Standard Operating Procedures
[SOP]

Institutional Ethics Committee (IEC)

Mansarovar Dental College, Bhopal

Address:
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	Institutional Ethics Committee (IEC) Mansarovar Dental College Kolar Road Bhopal (M.P)- 462042	SOP Effective from 1st March 2022 Valid up to 29 Feb. 2025
	Constituting Institutional Ethics Committee	

Title: Constituting Institutional Ethics Committee

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Members of IEC,
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Standard Operating Procedures (SOP) for Institutional Ethics Committee

1. INTRODUCTION TO ETHICS COMMITTEE

Mansarovar Ethics Committee, constituted for discussion and approval of institutional research projects with respect to safeguard dignity, rights, safety and well being of all research participants and to ensure that the research is carried under prescribed guidelines laid down by ICMR.

a. Name of Institutional Ethics Committee (IEC)

This committee will be known as the MDC Ethics Committee (IEC), Mansarovar Dental College, Kolar Road Bhopal- 462042.

This name will remain unchanged until the members choose to change it by a vote of Three-fourths of the current strength.

b. Purpose of IEC

The purpose of this committee will be scientific and ethical review, approval and monitoring of research studies.

1. To safeguard the rights, safety and well-being of human participants involved in a research project.

2. To ensure compliance to Good Clinical Practices (GCP) guidelines during research involving human participants.

c. Scope

The SOP applies to all activities performed by the Institutional Ethics Committee.

d. Ethical Basis

- The IECs will function independently without any interference in the review and decision making process from the Head of the Institute and administrative department of the Institute.
- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of research projects involving human participants.
- In evaluating protocols and ethical issues, the IEC is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed research is being considered.
- The IEC will work according to its established Standard Operating Procedures based on the Operational Guidelines for IEC that review Biomedical Research (WHO, 2000), International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines (1996), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005 and prevailing amendments from time to time), Indian GCP guidelines (2001) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006). The mandate will be

- To ensure the protection of the rights, safety and wellbeing of human participants involved in a research project.
- Provide public assurance of that protection.

- The IEC is established and functions in accordance with the relevant national law and regulations in force from time to time.
- The IEC will review only those projects which are carried out in this institution by the staff members and students of the institution.
- The IEC will also review projects which are carried out by institutional members in collaboration with other national or international institutions.

2. ROLE & RESPONSIBILITIES OF ETHICS COMMITTEE

IEC will review and approve all types of research proposals involving human participants with a view to safeguard the dignity, rights, safety and well being of all actual and potential research participants. The goals of research, however important, should never be permitted to override the health and well being of the research subjects.

The IEC will take care that all the cardinal principles of research ethics viz. Autonomy, Beneficence, Non - malfeasance and Justice are taken care of in planning, conduct and reporting of the proposed research. For this purpose, it will look into the aspects of informed consent process, risk benefit ratio, distribution of burden and benefit and provisions for appropriate compensations wherever required. It will review the proposals before start of the study as well as monitor the research throughout the study until and after completion of the study through appropriate well documented procedures for example annual reports, final reports and site visits etc. The committee will also examine compliance with all regulatory requirements, applicable guidelines and laws.

The mandate of the IECs will be to review all research projects involving human subjects to be conducted at the Institute, irrespective of the funding agency. The role of IEC can be modified according to the requirement of each Institute.

It is the responsibility of the Institutional Ethics Committee members and the Secretariat to read, understand, follow and respect the SOP set by the Institutional Ethics Committee.

No.	Activity	Responsibility
1.	Ethical basis	Institutional Ethics Committee (**IEC)**
2.	Composition of the Institutional Ethics Committee	Head of the Institute ,Chairperson, IEC Members and Secretariat
3.	Membership requirements	Head of the Institute , Chairperson,
4.	Tenure of Membership	Chairperson, IEC Members and Secretariat
5.	Policy statement of the institution &Appointment of new members and alternate members:	Head of the Institute
6.	Resignation and disqualification of members	IEC Members and Secretariat
7.	Conditions of appointment	IEC Members and Secretariat
8.	Training of the IEC Members in Research Ethics	IEC Chairperson / Member Secretary
9.	Hierarchy	IEC
10.	Selection and appointment of Chairperson, Member Secretary, Joint Member Secretary	Head of the Institute
11.	IEC staff	Member Secretary
12.	Role of IEC members	IEC
13.	Quorum requirements	IEC Members and Secretariat
14.	Honorarium to the Members/ Independent Consultants	IEC
15.	Responsibilities of IEC	HOI, IEC
16.	Evaluation of IEC/Chairperson/Member Secretary/Members/Staff	HOI, IEC
17.	Prepare an annual activity report of the IEC for submission to the Head of the Institute	IEC Secretariat

ROLE & RESPONSIBILITIES OF ETHICS COMMITTEE

• To attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.

• To review, discuss and consider research Proposals submitted for evaluation.

• To monitor Serious Adverse Event reports and recommend appropriate action(s)

• To review the progress reports and monitor ongoing studies as appropriate.

• To evaluate final reports and outcomes.

• To review clinical trial agreement, Insurance policy and informed consent document Specifically by the **legal expert** of the IEC.

• To maintain confidentiality of the documents and deliberations of IEC meetings.

• To declare any conflict of interest.

• To sign the Confidentiality / Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.

• To participate in continuing education activities in biomedical ethics and biomedical research.

• To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat

• To provide an updated CV when requested for by the IEC secretariat

• To carry out the work delegated by Chairperson, Member-secretary and Jt. Member-secretary.

