MALLA REDDY INSTITUTE OF DENTAL SCIENCES
(SPONSORED BY : CHANDRAMMA EDUCATIONAL SOCIETY)
Affiliated to Kaloji Narayanarao University of Health Science, Warangal,Telangana
Recognised by Dental Council of India, New Delhi

CODE OF RESEARCH ETHICS

Survey No. 138, Malla Reddy Health City, Suraram 'X' Road, Quthbullapur Municipality,
Hyderabad - 500 055. Phone : 040 – 6999 1107
Email: mrids.2012@gmail.com Website: www.mrids.org

MRIDS

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Ref.MRIDS/Circular/2019-20/BOG/01 01/07/2019

CIRCULAR

Sub: Code of Research Ethics -reg.

Ref: BOG meeting held on 25-06-2019 – Agenda 7.

As Discussed under Agenda 7 of the BOG meeting held on 25th June 2019, it was resolved to approve the code of research ethics and same is being notified with effect from 01-07-2019.

Dr.B. Chittaranjan.
Co-ordinator BOG,
Principal/Dean,
MRIDS.

Principal / Dean
Malla Reddy Institute of Dental Sciences

Encl:

Code of Research Ethics.

To:

Research and Development Cell

Survey No. 138, Malla Reddy Health City, Suraram 'X' Road, Quthbullapur Municipality,
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TABLE OF CONTENTS

1. INTRODUCTION

Malla Reddy Institute of Dental Sciences, Hyderabad, is dedicated to fostering a robust research environment characterized by integrity, academic excellence, accountability, inclusiveness, and professionalism. These principles are upheld within the ethical and legal frameworks that guide our institution's operations.

The credibility and public perception of scientific research are deeply influenced by the adherence to the highest ethical standards. Ethical conduct not only reflects a commitment to a scientific moral code but also contributes to the quality of scientific outcomes. Collaborations across disciplines and with external partners necessitate strict adherence to ethical research practices, which in turn fosters meticulous attention to scientific details, including qualitative analysis, quantitative methodologies, and statistical techniques. Instances of research misconduct, such as plagiarism, are viewed with severity and are subject to sanctions by relevant regulatory bodies. Our code of ethics serves as a compendium of widely accepted practices, guiding both seasoned researchers and emerging scholars in their pursuit of ethical research.

This code of ethics is aligned with the best practices advocated by national and international regulatory bodies, such as the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants by the Indian Council of Medical Research (ICMR) in 2017.

2.SCOPE OF DEFINITIONS

This code shall apply to all the following stakeholders and activities in MRIDS.

1. Research:

   Any scientific activity undertaken to answer a specific research question, that is conducted systematically and within the existing regulations, utilizing human participants, patients, biological samples, data, with the objective of generating new knowledge, or adding to the body of existing knowledge, or disseminating such information as gathered in the course of healthcare or research.

2. Researcher:

   - Any appropriately qualified, trained and experienced person conducting research on human participants, patients, biological samples, data in MRIDS.
   - Teacher: Any employee in MRIDS who is engaged in research. (Full time Teachers)
   - Student: Any learner, with bonafide credentials (admitted provisionally or otherwise), to any course in MRIDS including and up to the point of receiving the degree/diploma, in the convocation.
   - Research Scholar/ Assistant/ Fellow: Any person appointed in the MRIDS for conducting research.

3. Patient and Research participant
    - Any person irrespective of caste, religion, gender or social status, visiting Oral Medicine Department in MRIDS, or being seen by any healthcare provider for health reasons (including in the villages, primary health centres, community, etc) or admitted to the wards of any of the teaching hospitals coming under the purview of Malla Reddy Health City (MRHC) for reasons of health care and or research.
4. Biological sample:
    - Human Biological Sample: Any tissue, fluid, cells, body part, specimen taken from a patient, a research participant for the purpose of conducting research, or during healthcare, taken for diagnosis or therapy or follow-up.
5. Ethics committee:

    A committee constituted by MRIDS as per the bye laws and existing regulations, whose main objective is to discuss and deliberate on the ethical issues arising out of biomedical and healthcare research protocols on human participants or biological samples and give ethical approval for the same and ensure the safety of research participants throughout the course of the research study.

