.

3. Purpose of Research:

- To enhance the knowledge related to human conditions while maintaining sensitivity to the Indian cultural, social and natural environment;
- Conducted under conditions such that no person or persons become mere means for the betterment of others and that human beings who are participating in any biomedical and/or health research or scientific experimentation shall be dealt with in a manner beneficial to and consistent with their dignity and well-being, under conditions of professional fair treatment and transparency;
- Shall be subjected to a system of evaluation at all stages of the research, such as design, conduct and reporting of the results there of. and
- Must improve the health outcomes of the community both local and global.

4. Research Ethics:

- The ethical conduct of research is essential for those working in all disciplines, particularly for researchers in medicine and life sciences. Research should avoid causing harm, distress, anxiety, pain or any other negative feeling to participants.
- Participants should be fully informed about all relevant aspects of the research, before they agree to take part in it.
- As professionals, researchers practice the value intrinsic to the research profession, to seek greater knowledge and understanding, and as members of wider society, they are responsible for respecting the values of society, not to cause harm and consider the public interest.
- Innovation, creativity and freedom of academic enquiry and expression are enshrined both by law and for the need to ensure openness and respect in relations within our community. Provided that these requirements are met, the University will support staff and students seeking to publicize the results of research and scholarship that has been carried out as a part of their roles with in the University. The University expects staff and students to share its values and requires that they do not associate the University, or other members of it, in matters which reflect their own opinions on topics that are not the outcome of work carried out as part of their roles in the University

4.1. Fundamental Principles:

Research on human participants pertains to a broad range of scientific enquiry aimed at developing generalizable knowledge that improves health, increases understanding of disease and is ethically justified by its social value. Every research has some inherent risks and probabilities of harm or inconvenience to participants/communities. Therefore, protection of participants should be built into the design of the study.

Do no harm(non-maleficence) has been the underlying universal principle guiding health care in all systems of medicine around the world. While conducting biomedical and health research, the four basic ethical principles namely; respect for persons (autonomy), beneficence, non-maleficence and justice have been enunciated for protecting the dignity, rights, safety and well-being of research participants.

These four principles that have been expanded into 12 general principles as in Hand Book on 'National Ethical Guidelines for Biomedical and Health Research involving human participants by ICMR 2018, ICMR policy on Research Integrity and Publication ethics 2019 and National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During COVID-19 Pandemic guidelines 2020 will be considered at the beginning as well as all stages of research and dissemination.

- Principle of essentiality whereby after due consideration of all alternatives in the light of existing knowledge, the use of human participants is considered to be essential for the proposed research. This should be duly vetted by an ethics committee (EC) independent of the proposed research.

- Principle of voluntariness where by 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 supreme. The informed consent process ensures that participant's rights are safeguarded.
- Principle of non-exploitation whereby research participants are fairly selected so that the benefits and burdens of the research are distributed objectively and without uncertainty or discrimination. Sufficient precautions to protect vulnerable groups should be ensured.
- Principle of social responsibility where by the research is planned and conducted so as to avoid creation or deepening on social and historic divisions or in any way disturbsocial harmony in community relationships.
- Principle of ensuring privacy and confidentiality whereby to maintain privacy of the potential participant, her/his identity and records are kept confidential and access is limited to only those authorized. However, under certain circumstances (suicidalideation, homicidal tendency, HIV positive status, when required by court of law etc.) privacy of the information can be breached in consultation with the EC for valid scientific or legal reasons as the right to life of an individual supersedes the right to privacy of the research participant.
- Principle of risk minimization whereby due care is taken by all stakeholders (including but not limited to researchers, ECs, sponsors, regulators) at all stages of the research to ensure that the risks are minimized and appropriate care and compensation is given if any harm occurs.
- Principle of professional competence whereby the research is planned, conducted, evaluated and monitored throughout by persons who are competent and have the appropriate and relevant qualification, experience and/or training.
- Principle of maximization of benefit whereby due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to the society.
- Principle of institutional arrangements where by institutions where the 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.
- Principle of transparency and accountability whereby the research plan and outcome semanating from the research will be brought into the public domain through registries, reports and scientific deliberations and other publications while safeguarding the right to privacy of the participants. Stakeholders involved in research shall disclose any existing conflict of interest and manage it appropriately. The research shall be conducted in a fair, honest, impartial and transparent manner to guarantee accountability. Related records, data and notes shall be retained for the required period for possible external scrutiny/audit.