• To assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out IEC work as per SOPs

• The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research participants.

• The Committee will keep all information submitted to them confidential specially the proprietary information.

• The Committee will maintain concise but clear documentations of its views on the research proposal.

• The Committee will review the progress of each research project at appropriate and specified Intervals, but not less than once a year and will also review the final report of the studies approved by them.

• The Committee will participate in activities that promote ethical research in the institution and community.

• The Committee will participate in and organize programs aimed at educating and training community members, members of the public, investigators, IEC members in ethical research.

3. ESTABLISHING & CONSTITUTING THE IEC

IECs should be multidisciplinary and multi-sectorial in composition. Independence and competence are the two hallmarks of an IEC.

The number of persons in an ethical committee should be kept fairly small (7-9 members). It is generally accepted that a minimum of five persons is required to compose a quorum. There is no specific recommendation for a widely acceptable maximum number of persons but it should be kept in mind that too large a Committee will make it difficult in reaching consensus opinions. 12-15 is the maximum recommended number.

The Chairperson of the Committee should preferably be from outside the Institution and not head of the same Institution to maintain the independence of the Committee. The Member Secretary who generally belongs to the same Institution should conduct the business of the Committee. Other members should be a mix of medical / non-medical scientific and non-scientific persons including lay public to reflect the differed viewpoints.

The composition may be as follows:-

1. Chairperson (Other than Dean/ Principal of the Institution)

2. One representative from MPMSU

(Medical scientist, clinician, academician in various fields of Medical sciences, Biostatistician, Professors or any other expert whom University feels appropriate)

3. 2 basic medical scientists, one of them is Biostatistician

4. 2 clinicians from various Institutes

5. One legal expert or retired judge

6. One social scientist / representative of non-governmental voluntary agency

7. One philosopher / ethicist / theologian

8. One eminent lay person from the community

9. Member-Secretary (One of the Professor of College Concerned)

The ethical committee at any institution can have as its members, individuals from other institutions or communities if required. There should be adequate representation of age, gender, community, etc. in the Committee to safeguard the interests and welfare of all sections of the community / society. Members should be aware of local, social and cultural norms, as this is the most important social control mechanism. The travelling and stay expenses of the MPMSU representative shall be borne by the institute concerned. If required, subject experts could be invited to offer their views, for example for drug trials a pharmacologist, preferably a clinical pharmacologist, should be included. IEC shall follow the guideline laid down by Government of India for drug trials and Institution shall be held responsible for deficiencies encountered, if any. The studies on animal should follow guidelines laid down by Purpose of Control and Supervision of Experimentation on Animals (CPCSEA)

and obtain necessary approvals from them. Similarly, based on the requirement of research area, for example HIV, genetic disorders etc. specific patient groups may also be represented in the Committee. The membership of IEC will include Epidemiologist(s), Sociologist(s), Lawyer(s), Theologian, Statistician(s), Clinician(s), Basic scientists, Pharmacist(s)/Clinical Pharmacologist(s) etc They should be appointed by the Head of the Institute based on their competencies and integrity, and could be drawn from any public or private Institute from anywhere in the country. IEC should be constituted in the following pattern:

i) A Chairperson

ii) A Deputy Chairman if need be,

iii) A Member Secretary,

iv) 5-15 members from different Departments / Specialties / disciplines or areas etc.

Authority under which IEC is constituted:

The Institutional Head constitutes the IEC. In future, MPMSU may make further recommendations for constitution of IEC as and when needed.

4. MEMBERSHIP REQUIREMENT & TENURE

- The Head of the Institute (HOI) is responsible for appointing new committee members.
- The Chairperson and IEC members can suggest names of potential members but the final decision will remain with the HOI.
- Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work.
- Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration.
- The tenure of Institutional Ethics Committee members will be for a continuous period of two (2) years from the date of appointment.
- The IEC secretariat will initiate the process of filling up the forthcoming vacancies two months prior to the end of tenure of a member, The Chairperson will recommend names of individuals to the HOI. The HOI will select and appoint a member for the new tenure from the list provided by the IEC or otherwise. The retiring member will be eligible to be appointed for the new tenure any number of times.
- At the end of 2-3 years, as the case may be, the committee is reconstituted, and 50% of the members will be replaced by a defined procedure.
- A member can be replaced in the event of death or long-term nonavailability or for any action not commensurate with the responsibilities laid down in the guidelines deemed unfit for a member.
- A member can tender resignation from the committee with proper reasons to do so.

4.1 Training of the IEC Members in Research Ethics

- An individual selected as a new member of the IEC will be required to attend two meetings as an 'Observer' before being inducted as a member of the IEC
- Member-secretary or an IEC member will provide an introductory training to the new member.
- All IEC members should undergo refresher course in Good clinical practice (GCP) annually.
- The IEC Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year.
- The IEC may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

Ethics and Legalities in dental practice

Dental profession is regulated by state laws and association rules. This course provides an insight to current regulation in practice, standards and significance of rules and practice. It also helps young practitioners to critically build risk management strategies to safely practice dentistry.

