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

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INSTITUTIONAL REVIEW BOARD

STANDARD OPERATING PROCEDURE

1. Objective

The IRB SOP aims to establish clear guidelines and procedures for the ethical review and approval of research involving human participants within the dental college. It outlines the roles, responsibilities, and protocols to ensure the protection of participants and compliance with ethical standards.

2. Composition of the Institutional Review Board

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

- Chairperson of the IRB (Appointed by the Dean)
- Faculty Representatives with expertise in research and ethics
- IRB Coordinator or Administrator

Committee constitution:

The Institutional Review Board is re-constitued with the following members with effect from 22.07.2024

S.No	Name	Designation/Department	Position held
1.	Dr. Bagavad Gita	Principal	Chair person
2.	Dr. C.S.Krishnan	Vice-Principal, Department of Periodontology	Member secretary
3.	Dr.V. Susila Ananad	HOD, Department of Conservative dentistry & Endodontics	Member
4.	Dr. Sharmila Hussain	HOD, Department of Prosthodontics and Crown and Bridge	Member
5.	Dr.Deepak Abraham Pandyan	HOD, Departmnet of Oral and Maxillofacial Surgery	Member

6.	Dr. N. Gautham Kumar	HOD, Department of Periodontology	Member
7.	Dr.Sivakumar G	HOD, Department of Oral Pathology and Oral Microbiology	Member
8.	Dr. I. NandaBalan	HOD, Department of Public health dentistry	Member
9.	Dr.E. Arun	HOD, Department of Pediatric and preventive dentistry	Member
10.	Dr. K. Vidhya Lakshmi	HOD, Department of Pharmacology	Member
11.	Dr. T. Sarumathi	HOD, Department of Oral medicine and Radiology	Member
12.	Dr.Navneethanambi	HOD, Departmnet of Orthodontics and Dentofacial Orthopaedics	Member
13.	Dr.Zoha Abdullah	Reader,Department of Public health dentistry	Statistician
14.	Mr. Baba	Advocate	Nominee from local society

3. Roles and Responsibilities

3.1 Chairperson of the IRB

Provide leadership and direction to the IRB.

Oversee the ethical review process and ensure compliance with regulations.

Represent the IRB in discussions with college administration.

3.2 Faculty Representatives

Review research proposals submitted for ethical approval.

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

Participate in IRB meetings and contribute to discussions.

3.3 IRB Coordinator or Administrator

Manage administrative tasks related to the IRB.

Facilitate communication between researchers, IRB members, and the administration.

Maintain accurate records of IRB activities.

4. Functions

- The IRB is a committee that performs ethical review of proposed research involving human subjects and monitors continuing research
- IRB reviews the appropriateness of the clinical trial protocol as well as the risks and benefits to study participants.
- It ensures that clinical trial participants are exposed to minimal risk in relation to any benefits that might result from the research.
- The IRB is also responsible for providing training on the protection of human subjects in research.

5. Submission and Review Process

5.1 Research Proposal Submission

Develop a standardized format for researchers to submit proposals.

Outline the required components, including research objectives, methodology, risks, and informed consent procedures.

5.2 Initial Review

Conduct an initial review to ensure that proposals meet ethical standards and regulatory requirements.

Identify any deficiencies or areas requiring clarification.

5.3 Schedule Meetings

Schedule and conduct full IRB meetings to review proposals.

Discuss research protocols, ethical considerations, and participant protections.

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. Documentation and Record Keeping

7.1 Meeting Minutes

Maintain detailed minutes of IRB meetings.

Document discussions, decisions, and recommendations.

Ensure accuracy and completeness of meeting records.

7.2 Researcher Correspondence

Keep records of all correspondence with researchers, including feedback and approval notifications.

Maintain a comprehensive file for each submitted research proposal.

7.3 Regulatory Compliance

Ensure compliance with relevant regulations and guidelines.

Keep records of compliance documentation and reporting.

8. Approval and Communication

8.1 Approval Decision

Communicate approval decisions promptly to researchers.

Provide clear guidelines on any required modifications to the research protocol.

8.2 Reporting to Authorities

Fulfill reporting requirements to regulatory authorities, if applicable.

Submit required documentation and reports in a timely manner.

8.3 Feedback to Researchers

Provide constructive feedback to researchers on rejected proposals or required modifications.

Support researchers in addressing ethical concerns.

9. Periodic Review

9.1 Continuing Review

Establish procedures for the periodic review of ongoing research.

Ensure that the ethical considerations and participant protections remain valid.

9.2 Amendments to Approved Research

Define the process for reviewing and approving amendments to approved research protocols.

Assess the impact of proposed changes on ethical considerations.

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 IRB.

10.2 IRB Member Training

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

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

11. Review and Revision

Periodically review the SOP to ensure its relevance and effectiveness.

Revise the SOP as needed to accommodate changes in regulations or institutional policies.

12. 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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