- Principle of totality of responsibility whereby all stakeholders involved in research will be responsible for their actions. The professional, social and moral responsibilities compliant with ethical guidelines and related regulations will be binding on all stakeholders directly or indirectly.
- Principle of environmental protection where by researchers will be accountable for ensuring protection of the environment and resources at all stages of the research, in compliance with existing guidelines and regulations.

4.2. Objectives of the Research:

- Protect the dignity, rights, safety and well-being of human participants,
- Recognize University's position on research ethics for research involving human participants, personal data and human tissue
- Demonstrate anobligation for good quality, clear and responsible research ethics throughout the University,
- Endorse the process of the University's Ethics Committee Procedure and provide guidance on research ethics involving human participants, personal data and human tissue for all staff and students,
- Reduce risks to the University, constituent Units and departments and individual researchers,
- Enhance the University's standing in the society, academic professions, among external collaborators and funding agencies.

4.3. Research Integrity:

Research integrity represents obligation to intellectual honesty and personal responsibility for behavior and actions for the University, institutions as well as individual researchers.

The value and benefits of research will be dependent on the integrity of the researchers. Scientists have a significant social responsibility to prevent research misconduct and misuse of research. All members of a research team will be expected to maintain high standards and to uphold the fundamental values of research. Ethic alconcerns shall be at the forefront of any research project and shall continue through to the write-up and dissemination stages.

4.4. Responsible conduct of Research:

The responsible conduct of research (RCR) involves the following major components: values, policies, planning and conducting research, reviewing and reporting research and responsible authorship and publication.

4.5. Responsibilities of the Researcher:

- Honesty and integrity as an investigator
- Minimal possible risk to participants and to themselves
- Respect for other people, their values and their cultures.
- Think through ethics issues for the particular project – minimize harms, choose populations fairly, develop respectful procedures
- Submit protocol to IRB, submit annual reviews to IRB, submit changes to IRB, submit adverse or unanticipated events to IRB
- Maintain records (with IRB, with subjects)
- The university expects that these principles are taken into consideration from the beginning, and throughout project's lifetime.
- Research projects shall be designed with a specific outline which may include a data management plan and define the project's operational procedure and timelines;
- An explicit statement on how the project can benefit the society shall be mentioned wherever appropriate.
- Any risks to people and/or animals and/or the environment and/or to cultural should be recognized wherever probable, and actions should be taken to manage/minimize risks,
- Potential or real conflicts of interest should be declared and where necessary, managed.
- In collaborative R&I, an initial arrangement shall be made as to the roles and responsibilities of researchers involved in a R&I project, and the nature and manner for communications, transparent criteria for publication strategy, authorship, acknowledgements and intellectual property rights (IP rights) shall be explicitly agreed upon by all involved.

4.6. Research Governance and Guidelines:

- Custodian of Policy: The implementation and updating of Research Policy shall be carried out by Directorate of Research, KLE Academy of Higher Education and Research. The Research policy will have an advisory panel under Vice Chancellor for assistance and counsel in matters related to research within the University.
- The Principals and Deans of the various constituent colleges are responsible for the conduct of the research that is undertaken in their Institutions. They will ensure that all researchers are applying to the ethics review procedures for research activities that involve human participants, personal data or human tissue, in line with the University's Ethics Policy, governing the research involving human participants, personal data and human tissue. They will also be responsible for ensuring that all staff and students engaging in research are familiar with the content of the Policy and that appropriate training and guidance is made available.

Following committees of the University shall look in to the multitudes of research.

- **University Research Co-ordination Committee (URCC)**

  Committee meets biannually. The committee discuss about broad overview of all the research facets of the University including faculty wise / interdisciplinary research, funds (University, National and international), seed money for research, research output are discussed. Fairness, variety and inclusion of all faculties is looked in to. Grow Indigenous research capacity with Indigenous communities by co-developing and supporting new models for research and research training.

