3.3.1 Any other relevant information

Sr.No.	Contents
1.	**Registration of Institutional Ethics Committee**
2.	**Composition of Institutional Ethics Committee**
3.	**Standard operating procedure (SOPs) of Composition of Institutional Ethics Committee**
4.	**Circulars. minutes of meeting and action taken reports w.r.t. research proposal approval**
5.	**Plagiarism software usage certificate with MOU with MGMIHS**

REGISTRATION

OF INSTITUTIONAL ETHICS COMMITTEE (MGMDCH)

DR. SRIVALLI NATARAJAN
DEAN
MGM Dental College & Hospital
Kamothe, Navi Mumbai - 410209

File No. EC/19/000122

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Ethics Committee Registration Division)

सत्यमेव जयते

FDA Bhawan, Kotla Road,
New Delhi - 110002, India
Dated: 08-Aug-2019

To

The Chairman
Institutional Ethics Committee
MGMs Dental College and Hospital
Junction of NH-4 and Sion Panvel Highway Sector - 1,
Kamothe Navi Mumbai Raigad Maharashtra - 410209
India

Subject: Ethics Committee Re-Registration No. ECR/786/Inst/MH/2015/RR-18 issued under New Drugs and Clinical Trials Rules, 2019.

Sir/Madam,

Please refer to your application no. EC/RENEW/INST/2019/2956 dated 09-Apr-2019 submitted to this Directorate for the Re-Registration of Ethics Committee.

Please find enclosed registration of the Ethics Committee in Form CT-02 vide Registration No. ECR/786/Inst/MH/2015/RR-18. The said registration is subject to the conditions as mentioned below:-

Yours faithfully

S ESWARA REDDY

Digitally signed by S ESWARA REDDY
Date: 2019.08.09 13:39:41 +05'30'

(Dr. S. Eswara Reddy)
Drugs Controller General (I) &
Central Licensing Authority

Conditions of Registration

1. The registration is valid from 09-Apr-2019 to 08-Apr-2024, unless suspended or cancelled by the Central Licencing Authority.

2. This certificate is issued to you on the basis of declaration/submission made by you.

3. Composition of the said Ethics Committee is as per the Annexure.

4. No clinical trial or bioavailability or bioequivalence protocol and related documents shall be reviewed by an Ethics Committee in meeting unless at least five of its members as detailed below are present in the meeting, namely:-
(i) medical scientist (preferably a pharmacologist);
(ii) clinician;
(iii) legal expert;
(iv) social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian or a similar person;
(v) lay person.

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5. The Ethics Committee shall have a minimum of seven and maximum of fifteen members from medical, non-medical, scientific and non-scientific areas with at least,

(i) one lay person;
(ii) one woman member;
(iii) one legal expert;
(iv) one independent member from any other related field such as social scientist or representative of non-governmental voluntary agency or philosopher or ethicist or theologian.

6. One member of the Ethics Committee who is not affiliated with the institute or organization shall be the Chairperson, and shall be appointed by such institute or organization and one member who is affiliated with the institute or organization shall be appointed as Member Secretary of the Ethics Committee by such Institute or organization.

7. The Ethics Committee shall consist of at least fifty percent of its members who are not affiliated with the institute or organization in which such committee is constituted.

8. The committee shall include at least one member whose primary area of interest or specialisation is non-scientific and at least one member who is independent of the institution.

9. The Ethics committee can have as its members, individuals from other Institutions or Communities, if required.

10. Members should be conversant with the provisions of New Drug and Clinical Trials Rules, 2019, Good Clinical Practice Guidelines for clinical trials in India and other regulatory requirements to safeguard the rights, safety and well-being of the trial subjects.

11. The members representing medical scientists and clinicians shall possess at least post graduate qualification in their respective area of specialization, adequate experience in the respective fields and requisite knowledge and clarity about their role and responsibility as committee members.

12. As far as possible, based on the requirement of research area such as HIV, Genetic disorder, etc., specific patient group may also be represented in the Ethics Committee.

13. The Ethics Committee may associate such experts who are not its members, in its deliberations but such experts shall not have voting rights, if any

14. 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.

15. 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. Any change in the membership or the constitution of the registered Ethics Committee shall be intimated in writing to the Central Licencing Authority within thirty working days.

17. The Ethics Committee shall review and accord approval to a Clinical trial, Bioavailability and Bioequivalence study protocol and other related documents, as the case may be, in the format specified in clause (B) of Table 1 of the Third Schedule of New Drugs and Clinical Trials Rules, 2019 and oversee the conduct of clinical trial to safeguard the rights, safety and wellbeing of trial subjects in accordance with these rules, Good Clinical Practices Guidelines and other applicable regulations.

18. Where a clinical trial site does not have its own Ethics Committee, clinical trial at that site may be initiated after obtaining approval of the protocol from the Ethics Committee of another trial site; or an independent Ethics Committee for clinical trial constituted in accordance with the provisions of rule 7: provided that the approving Ethics Committee for clinical trial shall in such case be responsible for the study at the trial site or the centre, as the case may be: provided further that the approving Ethics Committee and the clinical trial site or the bioavailability and bioequivalence centre, as the case may be, shall be located within the same city or within a radius of 50 kms of the clinical trial site.

19. Where a Bioavailability or Bioequivalence study centre does not have its own Ethics Committee, bioavailability or bioequivalence study at that site may be initiated after obtaining approval of the

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from the Ethics Committee registered under rule 8:Provided that the approving Ethics Committee shall in such case be responsible for the study at the centre:Provided further that both the approving Ethics Committee and the centre, shall be located within the same city or within a radius of 50 kms of the bioavailability or bioequivalence study centre.

20. Ethics committee shall indicate the reasons that weighed with it while rejecting or asking for a change or notification in the protocol in writing and a copy of such reasons shall also be made available to the Central Licencing Authority.

21. Ethics committee shall make, at appropriate intervals, an on-going review of the trials for which they have reviewed the protocol. Such a review may be based on the periodic study progress reports furnished by the investigators or monitoring and internal audit reports furnished by the sponsor or by visiting the study sites.

22. Where any serious adverse event occurs to a trial subject or to study subject during clinical trial or bioavailability or bioequivalence study, the Ethics Committee shall analyse the relevant documents pertaining to such event and forward its report to the Central Licencing Authority and comply with the provisions of Chapter VI, New Drugs and Clinical Trials Rules, 2019.

23. The Ethics committee shall undertake proper causality assessment of SAE's with the help of subject experts wherever required, for deciding relatedness and quantum of compensation, as per condition no (22) mentioned above.

24. Where at any stage of a clinical trial, it comes to a conclusion that the trial is likely to compromise the right, safety or wellbeing of the trial subject, the Ethics committee may order discontinuation or suspension of the clinical trial and the same shall be intimated to the head of the institution conducting clinical trial and the Central Licencing Authority.

25. Ethics committee shall comply with the requirements or conditions in addition to the requirements specified under the Drugs & Cosmetics Act, 1940 and New Drugs and Clinical Trials Rues, 2019, as may be specified by the Central Licencing Authority with the approval of the Central Government, to safeguard the rights of clinical trial subject or bioavailability or bioequivalence study subject.

26. Ethics Committee shall review and approve the suitability of the investigator and trial site for the proposed trial.

27. The Ethics Committee shall maintain data, record, registers and other documents related to the functioning and review of clinical trial or bioavailability study or bioequivalence study, as the case may be, for a period of five years after completion of such clinical trial.

28. Funding mechanism for the Ethics Committee to support their operations should be designed and approved to ensure that the committee and their members have no financial incentive to approve or reject particular study.

29. SOP's for funding of the Ethics committee in order to support their operations must be maintained. The records of income & expenditure of Ethics Committee shall be maintained for review and inspection.

30. The Chairman of Ethics Committee shall enter into MOU with head of institution, that necessary support and facilities and independence will be provided to Ethics Committee and their records will be maintained.

31. The Ethics Committee shall allow any officer authorized by the Central Licencing Authority to enter, with or without prior notice, to inspect the premises, any record, or any documents related to clinical trial, furnish information to any query raised by such authorized person, in relation to the conduct of clinical trial and to verify compliance with the requirements of these rules, Good Clinical Practices Guidelines and other applicable regulations for safeguarding the rights, safety and well-being of trial subjects.

32. Where Central Licencing Authority is of the opinion that Ethics Committee fails to comply with any provision of the Drugs and Cosmetics Act, 1940and New Drugs & Clinical Trials Rules, 2019, it may issue show cause notice to such Ethics Committee specifying therein such non-compliances and the period within which reply shall be furnished by such Ethics Committee. After consideration of the facts and reply given by the Ethics Committee, the Central Licencing Authority may take one or more actions specified under provision of Rule 14, Chapter III of New Drugs and Clinical Trials Rules, 2019.

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COMPOSITION

OF INSTITUTIONAL ETHICS COMMITTEE (MGMDCH)

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STANDARD OPERATING PROCEDURES (SOP)

Institutional Ethics Committee (IEC)

MGM Dental College & Hospital, Kamothe Navi Mumbai

IEC, SOP Version 4, dt. January 2024

IEC SOP Author: Dr Shilpa Patel, Member Secretary; Reviewed by: Members, IEC

Sr. No.	Name of IEC Member	Designation	Affiliation	Signature
1.	Dr. Deepak Langade	Chairman	Prof. & Head, Pharmacology, D.Y.Patil Medical School of Medicine, Navi Mumbai	
2.	Dr. Shilpa Patel	Member Secretary	Prof. & Head, Dept of Oral Pathology, MGM Dental College & Hospital Kamothe Navi Mumbai	
3.	Dr Chandramani Pathak	Member	Research Director, MGM Institute of Health Sciences, Kamothe, Navi Mumbai	
4.	Dr Ashwin Jawdekar	Member	Prof & Head, Dept of Pediatric and Preventive Dentistry; Vice-Principal (Academic), Bharati Vidyapeeth Dental College and Hospital, Navi Mumbai	
5.	Dr Nilesh Joshi	Member	Professor, Dept of Periodontology, Bharati Vidyapeeth University Dental College & Hospital, Navi-Mumbai.	
6.	Dr Nikhil Bhanushali	Member	Associate Professor, Dept of Public Health Dentistry, Terna Dental College, Navi –Mumbai.	
7.	Dr. Vineet Kini	Clinician	Prof & Head, Dept of Periodontology, MGM Dental College & Hospital Kamothe Navi Mumbai	
8.	Dr. Ravindranath V. K.	Member	Prof & Head, Dept of Orthodontics and Dentofacial Orthopedics, MGM Dental College & Hospital Kamothe Navi Mumbai	
9.	Dr. Sumanthini M. V.	Member	Prof & Head, Dept of Conservative Dentistry & Endodontics, MGM Dental College & Hospital Kamothe Navi Mumbai	
10.	Dr Jyoti Nadgere	Member	Prof & Head, Dept of Prosthetic Dentistry, MGM Dental College & Hospital Kamothe Navi Mumbai	
11.	Dr. Usha Asnani	Clinician	Professor, Dept of Oral & Maxillofacial Surgery, MGM Dental College & Hospital Kamothe Navi Mumbai	

12.	Dr. Shakeeb Dhorajiwala	Basic Medical Scientist	Senior Resident, GS Medical College & KEM Hospital	
13.	Adv. Dr. Sheela Hosamani	Legal Expert	IC Principal, MGM Law College, Nerul, NaviMumbai	
14.	Priyanka Sharma	Lay Person	Mahatma Education Society College of Arts, Commerce and Science, New Panvel	
15.	Mrs. Rupali Gujar	Social Scientist	Asst. Registrar, Students affairs MGM Institute of Health Sciences, Navi Mumbai	

IEC SOP Approved by:

	Name of Authority	Signature	Seal
Approved by	Dr Deepak Langade Chairman, IEC Professor & Head, Dept. of Pharmacology, Padmashree Dr D Y Patil Medical College, Hospital and Research Center, Navi Mumbai		Chairman Institutional Ethics Committee MGM Dental College & Hospital Kamothe, Navi Mumbai - 410 209.
Confirmed by	Dr Srivalli Natarajan Dean, MGM Dental College and Hospital Navi Mumbai	S Srivalli	Dean M.G.M. Dental College and Hospital, Kamothe, Navi Mumbai 410 209.
Distributed to	• Members of IEC, MGM Dental College and Hospital, Kamothe, Navi Mumbai • Investigators		

STANDARD OPERATING PROCEDURES (SOP)

OF INSTITUTIONAL ETHICS COMMITTEE (MGMDCH)

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Standard Operating Procedures
[SOP]

Institutional Ethics Committee (IEC)

MGM Dental College & Hospital, Kamothe,
Navi Mumbai

EC Registration Number – EC/RENEW/INST/2019/2956, Valid till January 2027

SOP Version 4
Effective date January 2024
Valid till January 2027

IEC Office
Plot No 1& 2. Sector – 01 (Old 18 & 19)
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Phone No: 022- 27436604, Extn. 7868
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IEC SOP Amendment history:

Amendments in MGM Dental College & Hospital, Kamothe, Navi Mumbai IEC SOPs	
1.	Amendments in General SOP of IEC : SOPs Version 01 dated 9 September 2009
2.	Amendments in General SOP of IEC : SOPs Version 2 dated 2 May 2014
3.	Amendments in General SOP of IEC : SOPs Version 03 dated 26 November 2018
4.	Amendments in General SOP of IEC : SOPs Version 3.1 dated 3 December 2021
5.	Amendments in General SOP of IEC : SOPs Version dated January 2024

DCGI Registration History:

1	Registration of IEC under CDSCO as Institutional Ethics Committee	ECR/786/Inst/MH/2015	
2	Registration of IEC under CDSCO as Institutional Ethics Committee	EC/RENEW/INST/2019/2956	Valid till April 2024

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Abbreviations

AV	Audio-Visual
CAPA	Corrective Action and Preventive Action
CD	Compact Disc
CDSCO	Central Drugs Standards Control Organization
CIOMS	Council for International Organizations of Medical Sciences
Co-I	Co-Investigator
Co-PI	Co-Principal investigator
CRF	Case Record Form
CRO	Contract Research Organization
CTA	Clinical Trial Agreement
CTRI	Clinical Trials Registry of India
CV	Curriculum vitae
DCGI	Drug(s) Controller General of India
DD	Demand Draft
DVD	Digital Video Disc
FDA	Food and Drug Administration
GCP	Good Clinical Practice
HMSC	Health Ministry Screening Committee
IB	Investigator Brochure
ICD	Informed consent document
ICF	Informed consent form
ICH	International Conference on Harmonization
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
IRB	Institutional Review Board
MOHFW	Ministry of Health & Family Welfare
MOU	Memorandum of Understanding
NEFT	National Electronic Fund Transfer
NGO	Non-Government Organization
PAN	Permanent account number
PAN	Permanent Account Number
PD	Pen Drive
PDF	Printed Document Format
PI	Principal investigator
PIS	Participant information sheet
SAE	Serious adverse event
SOP	Standard Operating Procedures
SUSARS	Suspected Unexpected Serious Adverse Reactions
UAE	unexpected adverse events
WHO	World Health Organization

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Introduction

The first International statement on the ethics in medical research using human subjects, the Nuremberg Code was formulated in 1947 and it laid emphasis on consent and voluntariness. In 1964, the eighteenth World Medical Assembly at Helsinki, Finland adopted a code of ethics for the guidance of doctors involved in clinical research. This is popularly known as the "Declaration of Helsinki." In 1980, the Indian Council of Medical Research released a 'Policy Statement on Ethical Considerations involved in Research in Human Subjects' for the benefit of all those involved in clinical research in India.