Course contents:

This course is divided into 7 sections, providing useful information regarding ethics and legal issues in the dental practice

Section	**Objectives to be achieved at the end of each section**	**Duration**
1. Medical Negligence	➢ What constitutes medical negligence / res ipsa loquitor ➢ Duties of doctor / dentist towards patient ➢ Analytical comprehension through case illustration	3 hours

2. Informed consent	➢ What is Informed consent ➢ Types of consent ➢ Appropriate consentform designing ➢ Informed refusal and its significance	2 hour
Medical history takingand record keeping	➢ Preservation and Retention period ofdental records ➢ Importance of record keeping	2 hour
4. Ethics in dental practice	➢ Principles of ethics ➢ Application of ethical principles topractice ➢ Dentist patient relationship	2 hour

5. Consumer protection act	➢ Structure of CPA ➢ Procedure of filing acomplaint / addressing a litigation ➢ Do's and don'ts in case of litigation	2 hour
Licenses an dRegistration	➢ Types of licenses ➢ Importance of Biomedical waste management	2 hour
New practice set up and Ownership change	➢ Strategic plan for dental set up in India ➢ Brief insight into Clinic establishmentact, pollution control norms, fire safety norms and empanelment	1 hour
8. Child abuse and neglect	➢ Diagnose children who are victims of any kind of abuse ➢ Advocacy to work with organizations and community forfacilitating or helping child abuse	1 hour

	victims	
Dental practice among pandemics	➢ COVID 19 and dentistry – measuresneeded to safeguard dental team	1 hour
TOTAL	**16 hours**	

5. POLICY STATEMENT OF THE INSTITUTION & APPOINTMENT OF NEW & ALTERNATE MEMBERS

a) Policy statement of the institution

The policy statement of the institution will be issued by the head of institution (under whose authority it is governed) during new tenure and constitution of the IEC.

b) Appointment of new members and alternate members

i) The IEC members will be appointed by the HOI. New members will be appointed under the following circumstances:

1. When a regular member completes his/ her tenure.

2. If a regular member resigns before the tenure is completed.

3. If a regular member ceases to be a member for any reason including death or disqualification.

ii) New members will be identified by the Chairperson according to the requirement, membership requirement and provided the potential member fulfils the conditions of appointment. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the Head of the Institution HOI. The final decision regarding appointment of members will be taken by the HOI.

iii) Alternate member(s) will be appointed if deemed necessary by the HOI. The alternate member(s) will substitute a regular member and attend the meeting in absence of the regular member(s).

6. RESIGNATION & DISQUALIFICATION OF MEMBERS

- Resignation: An IEC member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.

- Disqualification for conduct unbecoming of an IEC member: A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been unbecoming of an IEC member.

i. The process will be initiated if IEC Chairperson or Member-secretary receives a communication in writing (provided by IEC member or a member of the public) alleging misconduct by a member.

ii. The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC could be questioned, the Chairperson may suspend the membership of the concerned IEC member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.

iii. The Chairperson may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.

iv. The member would stand disqualified if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.

- Disqualification for not attending IEC meetings: A member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IEC meetings without prior intimation. The process conducted will be as follows:

i. The member-secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC.

ii. The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IEC meeting.

iii. A written communication will be sent to the concerned IEC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned IEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson

iv. The matter will be discussed and reviewed at the IEC meeting. The concerned member will be provided adequate opportunity to represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting. • The Chairperson or Member-Secretary will inform the IEC members about the cessation of membership by a confidential written communication to other members of IEC or at the next meeting of IEC.

7. QUORUM REQUIREMENT

- The minimum of 5 members are required to compose a quorum. All decisions should be taken in meetings and not by circulation of project proposals.

- The full board meeting will be held as scheduled provided there is quorum. For the IEC meeting, a quorum will consist of at least 5 members one regular member (preferably one pharmacologist), the social worker, a clinician, the lay person and the legal expert besides Member Secretary and Chairperson. (For review of each protocol the quorum of IEC should be at least 5 members - one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person, one Lay person from the community).

8. OFFICES

The Chairperson will conduct all meetings of the IEC. If for reasons beyond control, the Chairperson is not available, the Deputy Chairperson or an alternate Chairperson will be elected from the members by the members present, who will conduct the meeting. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. He/she will prepare the minutes of the meetings and get it approved by the Chairman before communicating to the researchers with the approval of the appropriate authority.

9. APPLICATION PROCEDURES

a. All proposals should be submitted in the prescribed application form, the details of which are given under Documentation

b. All relevant documents should be enclosed with application form

c. Required number of copies of the proposal along with the application and documents in prescribed format duly signed by the Principal Investigator (PI) and Co-investigators / Collaborators should be forwarded by the Head of the Departments / Institution to the ethics committee.

d. The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.

e. The decision will be communicated in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.

f. Prescribed fee, if any, should be remitted along with the application.

10. DOCUMENTATION:

For a thorough and complete review, all research proposals should be submitted with the documents as per the prescribed proforma and shall include following details :

1. Name of the applicant with designation

2. Name of the Institute/ Hospital / Field area where research will be conducted.

3. Approval of the Head of the Department/s / Institution/s

4. Protocol of the proposed research

5. Ethical issues in the study and plans to address these issues.

6. Proposal should be submitted with all relevant enclosures like proformae, case report forms, questionnaires, follow - up cards, etc.

7. Informed consent process, including patient information sheet and informed consent form in local language(s).

8. For any drug / device trial, all relevant pre-clinical animal data and clinical trial data from other centers within the country / countries, if available.

9. Curriculum vitae of all the investigators with relevant publications in last five

years.

10. Any regulatory clearances required.

11. Source of funding and financial requirements for the project.

12. Other financial issues including those related to insurance.

13. An agreement to report only Serious Adverse Events (SAE) to IEC.

14. Statement of conflicts of interest, if any.

15. Agreement to comply with the relevant national and applicable international guidelines.

16. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of the arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (e.g., those leading to a negative decision or modified protocol) by other ECs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification(s) to the protocol made on that account. The reasons for negative decisions should be provided.