Composition:

Chairman: Hon VC, KLE Academy of Higher Education and Research
Members: Deans of all Faculty
Member Secretory: Director, Research Unit, KLE Academy of Higher Education and Research

- **Board of Post Graduate teaching and Research (BPGTR), Research and Recognition Committee (RRC), Research Grant Committee (RGC)**

  These committees will look in to overview of post graduate teaching /training and PhD programme. PhD Scholarships, contingency, publication policies are discussed. Considerations of recommendations and put out important resolutions relating to post graduate research, PG teacher recognitions and PhD supervisors, Conferment of Doctor of Philosophy which will be put forth to Academic council for approval.

  Composition of Board of Post Graduate teaching and research (BPGTR):

  Chairman: Hon Vice Chancellor, KLE Academy of Higher Education and Resaerch
  Members: Dean Faculty of Medicine, Dean Faculty of dentistry, Dean Faculty of Pharmacy, Dean Faculty of Ayurvrda, Dean Faculty of Science(Interdisciplinary Studies)
  Dean Faculty of Physiotherapy, Dean Faculty of Nursing Science, Director, Research Unit, Office In charge, RMRC, Belagavi, Director, Academic affairs, KLE Academy of Higher Education and Resaerch
  Member secretory: Registrar, KLE Academy of Higher Education and Resaerch

Composition of Research and recognition committee:

Chairman: Hon VC, KLE Academy of Higher education and research
Members: Dean Faculty of Medicine, Dean Faculty of dentistry, Dean Faculty of Pharmacy, Dean Faculty of Ayurveda, Dean Faculty of Science(Interdisciplinary Studies)
Dean Faculty of Physiotherapy, Dean Faculty of Nursing Science, Chairman, BoS in Para –clinical subjects(UG &PG)-Medical faculty, Chairman, BoS in Surgery &Allied Subjects (UG&PG)-Medical faculty, Chairman, BoS in Medicine & Allied Subjects(UG &PG), Chaiman, BoS of Interdisciplinary Board, Chaiman, Board of studies for superspeciality subjects, Director, Research Unit, Director, Academic affiars, KLE Academy of Higher Education and Resaerch
Member secretory: Registrar, KLE Academy of Higher Education and Resaerch

Composition of Research Grant Committee (RGC)

Chaiman: Vice Chancellor, KLE Academy of Higher Education and Resaerch

Members: Dean Faculty of Medicine, Dean Faculty of dentistry, Dean Faculty of Pharmacy, Dean Faculty of Ayurveda, Dean Faculty of Science(Interdisciplinary Studies), Director, Academic affairs,

Member Secretory: Registrar, KLE Academy of Higher Education and Research

- **Institutional Ethics Committee -**

  This Committee will,

  - Review the ethics of all medical research involving human participants, tissue and data and animals every 5 years to suggest any changes or modifications to the Senate, provide guidance on the understanding of the Policy in the University and monitor the ethics review measures in the constituent colleges
  - Dynamically promote the knowledge and awareness of research ethics and the policy there of by conducting training and other academic events.
  - be up-to-date regarding newer policies, regulations and improvements related to research ethics, and safeguard the University with respect to having all the necessities in place
  - Offer advice on any research ethical matters that are referred to the committee and look into matters of research misconduct within the University
  - Ensure recognition of the IEC by recognized bodies.

The IEC will be multi disciplinary and multi sectoral committee composed of 8-12 members.

The composition will be as follows:

1. Chairman : Chief officer, RMRC(NITM), Belagavi
2. Member secretory
3. Basic Science scientist
4. Basic Medical Scientist :3members
5. Clinicians:2 members
6. Social Scientist
7. Lay person
8. Legal expert

- **Ph.D. Ethics Committee for Human Research:**

  All research proposals by research scholars registered for PhD under all faculties (full time and part time) shall be scrutinized by this committee. The committee shall scrutinize applications for ethical approval for the research proposal, inspect and update the research scholar's regarding approval or recommend changes if need be. The research scholars are expected to address the concerns raised by the committee. The Committee provides guidance to all Faculties/Departments/constituent colleges.

Composition:

Chairman: External expert.

Members: 8 representatives of all faculties

Members: Legal expert

Representation from Office of Academic Affairs.

- **University Animal Ethics Committee:**

  Functions as per the guidelines of Committee for Purpose of Control and Supervision of Experiments on Animals. (CPCSEA). Provide avenues and directions towards participation in animal research in all constituent colleges.