Moreover, in 1996, the International Conference on Harmonization (ICH) published a tripartite guideline for Good Clinical Practice (GCP) to harmonies technical requirements for registration of pharmaceutical products in three regions namely the United States, the European Union and Japan). Today, the ICH-GCP guideline is followed globally for clinical research. This guideline elaborates the composition and functioning of an Institutional Ethics Committee to review clinical research proposals.

It was thus felt necessary to establish an Institutional Ethics Committee (IEC) consistent with the GCP Guidelines so as to facilitate the ethical review of any human research projects at institute. MGM Dental College & Hospital, Kamothe, Navi Mumbai is under-graduate and post-graduate medical teaching institution with all ultra-modern health care services with 1075 indoor admission bed capacities. The institution such provides support for conducting research on human subjects to researchers (self- funded) or those offered by the sponsored pharmaceutical companies. To protect interest of participating subjects it was felt necessary to start an institutional ethics committee for reviewing the scientific as well as ethical aspects in the projects planned in the MGM Dental College & Hospital, Kamothe, Navi Mumbai.

The Institutional Ethics Committee presently functions according to the provisions from chapter III and chapter IV of the New Drugs and Clinical Trials Rules (2019), Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2018, and guidelines for Good Clinical Practice (GCP), ethical principles set forth in the Declaration of Helsinki.

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The viewpoint of Clinical Trials and Biomedical Research

Clinical Trials and Biomedical Research should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki (Revised 1996) which lays down "the recommendations guiding physicians in biomedical research involving human subjects" and that are consistent with good clinical practice requirements and the applicable regulatory requirements.

The Declaration of Helsinki, in laying down the Basic Principles in Biomedical Research, states: "Biomedical research involving human subjects must conform to generally accept scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific tradition."

Good Practice in Research (GPR) refers to the international ethical and scientific standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that involve the participation of human subjects. Compliance with GPR provides public assurance that the rights, safety, well–being and confidentiality of trial subjects are protected, consistent with the principles of the Declaration of Helsinki, and that data and reported results are credible and accurate.

Definitions

Biomedical and health research means research including studies on basic, applied and operational research or clinical research, designed primarily to increase scientific knowledge about diseases and conditions (physical or socio-behavioral); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include clinical trial as defined in New Drugs & Clinical Trials Rules- 2019.

Clinical Trial in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its, -

(i) Clinical or;

(ii) Pharmacological including pharmacodynamics, pharmacokinetics or;

(iii) Adverse effects,

Categorization of Clinical Research in India

In India, for the purpose of regulation, medical research can be broadly categorized into:

i. Interventional Clinical Studies: Clinical studies which involve the administration of an intervention— new drug or investigational new drug for a commercial purpose, which are regulated under the CT Rules.

ii. Academic and Biomedical Clinical Studies: Academic clinical trials and biomedical and health research are regulated by the ICMR Guidelines. Biomedical and health research includes research where no investigational new drug or new drug is involved and is primarily conducted for the purpose of collecting scientific knowledge about diseases and conditions. While, academic clinical trials are conducted for drugs already approved for a certain claim and initiated by an academic or research institution or an investigator for a new indication, dosage form or route of administration.

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THE OBJECTIVES IN CLINICAL TRIAL/BIOMEDICAL RESEARCH

Any investigation in human subjects intended:

(a) To discover or verify the clinical, pharmacological, and/or other pharmaco-dynamic effects of an investigational product(s); and/or

(b) To identify any adverse reactions to an investigational product(s); and/or

(c) To study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. It implies a pre-determined protocol with a clearly defined endpoint.

ETHICS COMMITTEE FOR BIOMEDICAL AND HEALTH RESEARCH

Ethics Committee for biomedical and health research:

According to the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, any institution or organization that plans to undertake biomedical and health research must have an Ethics Committee to assess and supervise the conduct of such research.

Constitution of Ethics Committee for biomedical and health research:

1. The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, as may be specified from time to time by the Indian Council of Medical Research, shall be followed in the formation and operation of the Ethics Committee referred to in Rule 15 with regard to biomedical and health research.

2. The National Ethical Guidelines for Biomedical and Health Research Involving Human Participants state that the Ethics Committee mentioned in subrule (1) is responsible for reviewing the biomedical and health research center's work before it begins and for supervising it during the entire project.

3. Any biomedical and health study conducted by an institution, organization, or individual must have the Ethics Committee's permission before it can be registered under Rule 17 for biomedical and health research.

4. The National Ethical Guidelines for Biomedical and Health Study Involving Human Participants, which may be updated from time to time by the Indian Council of Medical Research, must be followed when conducting any biomedical or health study.

5. Institutions desirous of conducting biomedical and health research as well as clinical trials or bioavailability or bioequivalence study shall require obtaining registration from specified authorities as provided in rule 8 and rule 17.

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Registration of Ethics Committee related to biomedical and health research.

1. An Ethics Committee constituted under rule 16, shall be required to register with the authority designated by the Central Government in the Ministry of Health and Family Welfare, Department of Health Research under these rules for which an application shall be made in Form CT-01 to the said authority.

2. The application referred to in sub-rule (1) shall be accompanied with the information and documents as specified in Table 1 of the Third Schedule.

3. On receipt of application in Form CT-01(Application for renewal of ethics committee) under sub-rule (1), the authority designated under sub-rule shall grant provisional registration which shall remain valid for a period of two years.

4. After the grant of provisional registration under sub-rule (3), the authority designated under sub-rule (1) shall scrutinize the documents and information furnished with the application, and if satisfied that the requirements of these rules have been complied with, grant final registration to Ethics Committee in Form CT-03; or if not satisfied, reject the application, for reasons to be recorded in writing and the final registration in Form CT-03 shall supersede the provisional registration granted under sub-rule (3).

5. An applicant who is aggrieved by the decision of the authority designated under sub-rule (1), may file an appeal within sixty working days from the date of receipt of such rejection before the Central Government in the Ministry of Health and Family Welfare, and the Central Government, may, after such enquiry as is considered necessary in the facts and circumstances of the case, and after giving an opportunity of being heard to the appellant, dispose of the appeal within a period of sixty working days.

6. The Ethics Committee shall make an application for renewal of registration in Form CT-01 along with documents as specified in sub-rule (2) at least ninety days prior to the date of the expiry of its final registration: Provided that if the application for renewal of registration is received by the authority designated under sub-rule (1), ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on the application: Provided further that fresh set of documents shall not be required to be furnished, if there are no changes in such documents furnished at the time of grant of final registration, and if the applicant renders a certificate to that effect indicating that there is no change.

7. The authority designated under sub-rule (1) shall after scrutiny of information furnished with the application and after such further enquiry, as considered necessary and on being satisfied that the requirements of these rules have been complied with, renew the registration of Ethics Committee in Form CT-03, or if not reject the application, for reasons to be recorded in writing.

8. The authority shall take a decision under sub-rule (7) within a period of forty-five working days, from the date of application made under sub-rule (1).

9. The registration granted in Form CT-03 shall remain valid for a period of five years from the date of its issue, unless suspended or cancelled by the authority designated under sub-rule (1).

10. The function, proceedings of ethics committee and maintenance of records shall be as per the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.

11. In case there is a change in composition of registered Ethics Committee in an institution it shall be reported to the authority designated under sub-rule (1).

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Suspension or cancellation of registration of Ethics Committee for biomedical and health research.

(1) Subject to provisions of rule 17, where the Ethics Committee fails to comply with any provision of these rules, the authority designated under sub-rule (1), may, after giving an opportunity to show cause and after affording an opportunity of being heard, by an order in writing, take one or more of the following actions, namely:

(i) Issue warning to the Ethics Committee describing the deficiency or defect observed, which may adversely affect the rights or well-being of the study subjects;

(ii) Suspend for such period as considered appropriate or cancel the registration issued under rule 17;

(iii) Debar its members to oversee any biomedical health research in future for such period as may be considered appropriate.

(2) Where the Ethics Committee or its member, as the case may be, is aggrieved by an order of the authority designated under sub-rule (1), it may, within a period of forty-five working days of the receipt of the order, make an appeal to the Central Government in the Ministry of Health and Family Welfare, and that Government may, after such enquiry, as deemed necessary, and after giving an opportunity of being heard, pass such order in relation thereto as may be considered appropriate in the facts and circumstances of the case.

Conditions of Permission for Conduct of Academic Clinical Trial

No permission for conducting an academic clinical trial shall be required for any drug from the Central Licensing Authority where,

(i) the clinical trial in respect of the permitted drug formulation is intended solely for academic research purposes for a new indication or new route of administration or new dose or new dosage form; and

(ii) The clinical trial referred to in clause (i) has been initiated after prior approval by the Ethics Committee for clinical trial; and

(iii) The observations generated from such clinical trial are not required to be submitted to the Central Licensing Authority; and

(iv) The observations of such clinical trial are not used for promotional purposes.

(2) In the event of a possible overlap between the academic clinical trial and clinical trial or a doubt on the nature of study, the Ethics Committee concerned shall inform the Central Licensing Authority in writing indicating its views within thirty working days from the receipt of application to that effect.

(3) The Central Licensing Authority shall, after receiving the communication from the Ethics Committee referred to in sub-rule (2), examine it and issue necessary clarification, in writing, within thirty working days from the date of receipt of such communication: Provided that where the Central Licensing Authority does not send the required communication to such Ethics Committee within thirty working days from the date of receipt of communication from the said Ethics Committee, it shall be presumed that no permission from the Central Licensing Authority is required.

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(4) The approved academic clinical trial shall be conducted in accordance with the approved clinical trial protocol, ethical principles specified in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, notified by the Indian Council of Medical Research with a view to ensuring protection of rights, safety and wellbeing of trial subject during conduct of clinical trial of licensed and approved drug or drug formulation for any new indication or new route of administration or new dose or new dosage form for academic research purposes.

Academic clinical trial

(1) No permission for conducting an academic clinical trial shall be required for any drug from the Central Licencing Authority where,

(i) the clinical trial in respect of the permitted drug formulation is intended solely for academic research purposes for a new indication or new route of administration or new dose or new dosage form; and

(ii) The clinical trial referred to in clause (i) has been initiated after prior approval by the Ethics Committee for clinical trial; and

(iii) The observations generated from such clinical trial are not required to be submitted to the Central Licensing Authority; and

(iv) The observations of such clinical trials are not used for promotional purposes.

(2) In the event of a possible overlap between the academic clinical trial and clinical trial or a doubt on the nature of study, the Ethics Committee concerned shall inform the Central Licensing Authority in writing indicating its views within thirty working days from the receipt of application to that effect.

(3) The Central Licencing Authority shall, after receiving the communication from the Ethics Committee referred to in sub-rule (2), examine it and issue necessary clarification, in writing, within thirty working days from the date of receipt of such communication: Provided that where the Central Licencing Authority does not send the required communication to such Ethics Committee within thirty working days from the date of receipt of communication from the said Ethics Committee, it shall be presumed that no permission from the Central Licencing Authority is required.

(4) The approved academic clinical trial shall be conducted in accordance with the approved clinical trial protocol, ethical principles specified in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, notified by the Indian Council of Medical Research with a view to ensuring protection of rights, safety and wellbeing of trial subject during conduct of clinical trial of licenced and approved drug or drug formulation for any new indication or new route of administration or new dose or new dosage form for academic research purposes.

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Standard Operating Procedures (SOP)

1 Name

This committee will be known as the Institutional Ethics Committee (IEC), MGM Dental College & Hospital, Kamothe, Navi Mumbai

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

2 Purpose

The primary purpose of this committee will be:

1. To ensure the protection of the rights, safety and well-being of human subjects involved in a research project.
2. To provide public assurance of that protection.

3 Authority for Formation of Institutional Ethics Committee (IEC)

1. The Institutional Ethics Committee (IEC) is established under the authority of Dean, MGM Dental College & Hospital, Kamothe, Navi Mumbai. It is administratively governed under same authority.
2. Institution will support establishment of ethics committee including training, resources and infrastructure etc.
3. The IEC oversees other medical teaching institutions under umbrella of MGM Institute of Health Sciences such as Dental College and Hospital, School of Biomedical Sciences, School of Physiotherapy (MUHS), College of Physiotherapy, College of Prosthetics and Orthotics, New Bombay College of Nursing.
4. The IEC is an independent committee chaired by external personnel and has its own function and decision making. Institute management will not participate in its functioning and decision making. Dean, MGM Dental College & Hospital, Kamothe, Navi Mumbai will ensure independence of theIEC.
5. The IEC shall adhere to existing applicable rules and regulations (Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2018, CDSCO guidelines, NDCT (2019), ICH- GCP, Indian GCP, ICMR guidelines etc.) for its formation, registration, functioning etc. Any change in existing regulations shall be applicable as and when with immediate effects.

4 SOP on SOPs

1. Member Secretary shall be responsible for drafting the Institutional Ethics Committee SOPs.
2. It will be reviewed by all members and approved by chairperson, IEC.
3. The IEC SOPs shall be valid for a period of 3 years from effective date. Member secretary will review SOPs at least once in 3 years. SOPs can be amended in between 3 years if required.
4. Amendments to the SOP shall be proposed in writing or can be proposed in the IEC meeting by regular members.

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5. The proposal for amendment shall be presented to the regular members at a scheduled committee meeting.
6. Only regular members shall vote to accept or reject the proposed amendment.
7. A proposed amendment shall be approved by a vote of three-fourths of the members present in a quorum at a scheduled committee meeting, rounded to the next whole number.
8. If the changes on a final version are minor the version will be indicated as Version 1.1, version 1.2 etc. If there are major amendments, the version will be indicated as Version 2.
9. Storage and Distribution of SOPs

   Paper copies of current and superseded SOPs are maintained in SOPs master file. Soft copy (PDF format) shall be available for distribution among members and Investigators of projects.

   Administrative staff of IEC shall be responsible for distribution of SOPs to members, and or concerned Investigators of Projects.
10. The electronic copy of the SOPs (PDF format) can be obtained by request by mail on iercmgmdch@gmail.com.

5 Membership of IEC

The committee will consist of members who collectively have the experience and expertise to review and evaluate the scientific, medical and ethical aspects of a proposed research project. A list of committee members, their qualifications and their affiliations (hospitals, colleges etc.) described in this document will be maintained in the committee's records.