17. Plans for publication of results – positive or negative- while maintaining the privacy and confidentiality of the study participants. The investigator and Guide shall disclose the authors who shall be included in the list of authors to be included in the publication.

18. Any other information relevant to the study

11. REVIEW PROCEDURES:

a. The meeting of the IEC should be held on scheduled intervals as prescribed and additional meetings may be held as and when the proposals are received for review.

b. The proposals will be sent to members at least 2 weeks in advance.

c. Decisions will be taken by consensus after discussions, and whenever needed voting will be done.

d. Researchers will be invited to offer clarifications if need be.

e. Independent consultants/Experts will be invited to offer their opinion on specific research proposals if needed.

f. The decisions will be minuted and Chairperson's approval taken in writing.

g**. Mansarovar Ethics committee will review investigator initiated and academic projects and no fee will be charge for the application.**

12. ELEMENT OF REVIEW

a. Scientific design and conduct of the study.

b. Approval of appropriate scientific review committees.

c. Examination of predictable risks/harms.

d. Examination of potential benefits.

e. Procedure for selection of subjects in methodology including inclusion/ exclusion, withdrawal criteria and other issues like advertisement details.

f. Management of research related injuries, adverse events.

g. Compensation provisions.

h. Justification for placebo in control arm, if any.

i. Availability of products after the study, if applicable.

j. Patient information sheet and informed consent form in local language.

k. Protection of privacy and confidentiality.

l. Involvement of the community, wherever necessary.

m. Plans for data analysis and reporting

n. Adherence to all regulatory requirements and applicable guidelines

o. Competence of investigators, research and supporting staff

p. Facilities and infrastructure of study sites

q. Criteria for withdrawal of patients, suspending or terminating the study

13. EXPEDITED REVIEW

All revised proposals, unless specifically required to go to the main committee, will be examined in a meeting of identified members convened by the Chairman to expedite decision making. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The nature of the applications, amendments, and other considerations that will be eligible for expedited review should be specified.

14. DECISION-MAKING

a. Members will discuss the various issues before arriving at a consensus decision.

b. A member should withdraw from the meeting during the decision procedure concerning an application where a conflict of interest arises and this should be indicated to the chairperson prior to the review of the application and recorded in the minutes.

c. Decisions will be made only in meetings where quorum is complete.

d. Only members can make the decision. The expert consultants will only offer their opinions.

e. Decision may be to approve, reject or revise the proposals. Specific suggestions for modifications and reasons for rejection should be given.

f. In cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.

g. Modified proposals may be reviewed by an expedited review through identified members.

h. Procedures for appeal by the researchers should be clearly defined.

15. CONFLICT OF INTEREST

- No member of an Ethics Committee, having a conflict of interest, shall be involved in the oversight of the clinical trial or bioavailability or bioequivalence study protocol being reviewed by it and all members shall sign a declaration to the effect that there is no conflict of interest.
- While considering an application which involves a conflict of interest of any member of the Ethics Committee, such member may voluntarily withdraw from the Ethics Committee review meeting, by expressing the same in writing, to the Chairperson.
- The details in respect of the conflict of interest of the member shall be duly recorded in the minutes of the meetings of the Ethics Committee.

16. REVIEW OF PROPOSAL INVOLVING VULNERABLE POPULATION

SOP for reviewing proposals involving vulnerable Populations

Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to review proposals involving vulnerable populations. The SOPs provide clear, unambiguous instructions so that the related activities of the Board are conducted in accordance with Indian laws and relevant, National and International Guidelines. It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

The word vulnerability is derived from the Latin word vulnarere which means ‘to wound’. Vulnerable persons are those individuals who are relatively or absolutely incapable of protecting their own interests because of personal disability; environmental burdens; social injustice; lack of power, understanding or ability to communicate or are in a situation that prevents them from doing so. These vulnerable persons have some

Common characteristics which are listed in Box.

Characteristics of vulnerable individuals/populations/group

Individuals may be considered to be vulnerable if they are:
• socially, economically or politically disadvantaged and therefore susceptible to being exploited;
• incapable of making a voluntary informed decision for themselves or whose autonomy is compromised temporarily or permanently, for example people who are unconscious, differently abled;
• able to give consent, but whose voluntariness or understanding is compromised due to their situational conditions; or
• unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent.

The key principle to be followed when research is planned on vulnerable persons is that others will be responsible for protecting their interests because they cannot do so or arein a compromised position to protect their interests on their own.

Principles of research among vulnerable populations

- Vulnerable populations have an equal right to be included in research so that benefits accruing from the research apply to them as well.
- If any vulnerable group is to be solely recruited then the research should answer the health needs of the group.
- Participants must be empowered, to the maximum extent possible, to enable them to

Vulnerable populations or groups

Following are some examples of vulnerable populations or groups:
• economically and socially disadvantaged (unemployed individuals, orphans, abandoned individuals, persons below the poverty line, ethnic minorities, sexual minorities – lesbian/ gay/bisexual and transgender (LGBT), etc.);
• unduly influenced either by the expectation of benefits or fear of retaliation in case of refusal to participate which may lead them to give consent;
• children (up to 18 years);
• women in special situations (pregnant or lactating women, or those who have poor decision-making powers/poor access to healthcare);
• tribals and marginalized communities;
• refugees, migrants, homeless, persons or populations in conflict zones, riot areas or disaster situations;
• afflicted with mental illness and cognitively impaired individuals, differently abled – mentally and physically disabled;
• terminally ill or are in search of new interventions having exhausted all therapies;
• suffering from stigmatizing or rare diseases; or
• have diminished autonomy due to dependency or being under a hierarchical system (students, employees, subordinates, defence services personnel, healthcare workers, institutionalized individuals, under trials and prisoners).