  Composition: Chairman : will be a biological Scientist

  Member secretory: Scientist in charge of animal house facility

  Members: Scientist from different Disciplines and scientists from outside Institute, Socially aware nominee and Veterinarian.

- **Site Management Office (SMO)**

  The Site management office keeps track of design, implementation, evaluation, and maintenance of the process of clinical research/trial, to support the conduct of clinical trials on behalf of the pharmaceutical, biotech, and medical drug/device companies.

  A clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (vaccines, drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

  The office will also review and validate (monitor) the trial data during the clinical trial. Other services may include to determine whether new biomedical or behavioral interventions are safe and medical writing, also keeps track of sustenance/ improvement, efficiency and productivity of the material in use.

  SMO is an administrative committee that will facilitate the work progress under this category.

Composition:

- Chairman: Medical Director and Chief Executive,
  KLES Dr. Prabhakar Kore Hospital and Medical research center, Belagavi
  Medical Superintendent,
  KLE Dr. Prabhakar Kore Charitable Hospital, Belagavi
  Hon, Chancellors Nominee
  And 4-5 members: Clinicians/researchers in clinical trials

5. Good Research Practice:

Overall good research practice shall reinforce quality research with tangible outcome and shall support the robust evidence base needed to drive improvements in healthcare. It shall provide strong foundations for research, quality education and training, career building and mainly help to increase public confidence and trust in the research process and its outputs.

In general, following documented research ethics principles is fundamental to good research practice. University's Research and ethics policy governing research involving human participants, personal data and human tissue suggests:

- Maintenance of ethical standards in the conduct of research with recognition and valuing principles of honesty and integrity.
- Research with integrity means embracing intellectual honesty and accepting personal responsibility for one's own actions.
- Prior to, during, and following the completion of research activities, researchers are expected to consider the ethical implications of their research and, depending on its nature, the cultural, economic, psychological, physiological, political, religious, spiritual and social consequences of it for the human participants involved.
- Researchers should always consider their research from the perspective(s) of the participants and any other people who may possibly be affected by it.
- Safety and well-being are at the heart of research ethics. Researchers have a responsibility to protect all participants, as well as they can, from avoidable harm arising from their research. Researchers also have a responsibility to consider their own safety and that of any co-researchers or collaborators.

7. Specific Guidelines on Important Ethical Issues

7.1. Informed Consent Process:

Preamble:

All research involving human participants shall be conducted in accordance with the four basic ethical principles, namely autonomy (respect for person / participant), beneficence, non-maleficence (do no harm) and justice. Indian Council of Medical Research formulated ethical guidelines for biomedical research on human participants known as ICMR code (second revision 2006), which requires Institutional Ethics Review Committee of all research Institutions to review and give ethical clearance to all research studies of which informed consent will be an important component.

The principle of informed consent has been driven by two different agendas: a legal one and a moral one. While sponsoring agencies approach informed consent documents from legal angle, researchers shall consider the moral basis of consent requirements before the legal aspects as may be relevant to their State.

The researcher will obtain voluntary written informed consent from the prospective participant for any biomedical and health research involving human participants. This requirement will be based on the principle that competent individuals are entitled to choose freely whether or not to participate or continue to participate in the research.

Informed consent will be a continuous process involving three main components – providing relevant information to potential participants, ensuring competence of the individual, ensuring the information is easily comprehended by the participants and assuring voluntariness of participation.

7.2. Scope of Informed Consent:

Informed consent for research will be taken for

- Protection of Rights of participants
- Privacy and Confidentiality
- Future use of Information
- Right not to participate and withdraw
- Right to get help

7.3. Essential information for prospective research participants:

- Before requesting an individual's consent to participate in research, the researcher must provide the individual with detailed information and discuss her/his queries about the research in the language she/he is able to understand. The language should not only be scientifically accurate and simple, but should also be sensitive to the social and cultural context of the participant.
- The Informed consent Document (ICD) should have two parts – patient/participant information sheet (PIS) that contains information on known facts about the research and the informed consent form (ICF) where the participant concedes that she/he has comprehended the information given and is voluntarily participating in that research.
- Adequate time should be given to the participant to read the consent form, if necessary discuss it with family and friends, and seek clarification of her/his doubts from the researchers/research team before deciding to enroll in the research

8. Responsibility of Researchers:

- The researcher should only use the EC approved version of the consent form, including its local translations.
- Adequate information necessary for informed consent should be communicated in a language and manner easily understood by prospective participants.
- In case of differently abled participants, such as individuals with physical, neurological or mental disabilities, appropriate methods should be used to enhance the participant's understanding, for example, braille for the visually impaired.