3.PURPOSE

MRIDS has always upheld and will continue to uphold the highest levels of ethics, fairness, and integrity in all its affairs. To this end, this Code of Ethical Conduct serves:

1. To help the dental student, intern, faculty, or a researcher to reach professional standard guided by legal and ethical principles.

2. To help students to ensure their work is conducted in accordance with the institutional values and policies that form part of the terms and conditions of research.

3. To provide a reference of rules to follow when a researcher is in dought or when they experience ethical dilemmas during the study.

4. To provide reporting mechanisms for known or suspected ethical or legal violations;

5. To help prevent and detect wrong doing

4.UNIVERSAL ETHICAL PRINCIPLES AND VALUES IN RESEARCH WORK

The principles and values that underpin the integrity and reliability of science are fundamental and universal. They apply to all representatives of scientific disciplines without exception. Researchers, institutions, funders, publishers, and scientific organizers, all adhere to these principles and values. They should maintain ethical conduct in their interactions with each other and in their communication with the wider community. These universal principles include:

1) Conscientiousness in portraying the objectives and intentions of planned or ongoing research, outlining research methods and procedures, interpreting the results, and communicating information about possible threats and well-substantiated predictions regarding benefits and possible applications;

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

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

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

5) Openness in discussing one's own research with other researchers, which is one of the key conditions for advances in science and contributes to the accumulation of knowledge through the publication of research results, as well as in communicating this knowledge honestly to the public

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

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

8)Researchers' responsibility for the socioeconomic and environmental consequences of the conclusions being formulated;

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

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

11) The courage to oppose views contrary to scientific knowledge and practices incompatible with the principles of research integrity;

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

5. ETHICAL CONSIDERATIONS INVOLVED IN RESEARCH ON HUMAN SUBJECTS

I. Principles of essentiality whereby, the research entailing the use of human subjects is absolutely essential after a due consideration of all alternatives in the light of the existing knowledge in the proposed area of research and after the proposed research has been duly vetted and considered by an appropriate and responsible body of persons who are external to the research and who, research is necessary for the advancement of knowledge and for the benefit of all members of the human species and for the ecological and environmental well-being of the planet.

II. Principles of voluntariness, informed consent, and community agreement whereby, research subjects are fully apprised of the research and the impact and risk of such research on the research subject and others; and whereby the research subjects retain the right to abstain from further participation in the research irrespective of any legal or other obligation that may have been entered into by such human subjects or someone on their behalf, subject to only minimal restitutive obligations of any advance consideration received and outstanding.

Where any such research entails treating any community or group of persons as a research subject, these principles of voluntariness and informed consent shall apply, mutatis mutandis, to the community as a whole and to each individual member who is the subject of the research or experiment. Where the human subject is incapable of giving consent and it is considered essential that research or experimentation be conducted on such a person incompetent to give consent, the principle of voluntariness and informed consent shall continue to apply and such consent and voluntariness shall be obtained and exercised on behalf of such research subjects by someone who is empowered and under a duty to act on their behalf.

The principles of informed consent and voluntariness are cardinal principles to be observed throughout the research and experiment, including its aftermath and applied use so that research subjects are continually kept informed of all developments in so far as they affect them and others.

However, without in any way undermining the cardinal importance of obtaining informed consent from any human subject involved in any research, the nature and form of the consent and the evidentiary requirements to prove that such

consent was taken, shall depend upon the degree and seriousness of the invasiveness into the concerned human subject's personal and privacy, health, and life generally, and, the overall purpose and the importance of the research.