5.1 Composition of the Committee

1. The regular members of the committee will be at least 7 and a maximum of 15 individuals as follows:
   i. Medical scientists and clinicians with expertise in diverse health care specialties.
   ii. A basic medical scientist/pharmacologist
   iii. A legal expert.
   iv. A social worker/ representative of a non-governmental organization/theologian.
   v. A lay person from the community.
2. The committee will have representation from both men and women
3. Members from other areas, such as a journalist or a member from a consumer protection activity may be included in the committee.

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5.2 Chairperson

1. The Chairperson will be selected and appointed by Dean, MGM Dental College &Hospital, Kamothe, Navi Mumbai
2. Dean, MGM Dental College & Hospital, Kamothe, Navi Mumbai will select andappoint members of the committee.
3. The Chairperson will be responsible for conducting all committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.
4. The Chairperson will preside over the administrative matters pertinent to thecommittee's functions.
5. In case of anticipated absence, the Chairperson will nominate an external committee member, as Acting Chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

5.3 Members

1. The members will be selected and appointed by the Dean, provided they arewilling to work as an Ethics Committee member
2. A member shall be willing to publicize his/her full name, profession andaffiliation.
3. A member will sign a confidentiality agreement (Annexure – 10) and conflict ofinterest (Annexure – 11).
4. A member will have been trained in ethical issues or shall be willing to undergotraining in ethical issues.

5.4 Member Secretary

1. The Dean will elect a Member Secretary from among themselves.
2. In consultation with the Chairperson, the Member Secretary will be responsiblefor the following functions:
   i. Receiving all research proposals.
   ii. Numbering the proposals.
   iii. Forwarding all proposals to committee members for review.
   iv. Establishing time limits for receipt of reviewers' comments.
   v. Preparation of agenda for all committee meetings.
   vi. Inviting experts from relevant therapeutic areas to the scheduled meetings.
   vii. Notification of review outcome to investigators of research proposals.

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viii. Preparation and circulation of minutes

ix. Retention and safekeeping of all records and documentation.

x. Performance of other duties assigned by the Chairperson.

xi. Preparation and amendments of SOPs

xii. Communication to Investigators regulatory bodies or any other concernauthority on behalf of the IEC.

5.5 Tenure of Membership

i. A member will be a regular member for a period of up to 3 years.

ii. Extension of membership will be determined willingness of member to continue and appointment by Dean

iii. There is no limit to the number of times that the membership can be extended.

iv. New members will be appointed to replace members according to the process described in section 5.8 of this document.

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5.6 Resignation of Members

Members may resign before completing their terms by writing their intention to the chairperson and director of hospital

5.7 Termination of Membership

The membership will stand to be terminated under the following circumstances:

i. If a member resigns from the committee

ii. If a member remains absent for 3 consecutive meetings without informingeither telephonically/email or giving a valid reason.

iii. If a member is incapable of performing his/her duty as an ethics committeemember

iv. In case of conflicts of interested identified to limit independent functioning ofethics committee

v. In case of demise of a member.

5.8 Appointment of New Members

New members will be selected and appointed under the following circumstances:

1. When a regular member completes his tenure and does not wish tocontinue his/her membership.
2. If a regular member resigns.
3. In case of the termination of membership of a regular member
4. A new member will be preferably but not necessarily nominated from thesame category as that of the member being replaced.

5.9 Administrative Staff

1. Administrative staff for the IEC will be appointed by Dean.
2. Administrative staff may be present during course of meeting however theywill not participate in voting or in decision making process.
3. Role of administrative Staff

i. Collect documents received for IEC submission or notification andsubmit to member secretary for acknowledgement.

ii. Review documents received for each proposal for completion as per checklist.

iii. Preparation, maintenance and distribution of study files

iv. Organizing Ethics committee meeting regularly

v. Communicating Ethics committee meeting agenda to applicants andmembers

vi. Maintaining Ethics committee documentations and to archive the documents.

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vii. Communicating with Ethics committee members and applicants

viii. Communicate decision of IEC to Principal Investigator of researchproposal

ix. Organizing the distribution of SOPs and guidelines

x. Maintaining record for inward outward commutations of ethics committee.

xi. Providing the necessary administrative support for Ethics committee related activities to the Member Secretary (e.g. communicating a decision to the applicant)

xii. To receive fees and maintain record of Ethics committee fees and allfinancial transactions.

xiii. Maintaining Ethics committee documentations and to archive thedocuments

xiv. Any other work as told by Member Secretary

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6.0 Office Attendant

Office attendant will be appointed by Dean.

6.1 Role of Office Attendant

i. Arrange ethics committee meeting including maintenance of meeting room, circulating documents during meeting, water etc.

ii. Technical assistance for meetings including computer, projector, telecom etc.

iii. Maintenance of documents, filing of documents, storage cupboard etc.

7. Declaration of conflict of Interest and Confidentiality Agreement

a. Every member at beginning of the tenure must declare conflict of interest and sign conflict of interest (Annexure – 11) and confidentiality agreement form (Annexure – 10) and submit it to chairperson for acknowledgement.

b. Every observer attendee attending the IEC meeting must sign confidentiality agreement form (Annexure – 10) before initiation of meeting and submit it to chairperson for acknowledgement.

c. At start of every meeting, Chairperson will ask every member attending the Ethics Committee meeting to declare conflicts of interest for study projects to be discussed in respective meeting. Every member must read and sign conflict of interest form (Annexure – 11) and submit it to chairperson before initiation of meeting. After acknowledging, Chairperson will ask concerned member to leave meeting venue and he/she will not participate in voting or decision making process. The same will be recorded in minutes of meeting.

d. Every member of the IEC should declare any new conflict of Interest raised during his/her tenure to the chairperson.

e. Every Independent Consultant/Independent Monitor/Auditors should signs confidentiality agreement (Annexure – 10) and submit it to chairperson for acknowledgement.

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8. Responsibilities of the Committee

a. The committee's primary responsibility will be the protection of safety, rights,well-being and confidentiality of the research subjects.

b. The committee will review all research proposal in both scientific andethical perspective

c. The committee will review all research proposals submitted to it withinspecified time limits.

d. The committee will keep all information submitted to them confidentialespecially the proprietary information.

e. The committee will maintain concise but clear documentations of its viewson the research proposal.

f. The committee will review the progress of each research project atappropriate and specified intervals

g. The committee will review the qualifications of all investigators participatingin the proposed research study.

9. Functions and Operations of IEC

9.1 Submission of the Research Proposals

1. All research projects involving human participation must be approved by the IEC.
2. All prospective and retrospective studies (on drugs, investigational techniques as well as devices or any other procedure), involving human volunteers or patients to be conducted at MGM Dental College and Hospital, School of Biomedical Sciences, School of Physiotherapy (MUHS), College of Physiotherapy, College of Prosthetics and Orthotics, New Bombay College of Nursing.
3. Each project along with a duly completed application/submission form shall be submitted through electronic copy (PDF format) and at least 3 paper sets of the same. The application form will be available at the office of the IEC. The information to be given on the application form shall be filled in legible handwriting. It shall have the designation and signatures of Principal Investigator. All details in the form such as type of patients phase of drug trial, duration of study, sponsoring agency, budget of the trial, availability of Drugs Controller General of India [DCGI] permission and other relevant approvals etc. shall be completed while submitting the proposal.

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4. Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) shall submit along with the Protocol submission application form, a copy of the permission letter issued by the DCG(I) to the pharmaceutical company/investigator. If the DCGI permission is awaited, a letter of provisional approval from EC will be issued and final EC approval will be given after a copy of DCGI permission is submitted to the EC. A study cannot begin until the final letter of permission is issued by the EC.
5. In case a clinical study is planned on an "alternative system of medicine" a co-investigator from that system will be required on that study. For Ayurveda or herbal drugs, which are not marketed, a copy of the marketing/manufacturing license issued by FDA to the company shall be submitted.
6. All required fees shall be collected at the time of submission of the project. The amount to be collected, as processing fee will be reviewed at the end of 1 year.
7. The project proposal shall be submitted in soft copy (PDF format) via email and three hard copies. Documents should be submitted to at least 21 days prior to scheduled ethics committee meeting for initial review and amended documents. Each set shall contain the documents on A4 size paper arranged in a file in the order mentioned below:
   i. EC application form duly filled
   ii. Summary of protocol or Protocol Synopsis
   iii. Protocol and any amendments to it with version and date
   iv. The informed consent document (ICD), including any amendments / addendum and its translation(s) into regional language(s)
   v. A copy of Informed Consent Document for Audio visual Consent, if applicable
   vi. Case Record Form (CRF) / Questionnaire.
   vii. Principal investigator's current Curriculum vitae.
   viii. Subject recruitment procedures (e.g. advertisements/letters to doctors/posters)
   ix. Investigator Brochure (This should give details of the study drug, toxicology studies, phase I, II, III data wherever available, safety information etc)
   x. Insurance policy (if applicable)
   xi. DCG(I) clearance [for Phase I, II, III studies on new drugs and other studies as applicable as per Schedule 'Y' of the Drugs and Cosmetics Act]
   xii. Investigator's agreement with sponsor
   xiii. Investigator's undertaking to DCG(I) [for Phase I, II, III studies]
   xiv. Health Ministry Screening Committee (HMSC) clearance wherever applicable
   xv. Food and Drug Administration (FDA) marketing/manufacturing license for herbal drugs

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xvi. Any other applicable documents

The guidelines for submission of a research proposal are as described in Annexure 04 and the checklist for documents to be submitted is as described in Annexure 02.

9.2 IEC fees

Projects	Type of submission	IEC Fees
Investigator initiated/ Academic Projects	Any submission	Rs. 1000/-
Government sponsored projects	Initial submission	Rs.20,000/- plus taxes
	Study protocol document amendments (if full meeting required)	Rs.10,000/- plus taxes
Industries sponsored projects	Regular submission	Rs.50,000/- plus taxes
	Expedited submission	Rs.80,000/- plus taxes
	Amendment to Protocol or study documents	Rs.10,000/- plus taxes

Mode of payment : Cheque/DD/NEFT

Bank details : Savings A/C # 0183104000108263

IDBI Bank,
CBD – Belapur, Sec – 11,
Navi Mumbai
RTGS/ NEFT IFCS code –IBKL0000183

9.3 IEC Procedures

1. All communications with the committee shall be in writing.
2. The project proposals in the format mentioned in § 9.1 above will be accepted in office of the IEC as a soft copy (PDF format) and at least 3 set of paper copies.
3. The submitted project/s will be circulated 14 days prior to the IEC meeting for initial review to all committee members via email or paper copy and the proposal shall be reviewed for elements described in § 9.4 below.
4. A meeting, as described in § 9.6, of all members will be held preferably quarterly on 2nd Saturday of March, June, September and December where each proposal will be discussed and decisions arrived at. Any extra meeting required on urgent basis, respective proposal will be considered as expedite submission and has to pay IEC fees mentioned in § 9.2.

9.4 Elements of Review

The submitted proposal with all necessary documents as needed shall be reviewed for ethical aspects and to safeguard the interests of the study participants/patients/ subjects in accordance with the principles of Good Clinical

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Practices (GCP).

The committee members shall review the proposal with reference to the following:

i. Justification/Rationale for human participants in the study
ii. Selection criteria for subjects
iii. Subject recruitment procedures and methods
iv. Patient retention activities
v. Potential benefits to the study subjects/participants
vi. Predictable risks to the study subjects/participants
vii. Criteria for discontinuation/withdrawal of subjects/participants
viii. Justification for use of placebo, if any
ix. Monitoring of serious adverse events
x. Compensation to subjects for participating in the study
xi. Compensation for study related injury
xii. Post-study benefits
xiii. Protection of privacy and confidentiality
xiv. Informed consent documentation and procedure
xv. Competence and necessary qualification of investigators, supporting staff and infrastructure facility
xvi. Study agreements including financial agreements (for funded studies/projects)
xvii. Approval of regulatory authorities wherever applicable

Members shall refer Annexure 26: Risk Benefit assessment tool to categorized research study project into any one of following category according to the revised ICMR document.

- Class A: Less than minimal risk
- Class B: Minimal risk
- Class C: Minor increase over minimal risk
- Class D: More than minimal risk

9.5 Review of Informed Consent Documents (ICD)

The IEC will examine the ICD for the presence of the following points (If applicable) while reviewing the patient information sheet/Informed Consent Form.

(Sample format of ICD, Annexure – 5)

- Voluntary, non-coercive recruitment, participation/ withdrawal
- Procedures for obtaining informed consent
- Consent for Audio-Video Recording
- Contents of the patient information sheet - title, objective, study design and procedures

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- Contents and language of the informed consent document
- Translation of the informed consent document in the local languages
- Language used – plain and easy to understand by general public
- Contact persons with address and phone numbers for questions about research participants rights and study or injury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social
- Alternative treatments
- Benefits – to participants, community, institution and society
- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/ psychosocial support
- Treatment for study related injuries
- Compensation for study-related injuries: Reasonable
- Travel Reimbursement
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness

All members of the IEC present during meeting will be responsible for review of projects. However, members are expected review specific documents in detail which are in their own expertise (e.g. legal expert are expected to review Clinical trial agreement and insurance policy).

Every reviewing need to fill study assessment form (Annexure – 9) present during meeting.

Study assessment form can be share either as Signed Hard copy or filled soft copy through email. Admin officer will keep all filled Study assessment form in respective study project file.

9.6 Meetings

The committee will hold a regular meeting once every month.

When there are no research proposals to review, the meeting may be held less frequently, but not less than once every 12 weeks.

All members will receive notification of meeting schedules at least 1 week in advance.

The committee members will review all the proposals before the meeting.

The proposal may be sent to a subject expert for his/her assessment and opinion of the research proposal. The subject expert may be invited for the meeting.

The investigator and/ or co-investigator may be invited to the meeting to provide clarifications on the study protocol. Member Secretary will invite concern investigator and/ or co-investigator for meeting if required.

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9.6.1 Quorum for the meeting

Meetings will be held as scheduled provided there is a quorum. In accordance with Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2018 (20th January 2005), the quorum of the IEC will be at least five members with the following representations:

- Basic Medical Scientist/Pharmacologist
- Clinician,
- Legal expert,
- Social scientist/worker/representative of NGO
- Lay person.

9.6.2 Hierarchy

- There will be one Chairperson and one Member Secretary.
- The Chairperson will be the head of the committee.
- The Member Secretary will be the guardian of all documents and funds in the committee's possession.
- All other members will be regular committee members with equal ranking.
- Members will elect 'Acting Chairperson' among available external members in case of chairperson absence or his/her conflict of interest. Elected acting chairperson will chair respective ethics committee meeting including all discussion as mentioned in agenda. In case chairperson has declared conflict of interest for particular project, the acting chairperson will convene the meeting for that particular project

9.6.3 Minutes of meeting

The Member Secretary will be responsible for coordination and recording of the proceedings of the meeting.

The proceedings of the meetings shall be recorded in English and in the form of minutes.

The minutes shall be approved by the chairperson and circulated within 14 days of the EC meeting.