- There shall be no restriction on the participant's right to ask questions related to the study or to discuss with family and friends or take time before coming to a decision.
- The researcher shall not give any unjustifiable assurances or influence or intimidate a prospective participant to enroll in the study.
- The researcher must ensure that the participant is competent and has understood all aspects of the study and that the consent is given voluntarily. Where the participant and/or the LAR are illiterate, an impartial literate person, not connected to the research, should be present throughout the consent process as witness.
- The researcher shall administer a test of understanding whenever possible for sensitive studies. If need be, the test will be repeated until the participant has really understood the content
- When a participant is willing to participate but not willing to sign or give a thumb impression or cannot do so, then verbal/oral consent may be taken on approval by the EC, in the presence of an impartial witness who should sign and date the consent document. This process can be documented through audio or video recording of the participant, the PI and the impartial witness, all of whom should be seen in the frame. However, verbal/oral consent should only be taken in exceptional circumstances and for specific, justifiable reasons with the approval of the EC. It should not to be practiced routinely
- The researcher must assure prospective participants that their decision whether or not to participate in the research will not affect their rights, the patient–clinician relationship or any other benefits to which they are entitled.
- Reimbursement may be given for travel and incidental expenses/participation in research after approval by the EC.
- The researcher shall ensure free treatment for research related injury (disability, chronic life-threatening disease and congenital anomaly or birth defect) and if required, payment of compensation over and above medical management by the investigator and/institution and sponsor(s), as the case may be.
- The researcher shall ensure that the participant can continue to access routine care even in the event of withdrawal of the participant

9. Waiver of Consent:

The researcher can apply to the EC for a waiver of consent if the research involves lessthan minimal risk to participants and the waiver will not adversely affect the rightsand welfare of the participants

The EC may grant consent waiver in the following situations:

- Research cannot practically be carried out without the waiver and the waiver is scientifically justified;
- Retrospective studies, where the participants are de-identified or cannot be contacted;
- Research on anonymized biological samples/data;

- Certain types of public health studies/surveillance programmes/programme evaluation studies;
- Research on data available in the public domain;
- Research during humanitarian emergencies and disasters, when the participant may not be in a position to give consent. Attempt should be made to obtain the participant's consent at the earliest.

10. Registration with Clinical Trials Registry–India:

Trial registration in the CTRI is mandatory by CDSCO as on 15 June 2009 for clinical trials that are registered under the Drugs and Cosmetics Act and its Rules. All clinical trials, as a part of postgraduate, doctoral thesis or sponsored research being conducted in the University must be registered in the Clinical Trials Registry–India, linked to WHO registry.

This includes all clinical research involving human participants including any intervention such as drugs, surgical procedures, devices, biomedical, educational or behavioral research, public health intervention studies, observational studies, implementation research and preclinical studies of experimental therapeutics and preventives or AYUSH studies that will be registered prospectively with the CTRI.

Trial registration should involve providing information regarding the study, investigators, Sites, sponsor, ethics committees, regulatory clearances, disease/condition, types of study, methodologies, outcomes, etc.

Registration of research in CTRI will ensure public availability comprehensive, authentic and voluntarily available data on research. This furthers transparency, accountability and ease of access.

11. Conflict of Interest:

Public relies on the validity of research conducted at universities, academic medical centres, and other institutions. Since much of this research done at these institutions is with the expectation that the work will adhere to the highest ethical standards and yield results that may benefit society.

Conflict of interest(COI) is a set of conditions in which professional judgment concerning a primary interest such as patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest such as financial gain or non-financial (personal, academic or political)have the potential to compromise, or are perceived as compromising the exercise of professional judgment.

COI can be at the level of researchers, EC members, institutions or sponsors and the types that can occur in research include conflicts of commitment, conflicts of conscience, and institutional conflicts of interest which vary from each other.