III. Principles of non-exploitation whereby as a general rule, research subjects are remunerated for their involvement in the research or experiment; and, irrespective of the social and economic condition or status, or literacy or educational levels attained by the research subjects kept fully apprised of all the dangers arising in and out of the research so that they can appreciate all the physical and psychological risks as well as moral implications of the research whether to themselves or others, including those yet to be born. Such human subjects should be selected so that the burdens and benefits of the research are distributed without arbitrariness, discrimination, or caprice. Each research shall include an in-built mechanism for compensation for the human subjects either through insurance cover or any other appropriate means to cover all foreseeable and unforeseeable risks by providing for remedial action and comprehensive aftercare, including treatment during and after the research or experiment, in respect of any effect that the conduct of research or experimentation may have on the human subject and to ensure that immediate recompense and rehabilitative measures are taken in respect of all affected, if and when necessary.

IV. Principles of privacy and confidentiality whereby, the identity and records of the human subjects of the research or experiment are as far as possible kept confidential; and that no details about identity of said human subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of

therapeutics or other interventions, without the specific consent in writing of the human subject concerned, or someone authorized on their behalf; and after ensuring that the said human subject does not suffer from any form of hardship, discrimination or stigmatization as a consequence of having participated in the research or experiment.

V. Principles of precaution and risk minimization whereby due care and caution is taken at all stages of the research and experiment (from its inception as a research idea, its subsequent research design, the conduct of the research or experiment and its applicative use) to ensure that the research subject and those affected by it are put to the minimum risk, suffer from no irreversible adverse effects and, generally, benefit from and by the research or experiment; and that requisite steps are taken to ensure that both professional and ethical reviews of the research are undertaken at appropriate stages so that further and specific guidelines are laid down, and necessary directions given, in respect of the conduct of the research or experiment.

VI. Principles of professional competence whereby the research is always conducted by competent and qualified persons who act with total integrity and impartiality and who have been made aware of, and are mindful of, the ethical considerations to be borne in mind in respect of such research or experiment.

VII. Principles of accountability and transparency whereby the research or experiment will be conducted in a fair, honest, impartial and transparent manner after full disclosure is made by those associated with the research or experiment of each aspect of their interest in the research, and any conflict of interest that may exist; and whereby, subject to the principles of privacy and confidentiality

and the rights of the researcher, full and complete records of the research may be prescribed or considered necessary for the purposes of post research monitoring, evaluation of the research, conducting further research (whether by the initial researcher or otherwise) and in order to make such records available for scrutiny by the appropriate legal and administrative authority, if necessary.

VIII. Principles of the maximization of the public interest and of distributive justice whereby the research or experiment and its subsequent applicative use are conducted and used to benefit all human kind and not just those who are socially better off but also the least advantaged; and the research subject themselves.

IX. Principles of institutional arrangements whereby there shall be a duty on all persons connected with the research to ensure that all the procedures required to be complied with and all institutional arrangements required to be made in respect of the research and its subsequent use or application are duly made in a bonafide and transparent manner; and to take all appropriate steps to ensure that research reports, materials and data connected with the research are duly preserved and archived.

X. Principles of public domain whereby the research and any further research, experimentation, or evaluation in response to, and emanating from such research is brought into the public domain so that its results are generally made known through scientific and other publications subject to such rights as are available to the researcher and those associated with the research under the law in force at that time.

XI. Principles of totality of responsibility whereby the professional and moral responsibility, for the due observance of all the principles, guidelines or

prescriptions laid down generally or in respect of the research or experiment in question, devolves on all those directly or indirectly connected with the research or experiment including the researchers, those responsible for funding or contributing to the funding of the research, the institution or institutions where the research is conducted and the various persons, groups or undertakings who sponsor, use or derive benefit from the research, market the product (if any) or prescribe its use so that, inter alia, the effect of the research or experiment is duly monitored and constantly subject to review and remedial action at all stages of the research and experiment and its future use.

XII. Principles of compliance whereby there is a general and positive duty on all persons, conducting, associated or connected with any research entailing the use of a human subject to ensure that both the letter and the spirit of these guidelines, as well as any other norms, directions and guidelines which have been specifically laid down or prescribed and which are applicable for that area of research or experimentation, are scrupulously observed and duly complied with.