9.6.4 Decision making

- Decision for each proposal shall be voting by simple majority.
- A majority vote for approval, disapproval, and request for modifications, suspension or termination of a research proposal or an ongoing study is defined as one-half of the members who have reviewed the project.
- All members present at the IEC will vote on the research proposal.
- Absent members will not vote.
- Member(s) of the committee who is/are listed as investigator(s) on a

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research proposal or having conflict of interest will opt out from all deliberations on the proposal and will not vote on the proposal.

- An investigator or study team member invited for the meeting will not vote or participate in the decision making procedures of the committee.
- Specific patient groups or Subject experts shall be invited for the meeting will not vote or participate in the decision making proceduresof the committee.

9.6.5 Review Outcome

The committee will document its view on the following:

- Final Approval
- Provisional approval subject to regulatory approval
- Request for modification giving reasons
- Request for additional information
- Clear disapproval giving reasons.
- Termination/suspension of an ongoing study giving reasons

9.6.6 Notification of Review Outcome

The outcome of committee's review shall be communicated to the investigator within 14 working days of the meeting and the reply for the same must be submitted by the principal investigator within 5 days of receipt of the letter. If there is no reply or any other communication within 5 days, the project will be considered closed and shall be archived

9.6.7 Approval

All projects will be given approval for the entire duration of the study.

9.6.8 Review of the Modified Proposal

1. When modifications to the proposal, as recommended by the committee, are minor, the revised documents may not be re-circulated. The revised proposal shall be reviewed by either the Chairperson of the committee, the Member Secretary of the committee, or by one or more experienced reviewers designated by the chairperson from among the members of the committee. An approval may then be issued if the revised documents are satisfactory. The committee will keep all members of the committee informed of these approvals.
2. When modifications to the proposal, as recommended by the committee, are major, the revised proposal will be re-circulated and discussed again at next meeting.

9.7 Procedures for Appeal

For research proposals rejected/disapproved by the committee, the applicant may appeal for a repeat review in within 90 days of the receipt of the committee's decision. While doing so, the applicant shall give justification relevant to the issues/objections raised by the committee.

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9.8 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 ofreview

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.	Institutional Research Review Committee or Scientific Advisory Committee approval is final (Exempted)
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 orplacebo group during randomized trials; use of minimally 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.	Full board review
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 invasiveprocedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.	Full board review

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9.9 Expedited Review Procedures

1. The committee may use expedited review procedure in case of minorchanges/ amendments in the previously approved research proposal that appear to involve no more than minimal risk to the study subjects.
2. As per ICMR guidelines 2018, biomedical research with less than minimal risk or minimal risk shall be reviewed by the sub-committee members of the Institutional ethics committee only without the board meeting. Subsequently the matter will be conveyed and discussed with the board members during the meeting.
3. Under an expedited review procedure, the review may be carried out by the Member Secretary of the committee, or by one or more experienced reviewers designed by the chairperson from among the members of the committee. The reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research.
4. An on-going research activity may be disapproved only after review in accordance with non-expedited review.
5. The committee will keep all members of the committee informed of these approvals under the expedited review procedure.
6. Only the Member Secretary shall make the decision to allow an expedited review.

Sr.No	Name of the Member	Designation
01	Dr Shakeeb Dhorajiwala	Pharmacologist
02	Dr. Shilpa Patel	Member Secretary
03	Dr Nikhil Bhanushali	Member
04	Dr. Sumanthini MV	Member
05	Dr. Vineet Kini	Clinician
06	Dr Jyoti Nadgere	Member
07	Miss Priyanka Sharma	Lay person

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9.10 Review of Subject Recruitment Procedures

All advertisements, letters to doctors, posters, notices to be used for recruitment of subjects shall be reviewed and approved by the committee in full Boardmeeting prior to their implementation in the study.

9.11 Review of On-going Studies

1. The committee will conduct a continuing review of each on-going study every 6 months.
2. The committee can monitor study as is felt appropriate to the degree or risk to the human subjects
3. The committee may also ask for a status report from the investigator at earlier intervals as is felt appropriate to the degree or risk to the human subjects.
4. On the basis of the review, the committee shall recommend continuation with/without modifications, temporary suspension or termination of on-going clinical trials for reasons such as patient safety.

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9.12 Review of Amended protocol/ Protocol related documents for Approved Projects

1. No changes in the protocol, case record form, ICD or any other protocol related documents shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the subject
2. The amendment package (hard and soft copy) forwarded by the Principal Investigator will be received by the Admin staff of the IEC.
3. The documents should highlight changes from previous version and should submit Annexure 06 which mentions;
   - Mention the amendment/List of Amendments
   - Provide the reason for the amendment
   - State any untoward effects with original protocol
   - State expected untoward effects, if any because of the amendment
4. Member Secretary will acknowledge amended documents along with all requirements after confirmation from Admin staff. The Member Secretary/ Chairperson decides whether the proposed protocol amendment(s) need to undergo a full board review, review by designated IEC members or a review bythe Member Secretary/Chairperson. The Member Secretary / Chairperson can take the decision if the amendment(s) is / are of administrative nature.
5. The Protocol or other study related documents amendment which increases risk to study participants, as judged by the Chairperson and/ or the Member Secretary, such as a change in study design, which may include but is not limited to:
   - Additional treatments or the deletion of treatments
   - Changes in inclusion/exclusion criteria.
   - Change in method of dosage formulation, such as, oral changed to intravenous
   - A significant change in the number of research participants (if the decrease/increase in the number of research participants alters the fundamental characteristics of the study, it is significant)
   - Change in study schedule or any study procedures
   - Significant Changes in informed consent documents which may affect subject decision to participate
   - Significant change in case record form/ Additional data recording
6. The Member Secretary will indicate decision on the Protocol/Protocol related Documents Amendment (Annexure – 6). Documents will be considered for next full board review after confirmation from Member Secretary/Chairperson
7. If the IEC approves the protocol/ protocol related documents amendment, the member Secretary will send a signed and dated Amendment Approval Letter to the Principal Investigator (PI) within 14 days of the meeting. The decision regarding disapproval (stating reasons) or request formodifications (stating specific changes needed) shall be communicated in writing to the investigator within 14 days of the meeting.

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8. In a case of minor/administrative changes in protocol/ Protocol related documents amendment approved by Member Secretary/Chairperson, Member Secretary will send a signed and dated Amendment Approval Letter to the Principal Investigator (PI) within 7days of submission of documents. The decision regarding disapproval (stating reasons) or request for modifications (stating specific changes needed) shall be communicated in writing to the investigator within 7 days of submission of documents if applicable. Member secretary will inform this decision to all members in next full Board meeting.

9.13 Notification received from Principal Investigator regarding on-going approved projects

1. Notification along with supporting documents if any (hard and soft copy) forwarded by the Principal Investigator will be received by the IEC.
2. Notification received from Principal Investigator regarding ongoing approved projects may include but not limited to
   - Change in study team delegation
   - Administrative Change in Clinical Trial Agreement (CTA) / Memorandum of Understanding (MOU)
   - Updated Insurance policy
   - CTRI registration number
   - Administrative changes related to Principal Investigator Institute or Sponsor
3. Member Secretary will acknowledge and review notification received from PI along with any supporting documents. Member Secretary may send a letter to PI requesting more clarification or any documents if required within 7 working days of notification.
4. Any other internal IEC member preferably clinician may acknowledge notification in case of non-availability of Member Secretary or conflicts of member secretary in any study projects.
5. The IEC will send acknowledgement letter within 7 working days of receipt of notification
6. Member Secretary will inform all notification received from PI to all members in next full Board meeting

9.14 Protocol Deviation/Non-Compliance/Violation

1. Protocol deviation/ non-compliance/ violation may be reported by Investigator/ study site staff to the Chairman/Secretary of the IEC. Members may detect protocol deviation/non-compliance/violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator or site.
2. Member secretary will acknowledge reported Protocol deviation/non-compliance/ violation and present it in next full Board meeting. Member secretary shall inform Protocol deviation/ non-compliance/ violation to all members considering seriousness and may schedule urgent full board meeting within 7 working days.

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3. IEC members will review the information available and take a decision depending on the seriousness of the violation in full board meeting. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus In case, the decision is not reached by consensus, voting will be taken. The actions taken by the IEC could include one or more of the following:
   - Inform the Principal Investigator (PI) that the IEC has noted the violation/ non- compliance/ deviation and direct the PI to ensure that deviations/non-compliances/violations do not occur in future and follow IEC recommendations.
   - Enlist measures that the PI would undertake to ensure that deviations/non - compliances/violations do not occur in future Reprimand the PI.
   - Call for additional information.
   - Suspend the study till additional information is made available and is scrutinized.
   - Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
   - Inform the Dean of the Institute
   - Revoke approval of the current study and Inform DCGI/ Other relevant regulatory authorities (if applicable).
   - Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.
   - Any other action considered appropriate by the IEC for safeguarding the interests of the research participants participating in the current trial or in future trials.
4. The IEC will send communication with action to concerned PI/Institutedirector (If applicable) /Regulatory body (If applicable) signed by the Member Secretary within 14 days of the meeting.

9.15 Reports required from investigators

The research investigator shall submit the following reports to the committee:

1. Continuing Review Application form should be submitted 6 months following the date of the final IEC approval as per Annexure – 7.
2. Subsequent reports shall be submitted at every 6 monthly following the first report.
3. The investigator should ask written permission to recruit more patients than no of patients approved by the IEC along with the Continuing Review Application Form (Annexure - 7).
4. Study completion report: A brief report of the study shall be submitted to the committee at the end of the study as per Annexure – 8.
5. Member Secretary shall present all Continue Study reports/ Study completion reports to all members in next full board meeting.
6. Member Secretary shall communicate in written to Principal Investigator after reviewing continues review reports regarding ongoing review within 14days from meeting.

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7. Member Secretary shall send confirmation letter to Principal Investigator for closing study after submission of final study completion reports with 14 days from meeting
8. If the Principal Investigator fails to submit the continuing review report within one month of the due date (i.e. 6 months from the date of approval or last review report, unless specified otherwise), Member Secretary will send a reminder as per the format mentioned within 14 working days of this due date.If there is no response within 15 days after the date of reminder, Member Secretary will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to:

   A letter of reprimanding the Investigator.

   - Not reviewing future projects from the PI for a specified period of time.
   - A letter asking the Investigator to put recruitment of new participants on hold.

In addition, the investigator shall also promptly report the following to the committee:

- Deviations from/changes to the protocol to eliminate immediate hazards to trial subjects.
- Changes that may increase the risk to subjects and /or affect the conduct of the trial.
- New information that may affect adversely the safety of the subjects or the conduct of the trial.

9.16 Study Monitoring

1. Selection of study: The IEC will identify the study projects for routine monitoring at the time of approval of the project depending on risk profile.
2. The IEC may initiate 'for cause' monitoring due to following reason but not limited to
   - High number of protocol violations or non-compliance
   - Large number of studies carried out at the study site or by the investigator
   - Remarkable number of SAE reports
   - High recruitment rate,
   - Non-compliance
   - Suspicious conduct
   - Complaints received from participants,
3. The Chairperson will identify and select one or more members or independent monitor to conduct monitoring of a site.
4. The Member Secretary will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator, study team members and study participants (if necessary) to be available for the monitoring visit.

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5. Designated Monitors will conduct monitoring of all study documents including but not limited to ICD, AV Consent recording, Source documents, Case record forms, Subject files, study Master file IP, storage facility, Clinical Examination, lab reports etc.
6. Monitors shall conduct interview of PI, other study team members and few study participants during monitoring visit. Monitors will complete monitoring report as per Annexure – 19.
7. The member-secretary will present the monitoring report at the next full board meeting and the concerned member will provide additional details/ clarifications to members, as required.
8. The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
   - Continuation of the project with or without changes,
   - Restrictions on enrolment,
   - Recommendations for additional training,
   - Recruiting additional members in the study team,
   - Revising qualifications/experience criteria for members of the study team,
   - termination of the study,
   - Suspension of the study
9. The Secretariat will convey the decision to the principal investigator in writing within 14 days of the meeting including any recommendation and willask PI to submit action item report including Corrective Action and Preventive Action (CAPA), if applicable for the IEC review.

10. Training of Members- New Members and ongoing training

a. All new members will be trained on NDCT (2019), ICMR, Good Clinical Practices (GCP) guidelines, Current ethical and regulatory guidelines and the SOP of IEC.

b. The Chairperson will identify the training requirements of the committeemembers.

c. The Chairperson and the Member Secretary will organize workshops or training programs for the committee members. It is recommended to conduct GCP refresher training and training on current regulatoryguidelines once in 2 years.

d. The type of programs, areas for training and mentors (Internal/External) for these workshop or training programs will be decided by Member secretary. Members shall also be requested by the chairperson to attend workshops for training. Pre-tests and post-test assessments shall be conducted for members during in-house training programs.

e. The Chairperson and the Member Secretary will inform all members aboutany updates on ethical and regulatory guidelines regularly during meetings.

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11. Records Retention

a. All records including study documents shall be kept at the office of the IEC located in MGM Dental College and Hospital, Kamothe, Navi Mumbai

b. All documents will be accessed only by the IEC members and IEC staff.

c. IEC will maintain 1 copy of paper copy and electronic copy of all documents received by IEC and all communications for every study. Member secretariat will maintain individual study project file for each projects received by the IEC for review.

d. The committee will archive the following records for a period of at least five (5) years:

- Standard operating procedures (SOPs) of the committee.
- Guidelines for submission established by the committee.
- Membership list
- Curriculum Vitae of the members
- Agenda of meetings
- Minutes of meetings

The committee will also archive the following records for a period of at least 5 years following the completion of a study

- All correspondence by the committee with the research investigator regarding application, decision and follow–up.
- One copy of all materials submitted by a research investigator
- A copy of the decision and any advice or requirements sent to an applicant
- All written documentation received during the study
- The notification of the completion, premature suspension or premature termination of a study
- A summary of the final report of the study

The records shall be made available to relevant statutory authorities upon request.