Conflicts of Commitment:
This will be delt when it becomes difficult for individuals to balance the efforts necessary to perform their job duties while engaging in other activities that may or may not be job-related or when there is competing influence that affects an individual's research or work output. Completion of two separate yet important tasks by the individual will be a conflict in this case.

Ethical Aspects of Conflicts of Commitment
- Reduction in required employment duties due to an outside activity,
- Individual's research or work output being biased due to competing influence
- Employee and employer shall be made aware of the conflict (particularly when researchers receive grant support for their work).

Conflict of commitment from internal conflict:
Overburdening / researcher being unavailable to mentor their students due to their frequent travel or excess time spent consulting.
Regulatory Aspects: IEC will try to mitigate situations that could generate conflicts of commitment that could occur between faculty members, faculty and students, faculty and staff, and even institutions.
Conflicts of Conscience When an individual's personal, religious, or other beliefs might interfere with the ability to perform job duties objectively.

If COI is inherent in the research, it is important to declare this at the outset and establish appropriate mechanisms to manage it.
Institutional Ethics committee will have strategies to address, eliminate, reduce or manage these conflicts.

- Research being conducted in alliance with industries/ commercial companies will strongly review the possible COI between scientific responsibilities of researchers and business interests at the beginning.
- The Standard Operating procedure of Institutional Ethics committee and Site management Office will be strictly adhered to that will help the Self-regulatory processes to monitor, prevent and resolve conflicts of interest.
- The investigators shall declare conflicts of interest (financial interests, consulting fees or honorarium per participant, intellectual property rights from patents, copyrights and royalties from such rights, etc.) in the application submitted to IEC for review.
- The Institutional ethics Committee shall advice on future strategies, If the committee determines that a conflict of interest may damage the scientific integrity of a project or cause harm to research participants accordingly.
- The sponsorship of research shall be informed to the prospective participants so that they can be aware of the potential for conflicts of interest and commercial aspects of the research.

- The institution, IEC, audience when presenting papers, publications in popular media or scientific journals will also be informed of the secondary interest in financial terms.
- Compensation for individual participants, families and populations should be prohibited through undue inducement. This prohibition shall not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care reimbursement, costs of travel and loss of wages and the possible use of a percentage of any royalties for humanitarian purposes.
- ECs must evaluate each study in light of any disclosed interests and ensure that suitable means of justification are undertaken. COI within the EC should be declared and managed in accordance with standard operating procedures (SOPs) of that EC. Require their members to disclose their own COI and take appropriate measures to recuse themselves from reviewing or decision making on protocols related to their COI. EC must make appropriate suggestions for management, if COI is detected at the institutional or researchers level.

Good practices in management of conflicts of interest issues that are expected to be followed:

- All real or potential conflicts of interest that could compromise the credibility of their research work should be identified and transparent steps to be taken to disclose the conflicts of interest.
- Conflict of interest situation can arise in research funding applications; in research ethics applications, when seeking to recruit participants (i.e. Consent process); in research publications; during commercialization; when undertaking peer review for article or grant applications.
- A declaration of a conflict of interest, with a brief written record of that declaration, will suffice in most situations. Sometimes, may require modification of the project's plan.

The overall COI will be managed in following manner:

- Disclosure of financial interest to the other research personnel and to any research subjects as part of the informed consent process. The same shall be included in publications, presentation or any press releases.
- The individual serve as a co-investigator rather than as principal investigator
- Independent review or analysis of the data / restrictions on access to the data
- The investigator be removed from certain or all research activities such as subject enrolment or data collection
- The reduction or elimination of the financial interest.

12. Research Data Management Policy:

Preamble:

This policy aims to provide tactical basis for the data management yielded by research projects conducted at the University. Efficient research data management is vital in funded research projects, however, this policy will relate to all research carried out by faculty and students of the University. It will aim to encourage a positive approach to the management of research data across the institution.

Policy:

The University regards the effective management of the data generated by research projects as an essential part of good research and innovation practice.