The present guidelines are directed at the application of these principles to research involving human subjects.

Respect for persons incorporates at least two fundamentals ethical considerations, namely:

a. Respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination.

b. Protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence refers to the ethical obligation to maximize benefits and to minimize harms and wrongs. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, *non-maleficence* (do no harm).

Justice refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to *distributive justice*, which requires the equitable distribution of both the burdens and the benefits of participation in research. Differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions between persons; one such distinction is vulnerability. "Vulnerability" refers to a substantial incapacity to protect one's own interests owing to such impediments as lack of capability to give informed consent, lack of alternative means of obtaining medical care or other expensive necessities, or being a junior or subordinate member of a hierarchical group. Accordingly, special provisions must be made for the protection of the rights and welfare of vulnerable persons.

6.INFORMED CONSENT

Participants and providing them with the opportunity to make autonomous and informed decisions regarding whether to participate or not, is *informed consent*. For this reason, informed consent has been characterized as the cornerstone of human rights protections.

The three basic elements of an informed consent are that it must be (1) competent, (2) knowing, and (3) voluntary. Notably, each of these three prongs may be conceptualized as having its own unique source of vulnerability. In the context of research, these potential vulnerabilities may be conceptualized as stemming from sources that may be intrinsic, extrinsic, or relational.

1. *Intrinsic vulnerabilities are personal characteristics* that may limit an individual's capacities or freedoms. For instance, an individual who is under the influence of a psychoactive substance or is actively consent information. Such vulnerabilities relate to the first prong of informed consent, that of competence (also referred to in the literature as "decisional capacity"). Many theorists have broadly conceptualized competence to include such functions as understanding, appreciation, reasoning, and expressing a choice. However, these functions are

directly related to the legal and ethical concept of competence only in so far as they refer to an individual's intrinsic capability to engage in these functions.

2. *Extrinsic vulnerabilities are situational factors* that may limit the capacities or freedoms of the individual. For example, an individual who has just been arrested or who is facing sentencing may be too anxious or confused, or may be subject to implicit or explicit coercion to provide voluntary and informed consent. Such extrinsic vulnerabilities may relate either to knowingness or to voluntariness to

the degree that the situation, not the individual's capacity, prevents him or he from making an informed and autonomous decision.

3. *Relational vulnerabilities* occur as a result of a relationship with anothe individual or set of individuals. For example, a prisoner who is asked by the warden to participate in research is unlikely to feel free to decline. Similarly, a terminally-ill person recruited into a study by a caregiver may confuse the care giving and research roles. Relational vulnerabilities typically relate to the third prong of the informed consent process, voluntariness. Certain relationships may be implicitly coercive or manipulative because they may unduly influence the individual's decision.

7. GOOD PRACTICE IN ACADEMIC RESEARCH

1. Academic Freedom, Integrity, and Responsibility

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

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

Academic integrity requires that academic research follows elevated professional standards, including appropriate research design and frameworks, adheres to high levels of research ethics and abides by the requirements set out by professional and regulatory research guidance and research ethics frameworks issued in appropriate areas.

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

Honesty: A researcher should advance the quest for truth, knowledge, scholarship and understanding by requiring intellectual and personal honesty in learning, teaching and research. Trust: An academic community should foster a climate of mutual trust to encourage the free exchange of ideas and enable all to reach their highest potential.

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

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

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

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

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

2.Institutional Responsibilities

The responsibility of promoting a transparent and ethical academic environment for research rests with the researchers, ethics committee, and faculty of the institution. The Dean, Heads of Departments, Librarian, and teaching staff must endorse and model high professional and ethical standards for academic research. The research guides are expected to create and maintain an atmosphere of cooperation that fosters the open exchange of ideas and the development of research skills. Additionally, they are responsible for providing suitable supervision and guidance to researchers in alignment with the specific academic discipline and research methodology.

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

3. Training

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

The mentor or guide of the researcher will ensure that the researcher has proper knowledge, training, and institute ethical approval before start of the research.