12. Reports to the Dean

The committee will make a yearly activity report for submission to the Dean, MGM Dental College and Hospital, Kamothe, Navi Mumbai by Institutional Ethics Committee, which will include the following elements:

a. A quantitative evaluation of the activities of the committee in a year

b. The list of the proposals reviewed in a year

c. Status of each study proposal

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13. List of committee members with their affiliations and qualifications

The present composition* of the Institutional Ethics Committee (2021-2024) is as below:

Sr. No.	Name of IEC Member	Designation	Affiliation
1.	Dr. Deepak Langade	Chairman	Prof. & Head, Pharmacology,D.Y.Patil Medical School of Medicine, Navi Mumbai
2.	Dr. Shilpa Patel	Member Secretary	Prof. & Head, Dept of Oral Pathology, MGM Dental College & Hospital, Kamothe, Navi Mumbai
3.	Dr Chandramani Pathak	Member	Research Director,MGM Institute of Health Sciences, Kamothe, Navi Mumbai
4.	Dr Ashwin Jawdekar	Member	Prof & Head, Dept of Pediatric and Preventive Dentistry; Vice-Principal (Academic), Bharati Vidyapeeth Dental College and Hospital, Navi Mumbai
5.	Dr Nilesh Joshi	Member	Professor, Dept of Periodontology, Bharati Vidyapeeth University Dental College & Hospital, Navi-Mumbai.
6.	Dr Nikhil Bhanushali	Member	Associate Professor,Dept of Public Health Dentistry, Terna Dental College, Navi –Mumbai.
7.	Dr. Vineet Kini	Clinician	Prof & Head,Dept of Periodontology, MGM Dental College & Hospital Kamothe Navi Mumbai
8.	Dr. Ravindranath V. K.	Member	Prof & Head,Dept of Orthodontics and Dentofacial Orthopedics, MGM Dental College & Hospital Kamothe Navi Mumbai
9.	Dr. Sumanthini M. V.	Member	Prof & Head, Dept of Conservative Dentistry & Endodontics, MGM Dental College & Hospital Kamothe Navi Mumbai
10.	Dr Jyoti Nadgere	Member	Prof & Head, Dept of Prosthetic Dentistry, MGM Dental College & Hospital Kamothe Navi Mumbai
11.	Dr. Usha Asnani	Clinician	Professor, Dept of Oral & Maxillofacial Surgery, MGM Dental College & Hospital Kamothe Navi Mumbai
12.	Dr. Shakeeb Dhorajiwala	Basic Medical Scientist	Senior Resident, GS Medical College & KEM Hospital
13.	Adv. Dr. Sheela Hosamani	Legal Expert	IC Principal, MGM Law College, Nerul, Navi Mumbai
14.	Priyanka Sharma	Lay Person	Mahatma Education Society College of Arts, Commerce and Science, New Panvel
15.	Mrs. Rupali Gujar	Social Scientist	Asst. Registrar, Students affairs MGM Institute of Health Sciences, Navi Mumbai

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14. SOP for Review of Serious Adverse Events (SAE) Reports

14.1 Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) and unexpected adverse events (UAE) reported to MGM Dental College & Hospital,Kamothe, Navi Mumbai Institutional Ethics Committee occurred at MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee

14.2 Scope

This SOP applies to the review of SAE reports submitted to the IEC.

14.3 Responsibility

It is the responsibility of the IEC affiliated to MGM Dental College and Hospital, Kamothe, Navi Mumbai to review SAEs reported to the MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee. These could be SAEs occurring at MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee or other sites for the given project/related project.

14.4 Serious Adverse Event (SAE) Subcommittee

14.4.1 Purpose

1. The SAE Subcommittee will review serious adverse events (SAE) and unexpected adverse events (UAE) at MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee and allies (Sister Concerns) in all types of research studies involving human participants approved by MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee. The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants. SAE can be discussed directly in full board MGMDental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee meeting if meeting is already planned with review timeframe as per regulatory requirements
2. The SAE Subcommittee will work according to its established Standard Operating Procedures based on the NDCT(2019), Operational Guidelines for Ethics Committees that review Biomedical Research (WHO, 2000), International Conference on Harmonization, Good Clinical Practices (ICH-GCP) Guidelines (1996), Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2017 (Drugs and Cosmetic Act 1940; amendment 20th January 2005, 30th January 2013 and 8th February 2013) and Ethical Guidelines forBiomedical 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

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- To ensure appropriate compensation as per Schedule Y, 30th January 2013 amendment is provided to the research participants.

The SAE Subcommittee is established and functions in accordance with the relevant national law and regulations in force from time to time

14.4.2 Composition of the SAE Subcommittee

1. The SAE Subcommittee will be appointed by the Chairperson of MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee for tenure of 3 years.
2. The SAE Subcommittee will be multidisciplinary and multi-sectoral in composition.
3. The SAE Subcommittee will be composed of at least 4 members (including legal expert).
4. The members preferably should be from medical and scientific backgrounds.
5. All members will be from MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee.
6. There will be one SAE Subcommittee-Head, one executive Secretary of SAE Subcommittee
7. Head-SAE subcommittee and executive Secretary will be appointed by Chairperson of MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee.

14.4.3 Roles and Responsibilities of the SAE Subcommittee members

1. To attend the SAE Subcommittee Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
2. To review, discuss and consider adverse event reports submitted for evaluation.
3. To review Serious Adverse Event and unexpected adverse reports and recommend appropriate action(s) as follows:
   - SAE reports will be reviewed completely in the SAE subcommittee meeting with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participant as per Ethical Guidelines for Biomedical Research on Human Subjects laid down by the Indian Council of Medical Research (ICMR) 2018
   - The SAE subcommittee while reviewing may solicit opinion of one or more independent consultant (s) in writing, if the Sub-committee decides to consult experts. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality cause and abide bythe rules and regulations of IEC or the necessary confidentiality documents are signed. The independent consultant would be requested to provide an opinion in writing within 3-5 working days, depending upon the gravity and seriousness.

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4. The following decisions/actions including the following but not limited to, are listed below:
   - Note the information about the SAE in records for future reference
   - To opine on compensation entitled to research participants as per NDCT (2019), experiencing Serious Adverse Event and unexpected adverse events and adverse events and recommend appropriate action(s).
   - Request further follow up information and/ or additional details on causality of the event, provision of medical treatment till SAE is resolved and financial compensation
   - Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier).In case of pregnancy as SAE to send follow up reports of the child in utero and post-delivery of the baby till 1 year.
   - If appropriate to the discussions, the recommendation regarding a specific action or combination of actions to be taken is arrived at by the SAE subcommittee meeting. The recommendations will be communicated to all members within 5 working days.
5. To maintain confidentiality of the documents and deliberations of the SAE Subcommittee meetings and to declare any conflict of interest.

14.4.4 List of Members of SAE sub-committee

Sr.	Name of the Member	Designation	Gender
01	Dr. Deepak Langade	Chairman & Pharmacologist	Male
02	Dr Chandramani Pathak	Member	Male
03	Dr. Shakeeb Dhorajiwala	Executive Secretary Basic Medical Scientist)	Male
04	Dr. Usha Asnani	Clinician	Female
05	Dr. Vineet Kini	Clinician	Male
06	Adv. Dr. Sheela Hosamani	Lawyer	Female

Compensation:
New Drug & Clinical Trial Rules 2019 covers clauses related to compensation in case of injury or death in clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug under chapter VI, Rule 39 to Rule 43.

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14. 5 Process flow in case of an SAE

No.	Activity	Responsibility
1	Receipt of SAE report	Administrative staff, IEC
2	Circulation of SAE report to the all members within 2 days of receipt of Initial SAE reports	Member Secretary, IEC Administrative staff
3	Decide to call SAE subcommittee meeting or discuss in coming full Board meeting	Member Secretary, IEC
4	Scheduled SAE subcommittee meeting within 7 days of receipt of SAE analysis reports	Executive Secretary, SAE Sub-committee
5	Agenda and Minutes of the Subcommittee	Executive Secretary, SAE Sub-committee
6	Review and discussion of SAE report at the Subcommittee meeting	Members, SAE Subcommittee
7	Communication of the SAE Subcommittee decision about SAE review to Chairperson and other MGM Dental College and Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee members within 5 days of meeting	Executive Secretary, SAE Sub-committee
8	Schedule IEC full board emergency meeting if required within 5 days	Member Secretary, IEC Chairperson, IEC
9	Communication of the decision about SAE review to the principal investigator	Member Secretary, IEC
10	Communication of the IEC decision about SAE review to the Licensing authority /DCGI if applicable within 30 days	Member secretary, IEC
11	Discussion/ Information at the full board IEC meeting	Member secretary, IEC

14.6 Receipt of SAE on site: Detailed instructions

The IEC administrative staff will receive the following documents within the specified time frame pertaining to SAE experienced by the research participants ON SITE for research proposals approved by the MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee.

1. On site SAE Assessment Report report to be submitted by the Principal Investigator within 24 hours of their occurrence along with the SAE Assessment Report (Annexure – 12).
2. SAE Analysis Report with due analysis will be submitted by the Principal investigator and Sponsor within 14 calendar days along with the format specified in Annexure – 13.
3. The follow up reports of all on site SAE / unexpected AE reports till the event is resolved.
   - The IEC Secretariat will verify that the report is complete in all respects and is signed and dated by the Principal Investigator (PI) or Sponsor as the case may be and that it has been received at the IEC office within the specified timelines above. If the report has been received beyond the specified time, this will be considered as a violation.
   - The IEC Member Secretary will sign and write the date on which the report is received.

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14.7 Communication to the IEC Members

1. Member secretary will communicate minutes of SAE subcommittee meeting within 5 working days of meeting
2. After confirmation of comments from the IEC members, the decision will be communicated to the Licensing authority (DCGI) and PI within 30 calendar days of the occurrence of the SAE.
3. If objection is received from more than 2 members of IEC, an emergency meeting will be scheduled within 7 days for the same.
4. The decision taken at the emergency meeting regarding the onsite SAE report will be communicated to the Licensing authority (DCGI) and PI within 30 calendar days of the occurrence of the SAE.

14.8 Communication to Principal Investigator (PI)

1. The Member Secretary will draft a formal letter to the concerned Principal Investigator and inform him/ her about the IEC decision. This letter will be signed and dated by the Member-Secretary and will be sent to the Principal Investigator within a period of 7 days from the date of the SAE subcommittee meeting or full board meeting after submission of SAE analysis report
2. The Principal Investigator will be requested to reply to the query letter on the SAE report within 7 working days. If no response is received (within 7 days of dispatch of EC query letter) from the investigator regarding the query raised on the given SAE, a reminder letter will be sent to the investigator stating that the response to the query letter must be sent within 5 working days of the dispatch of reminder letter. If no response is received to the reminder letter, this should be informed by the member secretary of the IEC in the full board meeting and decision will be taken on case to case basis.
3. The principal investigator will be requested to forward follow-up reports after due analysis of the SAE report to the IEC till SAE resolves
4. The Administrative officer will file a copy of all SAE related communication in the study file.

14.9 Communication to Drug Licensing authority (DCGI)

1. The Member Secretary will forward the letter describing the opinion on the SAE report death or other SAE, along with the opinion on financial compensation as per applicable rule as and when, to the Licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE-death.
2. PI/Sponsor is also obliged to pay the expenses of the patients' treatment till the time that it is proved that the SAE is not related.
3. The Administrative officer will file a copy of these letters in the study file.

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14.10 SAEs occurring at other sites:

Sr	Country	MFR Control No. (If applicable)	Type of Report	SAE event	Date of Onset of ADR	Date of ADR report	Outcome	Causality	
								PI	Sponsor

The investigator will need to submit the SAEs occurring at other sites (CIOMS, SUSARS and Annexures 12 and 13 as applicable) in the form of soft copies (in CD/DVD/PD) / hard copies along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details preferably in the following format:

1. The SAEs occurring at other sites will be acknowledged by member secretary and discussed in the forthcoming scheduled SAE Subcommittee or Full Board meeting whichever is earliest. The agenda and minutes of the SAE Subcommittee/Full Board meeting will include the information on SAEsat other sites.
2. The discussion will be communicated by the SAE Subcommittee Executive Secretary (if discussed in SAE subcommittee meeting) to all IEC members.

14.11 Review of SAE in IEC meeting

1. In case of the SAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on SAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.
2. If appropriate to the discussions and any issues regarding to SAE decision can be arrived at by voting (a majority vote for a decision is 2/3rd majority of the members present and voting) or by consensus.

14.12 Actions are listed below:

- Terminate the study
- Suspend the study till review is completed (safety monitoring of ongoing patients to be continued)
- Suspend the study till additional information is available
- Suspend the study for a specified duration of time
- Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents
- Suspend the study till amendments requested for by the IEC are carried out;
- Suspend enrolment of new participants;
- Suspend certain activities under the protocol

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- Direct the Investigator to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re- consent) regarding continuation in the research trial
- Direct the Investigator to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment
- Note the information about the SAE in records for future reference
- Request further follow up information and/ or additional details
- Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier)
- Any other appropriate action;

The decision shall be recorded in the minutes of the full board IEC meeting;

- If the recommendation from the IEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators' brochure), re-consenting of research participants, the decision will be conveyed to the Principal Investigator through telephone, fax or email within 24 hours. Such a communication will be documented by the Member-Secretary in the study file. A formal letter to the Principal Investigator informing about the IEC recommendations in such situations will be sent within 5 working days of the meeting of IEC having taken place.
- IEC will ensure that appropriate compensation is paid to the research participant as per applicable regulatory requirements.
- Investigator should ensure safety monitoring of recruited patients to be continued till SAE resolved.

14.13 Functions of the IEC Administrative staff

1. To prepare the agenda of the SAE discussion with help of Member Secretary of the SAE Subcommittee. The agenda for the SAE discussion will include the information on SAE at the site in the following format

Participant ID	Letter no./ and date of reporting	Type of report	Type Of SAE/ UAE	Date of onset	whether study drug withheld	Outcome	Causality in the opinion of PI

The agenda will also include information about onsite SAE reports for the SAE occurring at other trial sites.

2. To prepare the minutes (to be prepared within 5 working days of the meeting) with the help of the Member Secretary. The minutes of the SAE Subcommittee

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will include the information on SAE at the site in the following format:

Participant ID	Letter no./ and date of reporting	Type of report	Type of AE/SAE/ UAE	Date Of onset	whether study drug with held	SAE Outcome	Causality in the opinion of PI	Recommendations by the SAE Sub Committee

15. SOP for reviewing proposals involving vulnerable Populations

15.1.1 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.

15.1.2 Scope

This SOP covers the policies and procedures applied to all researchdealing with vulnerable population submitted to the MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee.

15.1.3 Responsibility

1. It is the responsibility of the IEC secretariat to maintain up-to-date tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.
2. IEC Chairperson/ Member Secretary is responsible for ensuring that the IEC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise or representative from the vulnerable population as needed for selected reviews.
3. All members are responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP.

15.1.4 Role of administrative staff

1. Administrator will maintain on file the update checklist (A-F) which conforms to applicable regulations and guidelines.
2. Document review of risk assessment in the IEC minutes for the protocols involving vulnerable population.

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3. Confirm that the complete informed consent and assent documents as relevant.
4. Chairperson/Member Secretary will select appropriate primary reviewer(s) as applicable for the vulnerable population.
5. IEC members will complete checklist during review of research with vulnerable populations and present recommendations at the convened meeting.

15.1.5 **Detailed instructions: Review of protocol with vulnerable population**

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable persons include patients with incurable diseases, people in nursing homes, unemployed or impoverished people, and patients in emergency situations, ethnic minority groups, homeless people, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox society.

The protocol should be reviewed keeping in mind the following points when it concerns research that involves groups that could be potentially vulnerable to coercion:

- Measures to protect autonomy
- Risk/benefit determinations with respect to the vulnerability
- Bearing unequal burden in research

Any member of the IEC who would be dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study. The checklist for different vulnerable population is being provided in Annexure – 14 to Annexure – 17.

