



MADHA DENTAL COLLEGE & HOSPITAL

(A Christian Minority Institution)

(Recognised by the Dental Council of India, New Delhi (F.No.v.12017/75/2006-DE dt.01.11.2011)
and affiliated to the Tamil Nadu Dr. M.G.R.Medical University, Chennai)

Madha Nagar, Kundrathur, Chennai - 600 069. Ph.: 72739 01234, 72749 01234, Fax : 2478 0798
E-Mail : info@madhadentalcollege.com Website : www.madhadentalcollege.com

Admin. Office : 1A, Chari Street, North Usman Road, T.Nagar, Chennai - 17. Ph : 2814 0212, Tele fax : 044-2814 0213

INSTITUTIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURE

1. Objective

The Institutional Ethics Committee SOP aims to establish clear guidelines and procedures for the ethical review and oversight of research involving human participants within the organization. It outlines the roles, responsibilities, and protocols to ensure the protection of participants and compliance with ethical standards.

2. Composition of the Institutional Ethics Committee

The Ethics Committee comprises key members responsible for overseeing the ethical review process. Members may include:

- Chairperson of the Ethics Committee (Appointed by the Principal)
- Faculty Representatives with expertise in research and ethics
- External Members with expertise in relevant fields (optional)
- Legal Advisor
- Community Representative (Optional)

Committee constitution:

The Institutional Ethical committee is reconstituted with the following members with effect from 16.10.2023

S.No	Name	Designation/Department	Position held
1.	Dr. Elizabeth Joshua	Professor Ragas Dental College, Chennai.	Chairman/ Chair person
2.	Dr. V.Susila Anand	Professor, Department of Conservative Dentistry and Endodontics	Member Secretary
3.	Dr. K.Vidyalakshmi Dr.G.Bhavani	HOD, Department of Pharmacology Associate Professor, Pharmacology, Meenakshi Ammal Dental College and Hospital, Chennai	Basic Medical Scientist(s) Basic Medical Scientist(s)



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4.	Dr. G.Sivakumar Dr. Sharmila Hussain Dr.Sarumathi Dr.Uma Sudhakar	Professor and HOD, Department of Oral Pathology and Oral Microbiology Professor and HOD, Department of Prosthodontics and Crown and Bridge Professor and HOD, Department of oral medicine and radiology Professor and HOD periodontology, Thai Mookambigai Dental College and Hospital, Chennai.	Clinician(s)
5.	Dr.Anitha Mahendran		Social scientist
6.	Dr.Zoha	Reader, Department of Public Health Dentistry	Statistician
7.	Mr.Ramamoorthy	Administrative Officer	Lay person
8.	Mr. Ajay Ravindra Kumar	Director	Legal expert/s

3. Roles and Responsibilities

3.1 Chairperson of the Ethics Committee

Provide leadership and direction to the Ethics Committee.

Oversee the ethical review process and ensure compliance with regulations.

Represent the committee in discussions with the organization's administration.

3.2 Faculty Representatives

Review and evaluate research proposals submitted for ethical approval.

Provide expertise on research design, methods, and ethical considerations.

Participate in Ethics Committee meetings and contribute to discussions.



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3.3 External Members (optional)

Bring external expertise to the Ethics Committee, particularly in areas relevant to ongoing research projects.

Provide insights and recommendations on ethical considerations.

Participate in the evaluation of research proposals.

3.4 Legal Advisor

Offer legal guidance on ethical and regulatory compliance.

Assist in interpreting and applying relevant laws and regulations.

Provide input on liability and risk management.

3.5 Community Representative (optional)

Represent the interests of the community in the ethical review process.

Contribute perspectives on the potential impact of research on the community.

Enhance community engagement and transparency.

4. Functions

- The Ethical committee is responsible for scientific and ethical review of research proposals.
- Ethical committees are entrusted with the initial review of research proposals prior to their initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research.
- The Ethical committee should be competent and independent in its functioning.

5. Research Proposal Submission

5.1 Define Submission Procedures

Develop a standardized format for researchers to submit research proposals.

Outline the required components, including research objectives, methodology, ethical considerations, and potential risks.

5.2 Initial Review

Conduct an initial review to ensure that proposals meet basic ethical standards.

Identify any deficiencies or areas requiring clarification.



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5.3 Full Committee Review

Schedule and conduct full committee meetings to review and evaluate research proposals.

Discuss research protocols, ethical considerations, and potential impact.

Provide recommendations for modifications or approval.

6. Informed Consent Process

6.1 Informed Consent Documents

Review and approve informed consent documents provided by researchers.

Ensure that consent forms are clear, comprehensive, and understandable.

6.2 Participant Information

Assess the adequacy of information provided to participants.

Confirm that participants are adequately informed about the research and its potential risks and benefits.

6.3 Consent Monitoring

Monitor ongoing studies to ensure the continued appropriateness of the informed consent process.

Address any changes or concerns related to participant consent.

7. Ethical Considerations

7.1 Human Participants Protection

Assess the potential risks and benefits to human participants.

Ensure that research procedures are designed to minimize harm and protect participants' well-being.

7.2 Confidentiality and Privacy

Evaluate the measures in place to maintain participant confidentiality and privacy.

Address any potential risks to the confidentiality of participant information.

7.3 Vulnerable Populations

Consider the ethical implications of research involving vulnerable populations.

Ensure additional safeguards are in place to protect vulnerable participants.



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8. Decision-Making and Approval

8.1 Committee Meetings

The Committee shall formally meet at the start of the academic year to plan for the ethical committee activities of the aforementioned year.

The second meeting for the academic year shall be conducted at the end of the academic year to review the ethical committee activities of the institution.

Schedule committee meetings to discuss and make decisions on each research proposal.

Ensure that the committee functions with fairness and impartiality.

8.2 Quorum and Voting

Establish quorum requirements for committee meetings.

Determine the voting procedures for deciding on research proposals.

8.3 Resolution Options

Identify potential resolutions, such as approval, approval with modifications, or rejection.

Prioritize solutions based on the nature of the ethical considerations.

8.4 Communication

Communicate the decision and resolution to the researcher.

Provide clear explanations for the committee's decision.

9. Follow-Up and Monitoring

9.1 Implementing Resolutions

Implement the decided-upon resolutions in a timely manner.

Ensure that researchers adhere to approved protocols and modifications.

9.2 Ongoing Monitoring

Monitor ongoing studies to ensure continued ethical compliance.

Conduct periodic reviews to assess ongoing ethical considerations.

9.3 Reporting to Authorities

Fulfill reporting requirements to regulatory authorities, if applicable.

Submit required documentation and reports in a timely manner.



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10. Training and Education

10.1 Researcher Training

Develop and implement training programs for researchers on ethical research conduct.

Provide resources and guidance on submitting proposals to the Ethics Committee.

10.2 Committee Member Training

Ensure that Ethics Committee members receive training on ethical principles, regulations, and review processes.

Encourage ongoing education to stay informed about developments in research ethics.

11. Record Keeping

Maintain accurate and up-to-date records of Ethics Committee activities.

Archive documentation for auditing purposes and reporting requirements.

12. Communication

Communicate ethical review procedures to researchers, faculty, and staff.

Provide regular updates on the status of ongoing ethical reviews and decisions.

13. Review and Revision

Periodically review the SOP to ensure its relevance and effectiveness.

Revise the SOP as needed to accommodate changes in ethical considerations or regulations.

14. Approval

This SOP is approved by the Principal or relevant academic authority and will be reviewed annually or as needed.

PRINCIPAL
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