- Exploiting the impact of data-intensive research
- Assurance of research integrity
- Enhanced data protection and storage and minimize the risk of data loss
- Enablement of data sharing and collaboration
- Open access principle to publicly-funded research outputs
- Compliance with the requirements of research funders.
- The primary responsibility for effective research data management during the course of research projects lies with lead researchers. However, all researchers, including postgraduate and undergraduate students undertaking research, have a personal responsibility to manage effectively the data they create.
- All research proposals for funded research shall include a data management plan. This will help to ensure that research data management is be considered at every stage of a research project, from the initial proposal and research costing, through to provision for long-term data curation.
- Data protection and storage is important and once collected, data must be properly protected, as it may be needed at a later stage to confirm research findings, establish priority, or be re-analyzed by other researchers. Responsible data handling begins with proper storage and protection from accidental damage, loss or theft.
- Care should be taken to reduce the risk of fire, flood and other catastrophic events. Computer files should be backed-up and the back-up data saved in a secure place at a site that is different from the original data storage site.
- Data sharing is important as research data is valuable and needs to be shared, but deciding when and with whom to share may raise difficult questions. Once a researcher has published the results of an experiment, it is generally expected that all the information about that experiment, including the final data, should be freely available for other researchers to check and use. Data should be shared or placed in a public domain in a de-identified/anonymized form, unless required otherwise, for which applicable permissions/re-consent should be sought unless obtained beforehand.

13. Ethics in Collaborations:

- Researchers are increasingly collaborating with colleagues who have the expertise and/or for resources needed to carry out particular research. This could be inter-departmental/ inter-institutional or international and also multicenter involving public and/or private research centers and agencies.
- Collaborative R&I ranges from international projects, potentially involving institutions from both countries in the developing and developed world, to mid-range collaborations involving several institutions within one country, through to projects involving two researchers from different disciplines. Collaboration includes R&I projects between researchers from different disciplines in the University, and R&I projects between the University and other institutions in India and/or in other countries.
- The main ethical issues surrounding collaborations pertain to sharing techniques, ownership of materials and data, IPRs, joint publications, managing research findings, managing COI and commercializing research outcomes.
- Researchers should familiarize themselves with all aspects including local, national and international requirements for research collaboration including necessary approvals, memorandums of understanding (MoUs) and material transfer agreements (MTA) and EC approval of collaborating institutes.

13.1. Ethical considerations in Collaborative Research

- Collaborative studies shall take into account the values/benefits expected from the research as compared to the risks involving the persons/population being studied.
- The participating center's should function as partners with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and IPR as appropriate. There must be free flow of knowledge and capacity at bilateral/multilateral levels.
- Careful consideration should be given to protecting the dignity, rights, safety and well-being of the participants in cases where the social contexts of the proposed research can create foreseeable conditions for their exploitation or increase their vulnerability to harm.
- The nature, magnitude and probability of all foreseeable harm resulting from participation in a collaborative research programme should be specified in the research protocol and well explained to the participants.
- The benefits and burdens should be equally distributed amongst participants recruited by all collaborating institutions.
- All participants in collaborative research should have access to the acceptable nationally available standard of care.
- If there is exchange of biological material involved between collaborating sites, the EC may require appropriate MoU and/or MTA to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.

14. Responsibilities of Ethics Committees, Researchers and Institutions:

- Ethics Committee shall review the protocols in the local social and cultural context and ensure respect for sensitivities and values of participants and communities at collaborative sites.
- A mechanism for communication between the ECs of different participating centers will be accessible. In case of any conflict, the decision of the local EC based on relevant facts/guidelines/law of the land shall prevail.
- An EC should examine whether the researcher has the required expertise and training in the area of collaboration
- An EC should protect the interests and rights of the collaborating researcher(s) and ensure that they are not treated as mere collectors of samples or data
- Participating researchers from collaborating sites should be adequately represented when designing the research proposal.
- Institutions are responsible for fair contract negotiation in collaborative research partnerships (including benefit sharing and avoiding unauthorized use of their expertise, biological samples and data) to safeguard the interests of participants, researchers and institutions.
- Institutions should provide opportunities for collaboration to build capacity and engage in research which is mutually beneficial.

Reviewing and Reporting Research:

The public's trust in published research is an essential component of ethical and responsible research.

- The basic principle of all reviewers and editors evaluating research is that the work has been performed honestly, its reporting is transparent and truthful and the researchers integrity is beyond doubt.
- Research that is completed, irrespective of results, must be published, since it would be unethical to expose another set of participant/patients/volunteers to the same risks to obtain the same results.
- Researchers should provide results of study in the public database of the Clinical Trial Registry-India (CTRI).