Special justification is required for inviting vulnerable individuals to serve as research subjects and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

16. Administrative officer Responsibilities

a. Provide a suitable checklist according to the subjects to be recruited in study tothe investigator. Inform the investigator to download the appropriate applicationform and informed consent document/ assent form from the

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internet/intranet site.

b. Provide appropriate reference material or help reviewer locate such material related to vulnerable populations when specifically requested for, by a reviewing member

17. Appointment of Reviewers

The Chairperson will appoint two or more members of the IEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. The reviewers should be familiar and trained in the concept of vulnerability and protections for participants with diminished autonomy.

Subject experts or representative of vulnerable subjects shall be invited as required with prior intimation. Subject experts or representative of vulnerable subjects will be asked for their inputs or opinion on respective research projects. Subject experts or representative of vulnerable subjects will not participate in voting or decision making process.

18. Reviewers responsibility

a. IEC Members will review the protocol and the informed consent documentor assent form.

b. The reviewer's comments will be discussed in the IEC meeting and the finalcomments will be sent to the PI.

c. The discussion will be documented in the minutes.

d. The member secretary will confirm that the IEC recommendations have been incorporated in the revised protocol and in the final draft of informed consent document or assent form.

19. Approval of the protocol

a. The final version of the protocol will be approved by the board with theappropriate checklist as given in annexure (1-5).

b. Wherever necessary the IEC approval should state that if in future the vulnerability status of the participant's changes for e.g.; unconscious patientgaining consciousness, then the protocol and ICD should be amended and resubmitted to the IEC for reconsideration and approval Following which the participant should be re-consented and reconsidered for the same.

20. 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), Director of Institute, and Sponsor (If required).

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

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20.1 Principal Investigator

- Study Project Approval/Rejection letter/ Query Letter
- Study documents Amendments Approval/Rejection letter/ Query Letter
- Response to Serious Adverse event notification SO
- Opinion on compensation of Study injury/death
- Response to Protocol deviation/Violation/Waiver
- Response to Continue review/study completion report
- Study termination letter

20.2 DCGI

- Opinion on compensation of Study injury/death
- Study Termination letter
- Ethics Committee Registration Communications
- Submission of protocol and protocol related documents in case of academic study with change of dose/administration route/indication etc.

20.3 Dean (Head of institute)

- Annual reports of IEC including status of all studies

20.4 Study Participants:

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

20.5 IEC members:

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

21. Policy on Financial declaration of payments received and disbursed

a. All payment received as submission fee are separately maintained under'Institutional Ethics Committee'

b. Account officer will receive all payment cheque/DD and will submit toaccount department of institute.

c. All expenditure of Admin is managed through payment received as fee including Admin Manager/EC supporting staff Salary, meeting arrangement cost, Travel reimbursement to chairperson and external members, Stationary charges, Cupboard, Electricity and telephone bills infrastructure requirement including Computer, Xerox, Scanner, Ethics CommitteeMember Training arrangement

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d. The chairperson will be provided a remuneration of Rs. 5000. External Members will be provided remuneration (including travel reimbursement) upto Rs. 2000 per meeting and internal members will be provided Rs. 1500 per meeting.

e. All financial payments received and disbursed shall be reviewed at end of every financial year and presented to all Admin members

f. All financial communication is liable under Institute's internal routinefinancial Audit.

22. SOP for complaints by the research participants

a. The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for dealing with requests by research participants/ patients regarding their rights as a participant or to resolve their complaint(s) that is/ are related to their participation in research/ trial approved by IEC.

b. Subject Participants can contact Secretariat of IEC for any request complaints or query as contact details are mentioned on IEC approved Informed Consent Documents.

c. Member Secretary will ascertain if the concerned individual has been approached to participate in the study or is already participating in the study based on documents available with. If required, Member Secretary will call for relevant information and documents from the Investigator, as required.

d. Member Secretary will inform to all members within 7 days of receipt ofcomplaint

e. Member Secretary may consider matter for next full board meeting with confirmation from chairperson. All available information along with required documents will be discussed in meeting

f. Chairperson may appoint 1 or 2 members from IEC for enquiry in order toresolve the matter.

g. The Chairperson/ Member Secretary will assess the situation and mediate a dialogue between the research participant and the investigator in an attempt to resolve the matter.

h. The final decision will be informed to the research participant, concerned investigator, Head of Institute by the Member Secretary within 4 week from filing of complaint.

i. The IEC members are informed about the action taken and the outcomes inthe forthcoming meeting.

j. All relevant records and communication regarding complaints aremaintained.

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23. Procedures to safeguard and monitor Research Participant's rights,safety and well-being

a. The IEC ensures that Rights and responsibilities of Research participants (Annexure – 22) are displayed at research site including OPD room, and office in English and Hindi languages.

b. Rights and responsibilities of Research participants are also displayed at electronic display of hospital and on Hospital website in English and Hindi languages.

c. IEC will instruct Principal Investigator in the approval letter to ensure that all rights and responsibilities of research participants as mentioned in Annexure25 are informed to all research participants to be enrolled in study.

d. IEC ensures contact details of IEC contact person (secretary) are included in the informed consent document to contact research participants in case of any issue related to rights and integrity.

e. Research participant can raise any complaint to IEC at any point as mentioned in section 22 (SOP for complaints by the research participants)

f. IEC shall monitor violation of any rights of research participants by interviewing research participants during onsite MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee monitoring.

g. Research participant can raise any complaint to IEC at any point as mentioned in section 22 (SOP for complaints by the research participants)

h. IEC shall monitor violation of any rights of research participants by interviewing research participants during onsite MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee monitoring.

i. IEC will monitor safety and well-being of research participants of ongoingstudy by reviewing

- Continue review report and study completion reports
- Review of Serious Adverse Events at site and other sites
- Review of period safety updates report and Investigational brochure or any other new information available which may affect participants safety
- Periodic on-site Monitoring of flagged High risk studies

j. IEC shall arrange periodic training of Admin staff, Investigators and other study staff on procedures to safeguard and monitor Research Participant's rights, safety and well being

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24. Self-Assessment of IEC

a. Self-Assessment of IEC shall be done on the basis of self-assessmentchecklist mentioned in Annexure – 21.

b. Self-Assessment shall be conducted 6 Monthly. Member Secretary and Admin officer will together conduct self-assessment and review performance of ethics committee.

c. Chairperson may appoint other ethics committee internal/external memberto conduct self-assessment if required.

d. The member Secretary will present Quality Assurance self-assessmentreports to all members in subsequent full Board meeting.

e. After reviewing Quality Assurance self-assessment, recommendationincluding corrective and preventive action will be finalized in full board meeting for its future implementation.

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25. References

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(Accessed at www.who.int/tdr/publications/publications)

International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- *(Accessed athttp://www.ich.org/LOB/media/MEDIA482.pdf)*

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IOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects *(Accessed at http://www.cioms.ch/frame_guidelines_nov_2002.htm)*

ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR(2006) *(Accessedathttp://www.icmr.nic.in/ethical_guidelines.pdf)*

Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) *(Accessed athttp://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm0*

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

Central Drug Standard Control Organization Gazette Notification rule 43(E) dated 24 Jan 2013
(Accessed at http://www.cdsco.nic.in/GSR%2043E%20jan%2024%202013.pdf)

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Central Drug Standard Control Organization Gazette Notification rule 72(E) dated 8 Feb 2013
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Central Drug Standard Control Organization Gazette Notification rule GSR 611 (E) dated 31 July 2015 *(Accessed at http://www.cdsco.nic.in/writereaddata/Gazette%20Notification%2031%20July%202015.pdf)*

Central Drug Standard Control Organization Gazette Notification rule GSR 889 (E) dated 12 Dec 2014 *(Accessed at http://www.cdsco.nic.in/writereaddata/Notificatiohn%20on%20Compensation%20on%20clincial%20trial%20(1).pdf)*

Hany Sleem, et al Development of an Accessible Self-Assessment Tool for Research Ethics Committees in Developing Countries Journal of Empir Research Human Research Ethics.2010 Sep; 5(3): 85–98.

National Ethical Guidelines for Biomedical and Health Research involving Human Participants dated April 2017 Accessed at *ICMR Ethical Guidelines (ncdirindia.org)*

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26. ANNEXURES

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Annexure - 1: Format for covering letter for submission of research proposal for IRB/IEC approval

Date: XX-XXX-XXXX

To,

The Chairperson / Secretary
Institutional Ethics Committee (IEC)
MGM Dental College and Hospital
Kamothe, Navi Mumbai – 410209

Through,

The Chairperson / Secretary
Institutional Review Board (IRB)
MGM Dental College and Hospital
Kamothe, Navi Mumbai – 410209

Subject: Research Proposal and documents for review and approval by the IRB/IEC

Study title: .....

Dear Sir/Madam,

With reference to the above subject and reference, please find attached the following study related documents for review and approval by the Institutional Review Board (IRB) and/or the Institutional Ethics Committee (IEC) as applicable:

1. Project Submission Application Form to IRB/IEC
2. Research Protocol/Synopsis
3. Check-list along with all necessary documents

I hereby state that I would conduct my research as per the principles of Good Clinical Practice guidelines issued by the ICMR and comply with all required regulations.

I request you to kindly review and approve the same.

Thanking you

Dr. XXXXX XXXXXX
Principal Investigator (PI)
Designation
Contact: XXXXXXXXXXX ; Mail: XXXXXXXXXXXX

For IRB/IEC Use only

☐ The proposal is hereby approved by the IRB and is being forwarded to the IEC for ethical review.

☐ IEC Approval is not required for this research as there is no human participation.

Date:

Chairperson/Secretary
IRB

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Annexure - 2: Project Submission Application Form to IRB/IEC

A. *Please fill in the details in legible hand writing*
B. *Tick √ in the box for the appropriate answer*
C. *Tick/ Write NA if question is not applicable*

Title of the study/protocol

_____
_____
_____
_____
_____
_____

	Name	Designation & Qualifications	Department & Institution	Signature
Principal Investigator				
Co- Investigator				
Co- Investigator				

If additional collaborators attach details and letter of Consent by the collaborator (s) on a separate page. Please attach brief curriculum vitae of the study team members. (Principal investigator, co-investigator, study coordinator)	Yes	No
Non-sponsored		
Investigator Initiated		
Sponsored study		

1. Sponsor Information:

1. Indian a) Government☐ Central / State☐ b) Private☐

2. International☐ Government ☐ Other agencies☐
Private

3. Industry☐ National☐ Multinational ☐

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Contact Address of Sponsor:

If sponsor is from out of India, contact address in India:

2. Total **Budget: Rs.**

Research Fund will be deposited in (Account details):

3. Type **of Study:** *(Tick the appropriate boxes)* Observational ☐ Interventional ☐

Prospective ☐ Retrospective ☐ Cross-sectional ☐

Human participant ☐ No human participation ☐ In-vitro ☐

Drug ☐ Devices ☐ Surgical procedure ☐ Life-style modification ☐

Single center ☐ Multi-centric ☐

Any other ☐ .....

If multicentric, how many centers: India.....Globally.....(attach list of countries)

Clinical Trials: *(Tick the appropriate boxes)*

Drug ☐ Vaccines ☐ Device ☐ Alternative systems therapy (AYUSH) ☐

Any other , specify : .....

Is it approved and marketed?

India ☐ UK & Europe ☐ USA ☐ NA ☐

Approved indications: .....

Other countries, specify .....

	Yes	No	NA
Does it involve change in use, dosage, route of Administration?	☐	☐	☐
If yes, whether DCGI's /any other Regulatory authority's Permission is obtained? **If yes**, Date of permission..... If No, whether DCGI's / any other Regulatory Authority's Permission applied for?	☐	☐	☐

	Yes	No	NA
Is it an Investigational New Drug (IND)? If yes, IND No:			
Investigator's Brochure (IB) submitted			
In-vitro studies data			

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Preclinical Studies done	Yes	No	NA	
Phase of Clinical Study in India	1	2	3	4
To submit package insert in case test drug is already marketed in India, attached?	Yes	No	NA	
Are you aware if this study is being done elsewhere? **If Yes**, Specify details.....	Yes	No	NA	
Whether DCGI's permission for testing IND Obtained? If yes, Date of permission	Yes	No	NA	
For any other formulations involving alternative systems of medicine (AYUSH), a copy of the marketing/ manufacturing license issued by the FDA to the company to be submitted	Yes	No	NA	

4. **Protocol of the research proposal**–(Submit as attachment)

Introduction & background

Aim(s) & objectives

Justification for study

Study methodology describing the potential risks & benefits

Outcome measures

Statistical analysis methods including sample size justification

5. Research participants selection:

Number of research participants at this centre :

Number of research participants at other sites in India :

Total number of research participants at all sites (in the world):

Duration of study:

Will research participants from both sexes be Recruited?	Yes	No	NA
Inclusion / Exclusion criteria given	Yes	No	NA

Type of research participants:

Healthy Volunteers ☐ Patients ☐ NA ☐

6. Vulnerable research participant		Yes	No	NA
Pregnant women ☐	Elderly/Geriatric ☐	Mentally challenged ☐		
Infants ☐	Illiterate ☐	Handicapped ☐		
Children ☐	Captives ☐	Terminally/Seriously ill ☐		
Students ☐	Dependent staff ☐	Institutionalized ☐		
Economically/Socially Backward ☐	Employees ☐	Any Other ☐		

7. Privacy and confidentiality:

Patient identity details (including face photograph) captured in study Yes ☐ No ☐

8. Biological material handling	Yes	No	NA
Use of biological/ hazardous materials	☐	☐	☐

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Use of fetal tissue or abortus tissue			
Use of organs or body fluids	☐	☐	☐
Use of pre-existing/stored/left over samples	☐	☐	☐
Use of Infectious/bio hazardous specimens	☐	☐	☐
Proper disposal of material	☐	☐	☐
9. Will any sample collected from the patients be sent abroad?	Yes	No	NA
If no, test on samples be carried out: Hospital	☐	☐	☐
If no, test on samples be carried out: Outside hospital	☐	☐	☐

If Yes,

Sample will be sent abroad because (Tick appropriate box):

Facility not available in India Facility ☐

Central laboratory for multicentric studies ☐

***10.* Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration?** *(required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)*

Yes☐ No ☐ NA ☐

11. In case of studies involving collaborations with other Indian or foreign Laboratory/ Clinic/Institution has administrative sanction obtained from appropriate authority?