8. INSTITUTIONAL REVIEW BOARDS (IRB)

The Institutional Research Board (IRB) represents the research interests and activities of Malla Reddy Institute of Dental Sciences (MRIDS). It aims to cultivate, design, and execute high-quality multidisciplinary research at MRIDS.

The policy includes the initiation, facilitation, integration, and support of research projects conducted by undergraduate and postgraduate students, as well as faculty of MRIDS. The IRB provides a mechanism for these research groups to interact within MRIDS and with external collaborating individuals and organizations. The IRB is the responsible body for managing this interaction.

The IRB offers timely and comprehensive critical appraisal and technical guidance for submitted research proposals. The review of these proposals is an in-house exercise aimed at assessing feasibility, improving relevance to the

regional context, ensuring technical quality, and addressing the ethical aspects of proposed research. The IRB encourages Good Research Practice and Good Authorship Practices at MRIDS.

Submitting and presenting the research proposals:

The investigators are advised to develop their proposals as per the pre-specified pro forma and checklist. Investigators are invited to present their proposed research work at a scheduled IRB meeting. Investigators are advised to make a PowerPoint presentation of not more than eight minutes as per the template prescribed by the Institutional Research Board. There will be three minutes allocated for questions and clarifications, and the members will review the proposals as per the review template. The reviewed proposals will be forwarded to the Ethical Committee.

9.THE INSTITUTIONAL ETHICS COMMITTEE

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

1. Chairperson
2. Member secretory
3. Basic medical scientist
4. Clinician
8. Legal expert
9. Philosopher/ representative of non-government agencies NGO

10. Social scientist

11. Lay person from community.

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

10.PURPOSE OF CODE ETHICS

The purpose of the Code of Ethics for Institutional Research at Mafia Reddy Institute of Dental Sciences is to provide clear guidelines aimed at upholding integrity throughout the research process. Adherence to this code empowers researchers to avoid ethical lapses *and* prevent serious transgressions that constitute research misconduct. Research misconduct encompasses fabrication, falsification, plagiarism, and misrepresentation of credentials in research proposals, execution, peer review, or reporting of results.

11.TASKS OF THE ETHICS COMMITTEE

1. Identifying the code of Conduct for the following stakeholders

- Students
- Teachers
- Administrators
- Other staff

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

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

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

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

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

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

Research institute must	**Researcher must**	**IEC must**
Develop policies and sops to address COI issues that arc dynamic, transparent and actively Communicated	Ensure that documents submitted to the EC include disclosure of COI (financial or nonfinancial) That may affect their research; Demands on researchers' time and loyalties	Evaluate each study in light of any disclosed COI and ensure appropriate action is taken To mitigate this.
Implement policies and procedures to address COI and conflicts of commitment,	Guard against conflicts of commitment that may arise	Require their members to disclose their own COI and

and educate their staff about such policies	from situations that place competing	take appropriate measures to rescue themselves from reviewing or decision making on protocols related to their COI
Monitor the research or check research results for accuracy and objectivity and not interfere in the functioning and decision making of the EC	Prevent intellectual and personal conflicts by ensuring they do not serve as reviewers for Grants and publications submitted by close colleagues, relatives and/or students.	Make appropriate suggestions for management, if COI is detected at the institutional or researchers' level

12.RISK CATEGORIES

As per Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2018 and type of review

TYPE OF RISK	DEFINITION/DESCRIPTION	TYPE OF REVIEW
Less than minimal risk	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.	IEC approval considered final
Minimal Risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.	Expedited review
Minor increase over minimal risk or Low risk	Increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and adolescents; research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials; use of minimally	Full board review of IEC

TYPE OF RISK	DEFINITION/DESCRIPTION	TYPE OF REVIEW
	invasive procedures that might cause no more than brief pain or tenderness, small bruises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women, etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.	
More than minimal risk or high risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.	Full board review of IEC

Prinicipal / Dean
Malla Reddy Institute of Dental Sciences