Decide by themselves whether or not to give assent/consent for participation.

- In vulnerable populations, when potential participants lack the ability to consent, a LAR should be involved in decision making.

- Special care must be taken to ensure participant's privacy and confidentiality, especially because breach of confidentiality may lead to enhancement of vulnerability.

- If vulnerable populations are to be included in research, all stakeholders must ensure that additional protections are in place to safeguard the dignity, rights, safety and wellbeing of these individuals.

Additional safeguards/protection mechanisms

When vulnerable individuals are to be recruited as research participants additional precaution should be taken to avoid exploitation/retaliation/reward/credits, etc., as they may either feel intimidated and incapable of disagreeing with their caregivers, or feel a desire to please them. In the first case, they may be subjected to undue pressure, while in the second, they may be easily manipulated. If they perceive that their caregivers want them to participate in research, or if the caregiver stands to benefit from the dependant's participation, the feeling of being pressed to participate may be irresistible which will undermine the potential voluntariness of the consent to participate.

Researchers must justify the inclusion of a vulnerable population in the research.

- ECs must satisfy themselves with the justification provided and record the same in theproceedings of the EC meeting.
- Additional safety measures should be strictly reviewed and approved by the ECs.
- The informed consent process should be well documented. Additional measures suchas recording of assent and reconsent, when applicable, should be ensured.
- ECs should also carefully determine the benefits and risks of the study and examine therisk minimization strategies.
- As potential participants are dependent on others, there should be no coercion, force, duress, undue influence, threat or misrepresentation or incentives for participation during the entire research period.
- Vulnerable persons may require repeated education/information about the research, benefits, risks and alternatives, if any.
- Research on sensitive issues such as mental health, sexual practices/preferences, HIV/ AIDS, substance abuse, etc. may present special risks to research participants.
- Researchers should be cognisant of the possibility of conflicting interests between the prospective participant and LAR and should be more careful.
- Participants may be prone to stigma or discrimination, specifically when the participant is enrolled as a normal control or is recruited from the general population in certain types of research.
- Efforts should be made to set up support systems to deal with associated medical andsocial problems.
- Protection of their privacy, confidentiality and rights is required at all times – during conduct of research and even after its completion.
- Whenever possible, ancillary care may be provided such as setting up of a

facility, school for unattended children of the participants or a hospital, or counselling centre

OBLIGATIONS/DUTIES OF STAKEHOLDERS

All stakeholders have different responsibilities to protect vulnerable participants. See Table 6.1 for further details.

Stakeholders	Obligations / duties
Researchers	• Recognize the vulnerability of the participant and ensure additional safeguards are in place for their protection. • Justify inclusion/exclusion of vulnerable populations in the study. • COI issues must be addressed. • Have well defined procedures (SOPs) to ensure a balanced benefit-risk ratio. • Ensure that prospective participants are competent to give informed consent. • Take consent of the LAR when a prospective participant lacks the capacity to consent. • Respect dissent from the participant. • Seek permission of the appropriate authorities where relevant, such as for institutionalized individuals, tribal communities, etc. • Research should be conducted within the purview of existing relevant guidelines/regulations.

Ethics Committees	• During review, determine whether the prospective participants for a particular research are vulnerable. • Examine whether inclusion/exclusion of the vulnerable population is justified. • Ensure that COI do not increase harm or lessen benefits to the participants. • Carefully determine the benefits and risks to the participants and advise risk minimization strategies wherever possible. • Suggest additional safeguards, such as more frequent review and monitoring, including site visits. • Only the full committee should do initial and continuing review of such proposals. It is desirable to have empowered representatives from the specific populations during deliberations. • ECs have special responsibilities when research is conducted on participants who are suffering from mental illness and/or cognitive impairment. They should exercise caution and require researchers to justify cases for exceptions to the usual requirements of participation or essentiality of departure from the guidelines governing research. ECs should ensure that these exceptions are as minimal as possible and are clearly spelt out in the ICD. • ECs should have SOPs for handling proposals involving vulnerable populations.
Sponsors	• The sponsor, whether a government, an institution or a pharmaceutical company, should justify the inclusion of vulnerable groups in the protocol and make provisions for protecting their safety. • The sponsor must enable monitoring and ensure that procedures are in place for quality assurance (QA) and quality control (QC). • The sponsor should ensure protection of the participants and research team if the research is on sensitive topics.

Box Risks for women participants in clinical trials/intervention studies

1. Researchers must provide the EC with proper justification for inclusion of pregnant and nursing women in clinical trials designed to address the health needs of such women or their foetuses or nursing infants. Some examples of justifiable inclusion are trials designed to test the safety and efficacy of a drug for reducing perinatal transmission of HIV infection from mother to child, trial of a device for detecting foetal abnormalities or trials of therapies for conditions associated with or aggravated by pregnancy, such as nausea, vomiting, hypertension or diabetes.
2. If women in the reproductive age are to be recruited, they should be informed of the potential risk to the foetus if they become pregnant. They should be asked to use an effective contraceptive method and be told about the options available in case of failure of contraception.
3. A woman who becomes pregnant must not automatically be removed from the study when there is no evidence showing potential harm to the foetus. The matter should be carefully reviewed and she must be offered the option to withdraw or continue. In case the woman opts for continued participation, researchers and sponsors must adequately monitor and offer support to the woman for as long as necessary.