Yes☐ No ☐ NA☐

12. Informed Consent:

Written* ☐ Verbal ☐ Audio-visual ☐ NA ☐ Waiver requested ☐

	Yes	No		Yes	No
Understandable language	☐	☐	Statement that study involves research	☐	☐
Alternatives to participation	☐	☐	Confidentiality of records of Sponsor of study	☐	☐
Purpose and procedures	☐	☐	Statement that consent is voluntary	☐	☐
Benefits	☐	☐	Right to withdraw	☐	☐
Compensation for study related injury	☐	☐	Compensation for participation	☐	☐
Benefits if any on future commercialization	☐	☐	Consent for future use of biological material	☐	☐
Risks & Discomforts	☐	☐			

	Yes	No	NA

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13. Will any advertising be done for recruitment of research participants? (posters, flyers, brochure, websites – if so kindly attach a copy)		☐	☐	☐
14. Risks & Benefits: Is the risk reasonable compared to the anticipated benefits to research participants / community / country?		☐	☐	☐
Is there a benefit	To the research participants?	☐	☐	☐
	Benefit to society	☐	☐	☐
Is there any anticipated risk or discomfort?	If Yes, minimal or no risk	☐	☐	☐
	More than minimum risk	☐	☐	☐
	High risk	☐	☐	☐
15. Data Monitoring Is there a data & safety monitoring committee/ Board (DSMB)?		Yes	No	NA
Is there a plan for reporting of adverse events?		☐	☐	☐
If Yes, reporting is done to :	Sponsor	☐	☐	☐
	Ethics Committee	☐	☐	☐
	DSMB	☐	☐	☐
Is there a plan for interim analysis of data?		☐	☐	☐
Are there plans for storage and maintenance of all trial databases? **IfYes,** for how long? -----years		☐	☐	☐
16. Is there compensation for participation If Yes, Monetary In kind Specify amount and type: ----------		☐	☐	☐
17. Is there compensation for injury? If Yes by		☐	☐	☐
Sponsor ☐				
Investigator ☐				
Insurance ☐				
Any other party .....☐				
18. Do you have any conflict of interest in the present study? (financia non-financial) If Yes, specify		Yes	No	
19. Current Brief Curriculum Vitae (signed and dated copy) of the study team members- principal investigator, co-investigator and study coordinator (Information required -age, designation and department, educational qualification, previous research experience in last five years) (To be enclosed along with the form)		Yes	No	
Information about GCP training of PI and co-investigator		Yes	No	

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20. GCP training certificates Certificates of principal investigator and coordinator/s (mandatory only for drug and device trials not for observational studies). Certificate to be enclosed along with the form.	Yes	No	
21. **Is the trial registered with Clinical Trial Registry?** (mandatory only for drug trials) Clinical Trial Registry of India (CTRI)/ any other WHO platform registry **Registration number:** If not registered, state the reason	Yes	No	NA
22. Whether study is approved by IRB? Date of Approval:	Yes	No	NA

Statement of Compliance:

We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the Schedule Y (Drugs and Cosmetic Act 1940), Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017).

We also ensure that Principal Investigator / Institution will pay for treatment and / or compensation if study related injury occurred due to protocol violation by PI / study team.

Signature of Principal Investigator (PI) with date: .....

Signature/s with date of Co-investigators:

Name	*Signature*
1.	.....
2.	.....
3.	.....

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Annexure - 3: Check-list of documents for research protocol submission

(Tick accordingly; compulsory documents have to be submitted)

Sr	Document	No. of copies	No	Date by which it will be submitted, if pending	NA
1.	Project submission application form duly filled				
2.	Letter to Member Secretary/ Chairperson				
3.	Summary of protocol (not more than 500 words)				
4.	Research Protocol / Synopsis (dissertation/thesis)				
5.	Informed Consent Document (ICD) in English				
6.	Informed consent documents in Regional languages (Total Languages .....)				
7.	Translation/backtranslation certificates				
8.	Case Record Form (CRF)				
9.	Research participants recruitment procedures: advertisement, notices (If applicable)				
10.	Patient instruction card, identity card, patient diary etc. (If applicable)				
11.	Research participants Questionnaire/s (If applicable)				
12.	Investigator Brochure (If applicable)				
13.	Insurance certificate and policy (If applicable)				
14.	Investigator's undertaking to DCGI (If applicable)				
15.	DCG(I) approval / Acknowledgement of application to DCG(I)				
16.	Clinical Trial Agreement (CTA) for drug trial / Memorandum Of Understanding (MOU) (as applicable)				
17.	FDA marketing/manufacturing license for alternative system of medicines (AYUSH)				
18.	Signed and dated brief current curriculum vitae (CV) of the study team members (principal investigator, co-investigator, study co-coordinator)				
19.	Documentation of CTRI registration/ any other clinical trial registry (WHO platform)				
20.	GCP training certificates of Principal Investigator				
21.	Any other Documents submitted (specify				

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Annexure - 4: Guidelines for Investigators

1. All the studies qualifying as 'clinical research' or involving human participation in any form need to be submitted to the Institutional Ethics Committee (IEC), MGM Dental College and Hospital, Kamothe, Navi Mumbai.
2. Approval of the Institutional Ethics Committee (IEC) is mandatory for all research involving human participation in any form before commencing any study related procedure.
3. Location and Office Address of the Institutional Ethics Committee (IEC):

   Institutional Ethics Committee (IEC)
   MGM Dental College and Hospital
   Kamothe, Navi Mumbai
   Contact No. 022 27436604
   Mail: iercmgmdch@gmail.com

4. Office hours of IEC:

Monday to Friday:	09.00 am to 04.00 pm
Saturday:	09.00 am to 01.00 pm

5. There will be no meetings held in the month of May and November. In case a meeting is to be held during this period due to unavoidable reasons, the decision will be taken by the Member Secretary in consultation with Chairperson.
6. The principal investigator (PI) should be GCP trained before initiating the study and copy of the GCP training certificate within the preceding five years should be provided to the IEC at the time of submission of a new study proposal.
7. The SOPs are available with the IEC office and can be shared on request (electronic copy) or can be downloaded from Website mgmdchnavimumbai.edu.in and iercmgmdch@gmail.com
8. The following steps need to be followed by investigators while communicating with the Institutional Ethics Committee:

A. Prior to approval of a research study

I. Submission of a New Study Proposal

i. Investigator(s) should submit study proposal only after approval of the study documents by the Institutional Review Board (IRB) of MGM Dental College and Hospital, Kamothe, Navi Mumbai.

ii. The submission should include the following:
   a. Cover letter of application (Annexure – 1)
   b. Project Submission Application Form (Annexure – 2)
   c. Check-list of documents for research protocol submission (Annexure – 3)
   d. Protocol/synopsis and all necessary documents as per the above check-list.

iii. Three sets of documents should be submitted along with a soft copy (pdf of word) of all the documents.

iv. Each set shall contain the documents mentioned in Annexures 1, 2 and 3 on A4 size paper arranged in a plastic file/binder in the same order.

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v. The investigator should ensure that there is an 'Ethics Section' in the protocol is in compliance with the ICMR-GCP Guidelines.

vi. An investigator is required to fill in all the details in the form ***Annexure 01*** very clearly in legible handwriting along with the photocopies of the same. **Incompletely filledforms / forms without signatures and seal will not be accepted.**

vii. All submissions should be made through heads of the respective departments.

viii. Documents should be submitted at least **21 days** prior to IEC meeting.

ix. The study proposals will be circulated to all the IEC members **10 days** prior to the IEC meeting for review.

x. All required fees shall be collected at the time of submission of the project as below:

Projects	Type of submission	IEC Fees
Investigator initiated/ Academic Projects	Any submission	Rs. 1000/-
Government sponsored projects	Initial submission	Rs.20,000/- plus taxes
	Study protocol document amendments (if full meeting required)	Rs.10,000/- plus taxes
Industries sponsored projects	Regular submission	Rs.50,000/- plus taxes
	Expedited submission	Rs.80,000/- plus taxes
	Amendment to Protocol or study documents	Rs.10,000/- plus taxes

Mode of payment : Cheque/DD/NEFT
Bank details : Savings A/C # 0183104000108263
IDBI Bank
CBD Belapur Branch
RTGS/ NEFT IFCS code –IBKL0000183

xi. Submissions for funded / sponsored studies/projects would not be processed by the IEC until receipt of the prescribed fees.

xii. The principal investigator (PI) / Co-investigator is required to be present during the IEC meeting to discuss issues related to the study proposal. The schedule of the IEC meeting at least 3 days before the IEC meeting.

xiii. The PI may call up the IEC office to know the date of next scheduled IEC meeting.

xiv. For clinical studies on "alternative system of medicine" (Ayurveda, Homeopathy, Siddha, Unani), a Co-Investigator/ Collaborator from that system should be included in the study team. The co-investigator appointed should be independent and he/she should not have a conflict of interest with the study, investigator or sponsor.

xv. An investigator is expected to submit reply to any recommendations/ queries sent by the IEC within 90 days of date of receipt of the letter. In the absence of any response, the project will be declared closed for the IEC office records.

xvi. The PI should register all clinical studies at the clinical trials registry of India on www.ctri.nic.inORany other WHO clinical trials platform.

B. Once approval for a study is granted

I. **An approval will be granted for the entire duration of the study**

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Submission of study related documents for IEC review

i. Any study related documents (updates to any study documents, IB updates, SAE reports, status reports, study completion reports, protocol deviations/ violations) to be submitted to IEC for review and approval as appropriate.

ii. Two sets of the above stated study related documents need to be submitted to the IEC.

iii. Agenda of the IEC meeting to discuss such matter will be prepared 2 days prior to the date of meeting and is sent to the members at least 1 day in advance. Hence, the responses to the IEC queries and other documents received within seven days and other types of documents within 2 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next IEC meeting for discussion *(Exception: any matter which in the opinion of the IEC secretary/chairman such as SAE report, major protocol violation).*

BI. Submission of Amended Protocol and Protocol Related Documents

i. All amendments to the approved research proposal should be submitted to the IEC as soft copy (PDF format) and only 2 set of hard copies for its review no later than 7 seven days prior to the date of forthcoming meeting.

ii. No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).

iii. A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents.

IV. Submission of report of protocol deviations/ violations

i. Please provide any deviation / non-compliance / violation report in writing to the IEC Office.

ii. Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC immediately.

iii. If an investigator wishes to appeal against the decision about rejection of a research proposal by the IEC, please contact the IEC secretary and submit your appeal in writing, addressed to the IEC Chairperson with justification relevant to the issues/ objections raised by the committee **within 90 days** of the receipt ofthe committee's decision. In absence of appeal, the project will be declared closed for the IEC office records.

V. Submission of study completion report/status review report

i. For studies which are completed within the IEC approval period, a study completion report as per the format given in *Annexure 8* should be submitted to the IEC by the principal investigator.

ii. The study completion report is expected for review within 1 month of completion of the study at the site.

iii. A brief study report containing data analysis from all centers should be submitted once available from the sponsor.

iv. Investigator need to submit continue review report every 6 monthly from date of approval or last reports submitted to IEC.

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VI. In case a study is not initiated or terminated

i. The same should be communicated to the IEC stating reasons for the same.

ii. The IEC archives all the study related documents for a period of 5 years after the study is completed / terminated/ reported as not initiated at our site.

iii. In case, an investigator needs a copy of any document submitted to the IEC, a written request can be made for retrieval of the same.

C. Regulatory permissions I.

DCGI approval:

i. Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) require DCGI permission. For such studies, a copy of the permission letter issued by the DCGI to the pharmaceutical company/investigator also needs to be submitted to the IEC along with application submission.

ii. If the DCGI permission is awaited, a letter of conditional approval will be issued by the IEC. However, the copy DCGI permission is to be submitted to the IEC before commencement of the study related procedures.

iii. For regulatory studies, no study should be initiated until the DCG (I) approval is received by IEC.

II. FDA marketing/manufacturing license for Ayurveda/ herbal formulations/ nutraceuticals

BI. Health Ministry Screening Committee (HMSC) approval in case a study involves collaboration with any foreign laboratory/clinic/institution

IV. Clinical Trials Registry Registration

It is mandatory as per the directive by the DCG(I) to register clinical trial at clinical trial registry of India at www.ctri.nic.in before enrolling first patient in the study. **(Registrationis mandatory for interventional clinical trials)**

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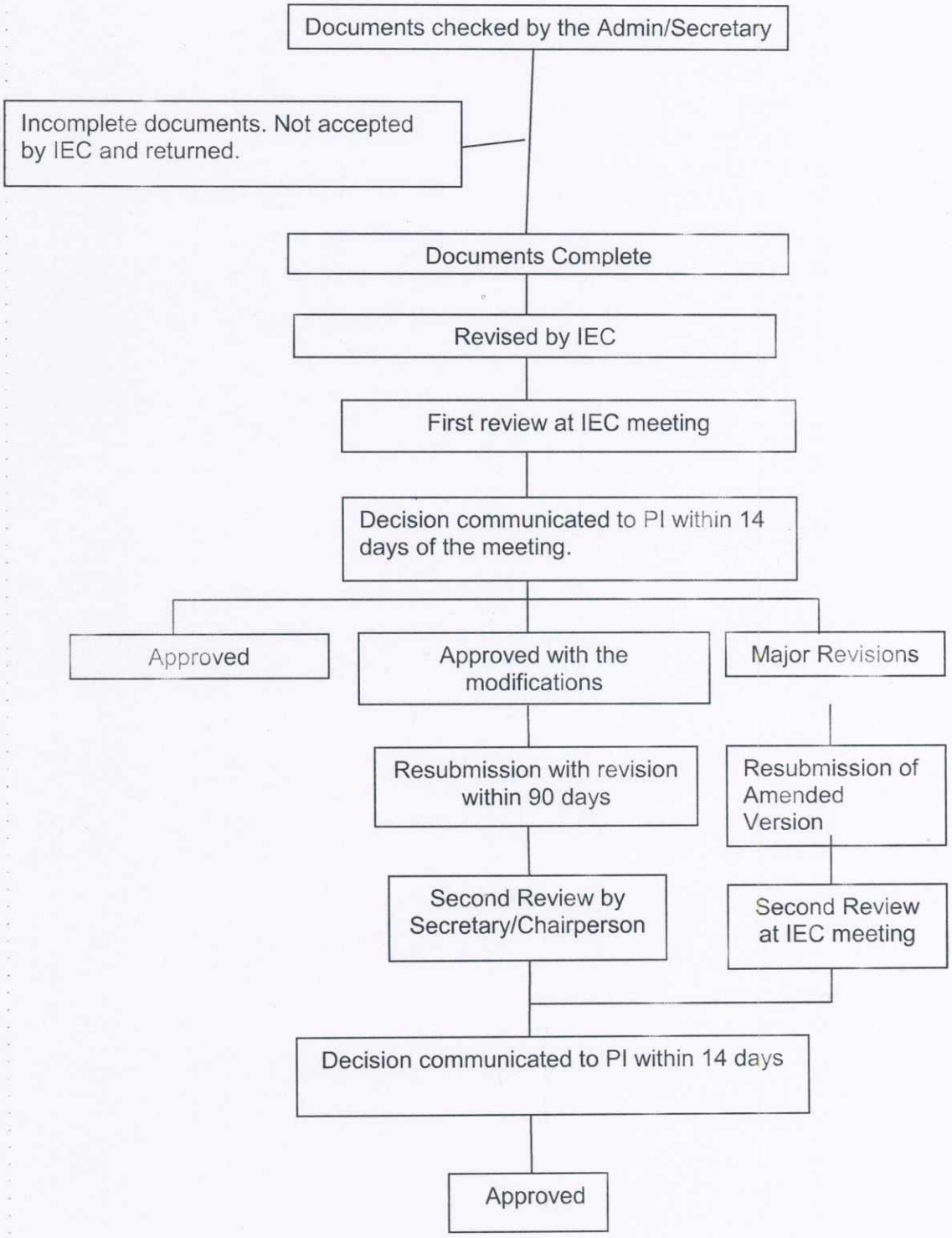
Process flow of Submission of Projects to IEC

Submission of project proposal by Investigator 21 days prior to meeting
(As per check-list in Annexure-3)



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Annexure - 5: Sample format for Informed Consent Document (ICD)

Informed Consent Document (ICD)

[Participant Information Sheet (PIS) & Informed Consent Form (ICF)]

Protocol No.: .....