15. Responsible Authorship and Publication:

- Authorship – The researchers shall follow the guidance of International Committee of Medical Journal Editors (ICMJE) on authorship which is largely accepted as a standard and is endorsed by the World Association of Medical Editors (WAME).
- According to the ICMJE, authorship entails the following criteria:
- Substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work;
- Drafting the work or revising it for important intellectual content;
- Final approval of the version to be published;
- Agreement to be accountable for all aspects of the work and ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

- Authorship should never be gifted and 'ghost' authors are not acceptable. The authorship of research should be considered at the time of its initiation.
- The primary author will be the person who has done most of the research work related to the manuscript being submitted for publication. Research performed as part of a mandatory requirement of a course / fellowship / training programme including student research should have the candidate as the primary author. All efforts must be made to provide the candidate with an opportunity to fulfil the second, third and fourth criteria of the ICMJE guidelines.

Good Research Practice in Authorship:

Decisions about authorship (e.g. the criteria for deciding who can be named as an author and the author sequence) and about acknowledgement (i.e. people who have contributed but who do not fulfil the authorship criteria) normally result from a process of ongoing communication, reflection and/or revision as the project evolves over its duration. The University trusts its researchers, as in all other matters, to remain professional and reasonable when communicating on this subject; the goal being to ensure that all individuals who fulfil authorship criteria are named as authors and all other contributors are acknowledged.

Good Research Practices in Publication:

- The researchers shall publish in highly prestigious and externally peer-reviewed publications (preferably Journals indexed in Scopus, Pubmed, Web of Science and UGC-Care list), wherever possible, to ensure opportunities for dissemination of our research are maximized.
- Research data and results should be checked rigorously for their integrity before being published and/or communicated with the public.
- All sources, materials and methods used to obtain and analyze research data should be explained clearly in the publication.
- Any potential or real conflicts of interest should be declared in the publication.

Peer Review:

- Scientific revelation and advancement has been reliant mainly on peers assessing research and adjudicating the quality and usefulness for conduct and publication of research.
- The peer review method rests on the fair, honest and transparent review of all participants – i.e. editors, reviewers and researchers. It usually involves one or more reviewers and must be finished in reasonable time.
- Researchers must avoid stating friends, supporters and advisors as reviewers and must not agree to review research of close acquaintances, friends and students.
- Funding agencies and journals must ask reviewers and researchers to inform them of COI, if any.
- Reviewers must maintain the confidentiality of manuscripts sent to them for review.

16. Research Misconduct:

Preamble:

Research misconduct will involve fabrication, falsification and plagiarism of data, that are serious issues both nationally and internationally.

Definitions:

The University has adopted the definitions of research misconduct set out by the ICMR Guidelines 2017. The following definitions give indicative descriptions of the types of activity covered by this Regulation. These descriptions are neither exclusive nor exhaustive. Interpretation of the terms will involve judgments, which should be guided by previous experience and decisions made on matters of misconduct in research.

These include:

- **Fabrication** is the intentional act of making up data or results and recording or reporting them.
- **Falsification** is manipulating research materials, equipment or processes, or changing or omitting / suppressing data or results without scientific or statistical justification, such that the research is not accurately represented in the research record.
- **Plagiarism** is the "wrongful appropriation" and "stealing and publication" of another paper or another author's "language, thoughts, ideas, or expressions" and the representation of them as one's own original work or duplicating one's own publication (self-plagiarism).

Policy on Research Misconduct:

The University considers any allegation of research misconduct to be a matter of great concern and will investigate any such allegation fully. Given its reputation and status, the University has a responsibility to the research community and to the public at large. Research misconduct, if suspected, will be investigated. If facts are not presented accurately, Institution will investigate all allegations of misconduct as present or future participants' lives may be endangered. Such investigations will be done in a timely, fair and transparent manner and the results will be made available in the public domain wherever appropriate.

The university has constituted an Institutional Academic integrity Panel (IAIP) for the individual constituent Units of the University that will submit its recommendations to the University Academic Integrity Panel (UAIP). A detailed Plagiarism Policy is also in place.

17. References:

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