Children

Children are individuals who have not attained the legal age of consent (up to 18 years). At younger ages, children are considered vulnerable because their autonomy is compromised as they do not have the cognitive ability to fully understand the minute details of the study and make decisions. At older ages, although they may attain the cognitive ability to understand the research, they still lack legal capacity to consent. Therefore, the decision regarding participation and withdrawal of a child in research must be taken by the parents/ LAR in the best interests of their child/ward. More details are available in ICMR "National Ethical Guidelines for Bio-Medical Research involving Children, 2017".

Research on children can be carried out in a situation, condition, disorder or diseases as described in Box

BOX CONDITIONS FOR RESEARCH ON

Children can be included in research if the situation, condition, disorder or disease fulfils one of the following conditions:

1. It is exclusively seen in childhood.
2. Both adults as well as children are involved, but the issues involved are likely to be significantly different in both these populations.
3. Both adults as well as children are involved in a similar manner and are of similar nature in terms of morbidity, severity and/or mortality, wherever relevant, and studies in adults have demonstrated the required degree of safety and efficacy.
4. Test interventions are likely to be at least as advantageous to the individual child participant as any available alternative intervention.
5. Risk of test interventions that is not intended to benefit the individual child participant is low as compared to the importance of the knowledge expected to be gained (minor increase over minimal risk).
6. Research is generally permitted in children if safety has been established in the adult population or if the information likely to be generated cannot be obtained by other means.
7. The physiology of children is different from that of adults, and the pharmacokinetics of many drugs is age-dependent based on the maturation of the drug metabolism pathways. For example, children metabolize many drugs much more rapidly as compared to adults, hence the dose of the drug per kg of body weight that needs to be given, is much higher in children as compared to adults. The absorption of drugs also varies with age. Pharmacokinetics and toxicity profile varies with growth and maturation from infancy to adulthood.
8. The adverse effects of many drugs may also be different in children as compared to adults. For instance, tetracyclines cause teeth discoloration in young children, aspirin use is associated with Reye's syndrome in children.
9. Age appropriate delivery vehicles and formulations (e.g. syrups) are needed for accurate, safe, and palatable administration of medicines to infants and children.
10. The pathophysiology of many disorders is dependent on a child's growth, development and adaptive plasticity. Examples include adaptive changes in the motor system following a perinatal stroke.

Box Consent of parent/LAR

1. The EC should determine if consent of one or both parents would be required before a child could be enrolled.
2. Generally, consent from one parent/LAR may be considered sufficient for research involving no more than minimal risk and/or that offers direct benefit to the child. Consent from both parents may have to be obtained when the research involves more than minimal risk and/or offers no benefit to the child.
3. Only one parent's consent is acceptable if the other parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, irrespective of the risk involved.
4. Whenever relevant, the protocol should include a parent/LAR information sheet that contains information about specific aspects relevant to the child such as effects on growth and development, psychological well-being and school attendance, in addition to all components described in the participant information sheet.
5. When the research involves sensitive issues related to neglect and abuse of a child, the EC may waive the requirement of obtaining parental/LAR consent and prescribe an appropriate mechanism to safeguard the interests of the child.
6. Cognitively impaired children or children with developmental disorders form one of the most vulnerable populations. In fact, their parents are also vulnerable and there is a high likelihood of therapeutic misconception. The potential benefits and risks must be carefully explained to parents so as to make them understand the proposed research.
7. Research involving institutionalized children would require assent of the child, consent of parents/LAR, permission of the relevant institutional authorities (for example, for research in a school setting: the child, parents, teacher, principal or management may be involved).

BOX CONSIDERATIONS FOR ASSENT

- There is no need to document assent for children below 7 years of age.
- For children between 7 and 12 years, verbal/oral assent must be obtained in the presence of the parents/LAR and should be recorded.
- For children between 12 and 18 years, written assent must be obtained. This assent form also has to be signed by the parents/LAR.
- Adolescents may have the capacity to give consent like adults. However, as they have not attained the legal age to provide consent, it is termed as assent and the consent of the parents/LAR should be obtained. If the latter will affect the validity of the study, waiver of consent from the relevant adult should be taken and recorded with the approval of the EC, for example, in behavioural studies in IV drug users where parental consent may not be possible.

17. COMMUNICATING THE DECISION

a. Decision will be communicated by the Member Secretary in writing.

b. Suggestions for modifications, if any, should be sent by IEC.

c. Reasons for rejection should be informed to the researchers.

d. The schedule / plan of ongoing review by the IEC should be communicated to the MPMSU.

18. FOLLOW-UP PROCEDURES

a. Reports should be submitted at prescribed intervals for review.

b. Final report should be submitted at the end of study.

c. All SAEs and the interventions undertaken should be intimated.

d. Protocol deviation, if any, should be informed with adequate justifications.

e. Any amendment to the protocol should be resubmitted for renewed approval.

f. Any new information related to the study should be communicated.

g. Premature termination of study should be notified with reasons along with summary of the data obtained so far.

h. Change of investigators / sites should be informed.

19.RECORD KEEPING AND ARCHIVING

a. Curriculum Vitae (CV) of all members of IEC.

b. Copy of all study protocols with enclosed documents, progress reports, and SAEs.

c. Minutes of all meetings duly signed by the Chairperson.

d. Copy of all existing relevant national and international guidelines on research ethics and laws along with amendments.

20. UPDATING IEC MEMBERS

a) All relevant new guidelines should be brought to the attention of the MPMSU.
b) Members should be encouraged to attend national and international training programs in research ethics for maintaining quality in ethical review and be aware of the latest developments in this area.

21. POLICY OF COMMUNICATION WITH DIFFERENT STAKE HOLDERS

IEC communicates with different stakeholder involved in research process

including Principal Investigator or any other study team designee, Regulator

(DCGI), Head of Institute, and Sponsor.

IEC may communicate following to respective stakeholder but not limited to:

Principal Investigator

• Study Project Approval/Rejection letter/ Query Letter

• Study documents Amendments Approval/Rejection letter/ Query Letter

• Response to Serious Adverse event notification

• Opinion on compensation of Study injury/death

• Response to Protocol deviation/Violation/Waiver

• Response to Continue review/study completion report

• Study termination letter

Dean (Head of institute)

• Annual reports of IEC including status of all studies

Study Participants:

• Response to complaints (if any) filed by study participants

IEC members:

• Study documents for review
• Agenda and Minutes of meeting
• Agenda and Minutes of SAE subcommittee

22. REFERENCES

(1) World Health Organization, Operational Guidelines for IEC that Review Biomedical Research, 2000. (Geneva 2000 www.who.int/tdr/publications/publications/- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- http://www.ich.org/LOB/media/MEDIA482.pdf

(2) CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects http://www.cioms.ch/frame_guidelines_nov_2002.htm

(3) ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) -

http://www.icmr.nic.in/ethical_guidelines.pdf

(4) Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005)

http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version- 2005)%20original.htm

(5) European Convention on Human rights and Biomedicine (1997).http://conventions.coe.int/treaty/en/treaties/html/164.htm

23. ANNEXURE

ANNEXURE-1

Request letter by the Principal to the Members.

Letter Ref. No.

From:

To,

Sub: Constitution of Institute Ethics Committee (Human Studies)

Dear Sir/Madam,

I am pleased to inform you that your name has been selected for the post of

Chairman/Secretary/Member of IEC. Kindly send your written acceptance in enclosed format.

On receipt of your acceptance, I shall send you the formal appointment letter.

Yours sincerely,

ANNEXURE-2

Consent letter by members of IEC.

From:

To,

The Principal

Sub: Consent to be a member of IEC

Ref. Your letter No.

Dear Sir,

In response to your letter stated above, I give my consent to become a Chairman/Secretary/Member of IEC of MDC, Bhopal. I shall regularly participate in the IEC meetings to review and give my unbiased opinion regarding the Ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anybody other than project related personnel.

Yours sincerely,

ANNEXURE-3

Request for approval from the IEC to conduct a study.

To,
The Chairman,
Institutional Ethics Committee(IEC),
Mansarovar Dental College.
Bhopal.
(Through proper channel)
Sub: Request for approval from the Institutional Ethics Committee to conduct a Study for the degree of MDS.
Respected Sir/Madam,
I propose to conduct a study titled
……
……
……
……
……
……
……
……at college……
…….Department
……
I request for an approval from the Institutional Ethics Committee. I am herewith enclosing the details of the project work. I submit the following undertaking:
*I will start the study after obtaining approval of the IEC .
* I will get informed consent from the patients and maintain confidentiality of the details and essentially obtain an informed consent from the family in case of post-mortem studies.
*I will carry out the work without any detriment to regular activities as well as without extra expenditure to the Institution or the Government.
* I will inform the committee in the occurrence of any change in the study procedure, site, investigation or guide.

*I will not deviate from the area of work for which I have applied for ethical clearance.
* I will inform the IEC immediately, in the occurrence of any adverse events or serious adverse reactions.
* I will abide by the rules and regulations of the institution.
* I will complete the work within the specified period I have applied for and if any extension of time is required, I shall apply for permission again and continue the work.
* I will submit the summary /report of the study/project to the IEC on completion.
* I will not claim funds from the Institution while doing the work or on completion.
* I understand that the members of the IEC have the right to monitor the study /project without prior intimation.
Thanking you,

Yours obediently,
(Dr …….)

Date:
Place:
Forwarded by
GUIDE: Dr ……

College:

City:

CO-GUIDE: Dr …….

College:

City:

ANNEXURE-4

Recommendation of the HOD

The dissertation/study titled……
……
……
……
……
…….by
Dr……..at
college……
……..will be done according to the regulations of the Institutional Ethics Committee and I recommend it for acceptance.

Dr ……

College:

City:

ANNEXURE-5

Recommendation of other research institution Head associated with the study

The dissertation/study titled……
……
……
……
……..by Dr ……..at college ……will be done according to the regulations of the IEC and I recommend it for acceptance.

Dr …….....

College:

Date- City :

ANNEXURE-6

Remarks of the Guide

This work undertaken / to be done by Dr ……titled
……
……
……
……
……
…..at
……college will be under my supervision and I ensure that the candidate will abide by the rules of the IEC.

Dr ……

Designation:

College:

Date.

City:

ANNEXURE-7

Review letter No. of IEC.

To,

The meeting of the IEC for the year _____ was held in MDC _____ under the Chairmanship of _____. Following members attended the meeting.

Name **Signature**

1)

2)

3)

4)

5)

6)

7)

8)

9)

10)

11)

12)

13)

14)

After the proceeding, the proposals listed for meeting were taken up for discussion. After deliberation

The following decisions were arrived at
No. of proposals received.
No. of proposals approved -_____. Proposals approved subject to correction_____.

S.No.	Ref.no. proposal	Name of Principal Investigator	Title of Research Propsal	Recommendation of the committee
1.				

Chairman **MPMSU Representative** **Secretary**

ANNEXURE-8

Format for approval of Ethics Committee.

To,

Dr.

Dear Dr.

The IEC, received and discussed your application to conduct the clinical trial entitled _____ on date_____.

The following documents are reviewed:

a) Trial Protocol (incl.Protocol amendments) dated _____

b) Patient information sheet and informed consent form (including updates if any) in English and /or Hindi.

c) Investigator's brochure dated _____, version No.

d) Proposed methods for patient accrual including advertisement(s) etc proposed to be used for the purpose.

e) Principal investigators current C.V.

f) Insurance policy /compensation for participation and for serious adverse events occurring during the study participation.

g) Investigator's agreement with the sponsor.

h) Investigator's undertaking (form 3)

The following members of the Ethics committee were present at the meeting held on _____ at _____ at _____.

_____ Chairman

_____ Secretary

_____ Name of each member with designation.

We approve the trial to be conducted in its presented form. The Institutional Ethics Committee expects to be informed about the progress of the study, any change in the course of the study, change in protocol and patient information/ informed consent (a copy to be provided).
Yours sincerely,

ANNEXURE-9

Acknowledgement letter.

IEC has received research proposal entitled ----------

Registration no of the above research proposal is _____

Secretary

ANNEXURE-10

Declaration form

I Dr. ---------- hereby declare that I will not disclose identity of the research participants any time during or after the study period or during publication.

Signature of Investigator

ANNEXURE-11

Initial check list to verify completeness of documents submitted.

For Office use only:

1. Three (for PG dissertation / Ph.D thesis) copies of proposal for Ethics sub committee.
2. Performa completely filled and duly signed by the investigators.
3. Consent form 3 for patients in English / Hindi.
4. Consent form 3 completely filled with all the questions answered in complete sentence and single language.
5. In case the research involves a study product (such as a pharmaceutical or device under investigation , an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study products to date (eg:- recent brochure published data, summary of the products, characteristics).
6. Investigator (s) CV (updated, signed and dated)
7. Materials to be used (incl. advertisements) for the recruitment of potential research participants.
8. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
9. Adscription of the arrangements for indemnity, if applicable.
10. A description of the arrangements for insurance coverage for research participants, if applicable.
11. A statement of agreement to comply with ethical principles set out in the relevant guidelines.

ANNEXURE-12

Conflict of Interest (COI) Declaration

(To be submitted by the members in case of any COI before meeting)

I …….. hereby declare that I have a conflict of interest for the study titled ……..

……..

……..

……..

……..

……..

Study identifier ……

Nature of conflict …….

I state that I would not participate in the decision-making process for the above Study.

Thank You

(……)
Date: ……
Time: ……

ANNEXURE-13

Performa to be submitted to the MDC Institutional Ethics Committee.(Proforma as given by MPMSU)

1. Title of the projects
2. Name of the Chief Investigator, Designation & department.
3. Name of the Co-Investigator (s), Designation & department.
4. Sources of funding and financial requirements for the project.
5. Objectives of study
6. Justification for conduct of Study.
7. Methodology- it should provide detail of numbers of patients , inclusion criteria, exclusion criteria, Control(s) , study design.
8. Ethical issue involved in study and plan
9. Cost involved.
10. Permission from Drug Controller General of India , if applicable.
11. Whether consent form in local language is enclosed.
12. Conflict of interest for any other investigator, if any.
13. Name of the Institute/Hospital/field where research will be conducted.

Signature of Investigator

DETAILS OF THE PROJECT TO BE SUBMITTED BY THE INDIVIDUAL DESIROUS FOR CLEARANCE FROM INSTITUTIONAL ETHICS COMMITTEE

SYNOPSIS /SUMMARY Title	*Detail title which shall be written in the final thesis*
Aims and Objectives	*Focused Aims of the study- point-wise* *Primary Objectives (s)* *Secondary Objective(s)*
Study Centre	*Name of institution/s which are part of the study*
Duration of the Study	*Month and Year of starting and ending collection of data*
Introduction	*Including risks and benefits of the study, Procedures / Device , why are you doing , what will you be doing, how it will done , why / what / when / how it will be done*
Study Design	*Prospective/ Retrospective* *Randomized/ Non-randomized* *Observational/ Comparative*
Methodology (Material & Methods)	*Detailed methodology as per format of structured abstract and paper writing*
Inclusion Criteria	*Point-wise*
Exclusion Criteria	*Point-wise*
Sample Size	*Approximate, on what basis the size is planned*
Procedure planned	*Detail description of mode of intervention*
Investigation Details	*Detail description of mode of intervention*
Data Collection and Methods	*Please include the details in the master chart*
Statistical Analysis Plan	*(Pl attach a summary certified by a statistician)*
Sponsorship (Yes/ No)	*If Yes details*
Conflict of Interest	
Informed consent form in Hindi and English	
Proposed Authors in the upcoming publication	*Names of all authors including co-guide/s and participants of other associated institution/s.*
Principle Investigator	*DR. _____,* *College:* *City:*
Supervisor and Guide	*DR. _____,* *College:* *City:*
Co-Guide/s	*DR. _____,* *College:* *City:*