Study title: .....

.....

.....

Principal Investigator Name: .....

Designation: .....

Address: .....

Phone (24 hours): .....

Mail: .....

Participant's Name: .....

Participant Information Sheet (PIS)

1. **Invitation paragraph**

You are invited to participate in the study titled '.....'.

The purpose of this document is to provide you with information about this study.

Please read this document carefully and ask your doctor questions or seek clarification if anything is not clear to you.

When all your questions have been answered to your satisfaction and if you are willing to participate in the study, you will be required to sign the consent form.

You will be provided with a copy of this information sheet for your reference.

2. **Information about the study (introduction)**

(Briefly explain in lay terms the background of the problem, the need & purpose of the study, Use simple explanatory language / words that can be understood by an averagely literate individual such as non-matriculate)

3. **Why am I being requested to participate in this study?**

You are requested to participate in this study as you are suffering from.....

4. **What are the benefits of my participation?**

State possible benefits of the study if any or print your participation may or may not benefit you directly,however the information obtained from the study will be of benefit in the treatment of future patients

5. **What will the study involve?**

(Explain how long the patient will be required to be in the research. How often will he / she will require to visit a clinic if applicable).

Provide details of the study procedure e.g. examination, intervention (drugs, surgery) tests, radiology etc. Explain *(allotment to a study group)* if it is a blinded study.

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6. **What are the risks involved?**

*For non-intervention studies state none as NO extra investigations or new therapy is involved.

* For intervention studies or where extra investigations are involved- list possible side effects *(common & uncommon)*

7. **What will be the cost of participation?**

All costs of the treatment or diagnostics, over & above those involved in standard diagnosis & treatment will be borne by the hospital.

Costs as involved in routine care will be borne by the patient

8. **Will my results be informed to**

me? *(print as applicable)*

9. **What are my responsibilities?**

Explain are there any lifestyle restrictions, dietary restrictions, advise to follow all study related instructions, keep follow up dates, report any adverse reactions etc.

10. **Is my participation compulsory?**

No, your participation is voluntary and non-participation will not in any way affect your treatment at the hospital.

11. **Can I withdraw from the study?**

You are free to withdraw from the study at any time without giving any explanation. This will not affect your care at the hospital. No further test(s) etc. will be done. However, data already collectedmay be used for analysis of results.

12. **If something goes wrong what happens? Who treats & bears the cost?**

Any study related complication (diagnostic procedures & therapy) will be treated by the hospital. The hospital will bear the costs of any conditions arising out of study participation.

Mention availability of insurance, if any.

(State if no additional or new intervention is done the patient will bear the cost for such events.)

13. **Do I get any compensation in case of research related injury?**

Research related injury is an injury that occurs to the subject as a result of research participation. Injuries may range from relatively minor harms (such as bruises or infected wounds) to major injuries (such as organ damage or temporary disability) to catastrophic injuries (such as permanent disability or death).

An injury may require only acute or emergency care, or it may require continuing care. Injuries can be physical or psychological/emotional.

In case of research related injury, the study subject shall be entitled for financial compensation as per the recommendation of the IEC and the expert committee as per prevailing regulatory guidelines.

In case of death of the subject, his /her nominees are entitled for financial compensation as per the recommendation of the IEC and the expert committee as per prevailing regulatory guidelines. The financial compensation shall be over and above any expense incurred on the treatment of the subject.

The decision for compensation shall be taken during the IEC meeting and adequately decided as per the provisions of rule 122DAB of The Drugs and Cosmetics Rules, 1945, and other guidelines provided by CDSCO.

14. **What about the confidentiality of my data?**

All the information obtained in this study will be kept strictly confidential and used for scientific purposes only.

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Data taken from this study may be published or presented in scientific meetings. However, your name and other identifying information will be kept confidential and will not be made publicly available. Investigators, study team members, ethics committee members & regulatory authorities (if required by law) may review your personal and medical records.

15. Is the study approved by ethics committee or review board?

Yes.

The study has been reviewed & approved by the Institutional Ethics Committee of MGM Dental College & Hospital, Kamothe, Navi Mumbai.

16. Whom can I contact for more information?

For any study related information:

PI / Research fellow and 24 hours contact details (refer first page)

For your rights contact the following:

Dr. Shilpa Patel
Member Secretary
Institutional Ethics Committee (IEC)
MGM Dental College and Hospital
Kamothe, Navi Mumbai
Contact No. 022 27436604 OR Mobile: 9987696594
Mail: iercmgmdch@gmail.com

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Informed Consent Form (ICF)

Protocol No.: .....

Study title: .....

.....

Principal Investigator Name: .....

Subject's Initials: .....

Subject's Name: .....

Date of Birth / Age: .....

Address of the subject: .....

Qualification: .....

Occupation: Student / self- employed / service / Housewife / Other

(Please tick as appropriate)

Annual Income of Subject: .....

Name of nominee: .....

Relation to the subject: .....

Sr.		Please initial inbox (Subject)
1.	I confirm that I have read and understood the information sheet dated_for the above study and have had the opportunity to ask questions.	[ ]
2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	[ ]
3	I understand that the study team member, Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.	[ ]
4	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)	[ ]
5	I agree to take part in the above study.	[ ]

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Signature (or Thumb impression) of Subject OR Legally Acceptable Representative (LAR)		Date:___/____/_____
Signatory's Name		
Signature of the Impartial Witness		Date:___/____/_____
Name of the Impartial Witness		
Signature of the Investigator		Date:___/____/_____
Study Investigator's Name		

(On every Page of ICF- Version no XXXX dated XXXXX Page No)

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Annexure - 6: Amendment Request and Assessment Form

IEC Protocol Number: IEC Approval reference No.	
Protocol Title:	
Principal Investigator : _ Department:	
Approved date:	No. of amendment: (Attach List of Amendment)
State/describe the amendment: type of document/ part of document amended Reasons **for the amendment** **Impact of your amendment on your present study at this site**: (modifications in the ICD,re-consent of research participants, untoward effects likely to occur because of the amendment or any other ☐ ☐	
Have the changes modifications in the amended versions been highlighted/ underlined? Yes No **Copy of List of Changes attached** - Yes No	
Name of Principal Investigator: **Signature with Date:**	
Type of review :- (Decision by the Chairperson/ Member Secretary) Review by Member ☐ Disapproved ☐ Next full board discussion Full Board discussion and review ☐ **Sign and Date of Member Secretary**	

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Full Board Decision: Approved ☐ No ☐
If disapproved, reasons for disapproval/Further revision or modification required

Sign and Date of Member Secretary

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Annexure - 7: Continuing Review Application Form

Date:

Protocol No.: IEC Approval reference No.	
Protocol Title:	
Principal Investigator :_____ Department : :_____	
Summary of protocol participants _____number of participants approved by MGM Dental College and Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee New participants recruited so far _____Number of ongoing patients_____ Number of patients who have already Completed the study_____	Has any information appeared in the literature, or evolved from this or similar research that might affect the MGM Dental College and Hospital, Kamothe Navi Mumbai Institutional Ethics Committee evaluation of the risk/benefit analysis of participants involved in this protocol? No Yes (attach separate sheet if needed)
Have any participants been withdrawn from this study? No Yes (state the number and reasons for drop- outs of each participant, attach separate sheet if needed)	Have any unexpected complications or SAEs been noted since last review at our site? No Yes (attach separate sheet if needed) No. of patients who had SAEs- _____
Impaired participants Physically Cognitively Both Have there been any amendments in protocol/ Informed Consent Document since the last review? NO YES	Have any unexpected complications or SAEs been noted since last review at our site? No Yes (attach separate sheet if needed) No. of patients who had SAEs- _____

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Were these protocol/ Informed Consent Document (ICD) amendments approved by MGM Dental College and Hospital Navi Mumbai Institutional Ethics Committee? No Yes If no, mention the amendments not approved	Which protocol amendment is the site following at this date _____ Which ICD amendment is the site following at this date
Number of Protocol Deviations_____ (Attach list of Protocol Deviations separately) No of Adverse Event_____ Types of adverse events with nos. of participants- (Attach list of adverse event with causality assessment separately)	Have any participating investigators been added or withdrawn since last review? No Yes (Identify all changes in the attached narrative)
Is report of interim data analysis available? No Yes (submit as an attachment) Is report of the data safety and monitoring board available? No Yes (submit as an attachment)	Have any investigators developed equity or consultative relationship with a source related to this protocol which might be considered a conflict of interest? No Yes (Append a statement of disclosure)

Signature of the Principal Investigator with Date:

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Annexure - 8: Study Completion Report Form

(To be filled by Principal Investigator)

Protocol No: IEC Reference No.	
Protocol Title:	
Principal Investigator:	
Department:	
Total no. of study participants recruited	
Total no. of study participants approved by the MGM Dental College and Hospital Navi Mumbai Institutional Ethics Committee for recruitment	
Duration of the study	
*Results (Summary) with Conclusion: (use extra blank paper, if more space is required). **Note: If the final report is not available from sponsor, it may be submitted later to the MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee once it is ready.*	
Number of SAEs at our center:	

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Reasons for withdrawal:	
Number of Adverse Events (Attach list of adverse Events with causality assessment separately)	
Number of Protocol Deviations/ Violations (Attach list of Protocol Deviations/ Violations separately)	
No. of patients withdrawn	
Signature of Principal Investigator	Date :-
Committee	

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Annexure - 9: Study Assessment Form to be used by the Reviewer

(Print copy or by Email)

IEC Protocol Number :			Date :
Protocol Title			
Principal Investigator:			
Department			
No. of Participants at the site:		No. of Study site(s):	

Mark and comment on whatever items applicable to the study.

1	Objectives of the Study ☐ clear ☐unclear	What should be improved?
2	Need for Human Participants ☐ Yes ☐ No	Comment:
3	Methodology: ☐ clear ☐ unclear	
4a	What should be improved? Background Information and Data ☐ sufficient ☐insufficient	Comment:
4b	Risks and Benefits Assessment ☐acceptable ☐unacceptable	
4c	Inclusion Criteria ☐ appropriate ☐ inappropriate	Comment:
4d	Exclusion Criteria ☐ appropriate ☐ inappropriate	Comment:
4e	Discontinuation and Withdrawal Criteria ☐ appropriate ☐ inappropriate	Comment:
5	Involvement of Vulnerable Participants: ☐ Yes No ☐	Comment:
6	Voluntary, Non-Coercive Recruitment of Participants ☐ Yes ☐ No	Comment:
7	Sufficient number of participants? ☐ Yes ☐ No	Comment:
8	Control Arms (placebo, if any) ☐ Yes ☐ No	Comment:

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9	Are Qualification and experience of the Participating Investigators appropriate? ☐ Yes ☐ No	Comment:
10	Disclosure or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No	Comment:
11	Facilities and infrastructure of Participating Sites ☐ Appropriate ☐ Inappropriate	Comment:
12	Community Consultation: ☐ Yes ☐ No ☐ NA	Comment:
13	Benefit to Local Communities ☐ Yes ☐ No	Comment:
14	Contribution to development of local capacity for research and treatment ☐ Yes ☐ No	Comment:
15	Availability of similar Study / Results: ☐ Yes ☐ No	Comment:
16	Are blood/tissue samples sent abroad? ☐ Yes ☐ No	Comment:
17	Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	Comment:
17 a.	Audio Visual Recording of Informed Consent (If Applicable) ☐ Yes ☐ No	Comment:
18	Contents of the Informed Consent Document: ☐ clear ☐ unclear	Comment:
19	Language of the Informed Consent Document: ☐ clear ☐ unclear	Comment:
20	Contact Persons for Participants ☐ Yes ☐ No	Comment:
21	Privacy & Confidentiality ☐ Yes ☐ No	Comment:
22	Inducement for Participation ☐ Unlikely ☐ Likely	Comment:
23	Provision for Compensation for Participation ☐ appropriate ☐ inappropriate	Comment:
24	Provision for Treatment for Study-Related Injuries	Comment:

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	☐appropriate ☐inappropriate	
25	Provision for Compensation for Study Related Injuries ☐appropriate ☐inappropriate	Comment:

Any other additional comments

1. _____

2. _____

3. _____

4. _____

Reviewer's Name: Signature with date

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Annexure - 10: Confidentiality Agreement

Confidentiality Agreement Form for those attending the IEC meeting

In recognition of the fact, that I, ...
.....
... (*Member'sname and his /her affiliation)* herein referred to as the "undersigned", have been appointed as a member/invitee of the Institutional Ethics Committee (IEC), MGM Dental College & Hospital,Kamothe, Navi Mumbai, and have been asked to assess research studies involving research participants inorder to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member/invitee of the IEC, is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member/invitee is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants;

The undersigned, as a member/invite of the IEC is expected to meet the same high standardsof ethical behaviour to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the Institutional Ethics Committee, MGM Dental College & Hospital, Kamothe, Navi Mumbai.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on filein the custody of the IEC office. A copy will be given to you for your records.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information").

I agree to take reasonable measures to protect the Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would resultin a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon terminationof my functions as a Committee member.

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I,_____

(Name of the member/invitee) have read and accept the aforementioned terms andconditions as explained in this Agreement and I acknowledge that I have received acopy of this

Signature Date

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IECChairperson and me.

Signature Date

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Annexure - 11: Conflict of Interest (COI) Form

It is recognized that the potential for conflict of interest will always exist but the Institutional Ethics Committee (IEC), MGM Dental College & Hospital, Kamothe, Navi Mumbai, and its Chairperson need to manage the conflict issues so that the ultimate outcome is the protection of research participants.

It is the policy of the IEC that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson/Secretary of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify theChairperson/Secretary and may not participate in the IEC review or approval except to provideinformation requested by the Committee.

Some examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

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Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above.

The original (signed and dated Agreement) will be kept on file in the custody of the office ofthe Institutional Ethics Committee (IEC), MGM Dental College & Hospital, Kamothe, Navi Mumbai,

A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.

I,_____

(Name of the member) have read and accept the aforementioned terms and conditionsas explained in this Agreement and I acknowledge that I have received a copy of this

Signature Date

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IECChairperson and me.

Signature Date

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Annexure - 12: Serious Adverse Event (SAE) Assessment Report

Serious Adverse Event Assessment Report (For SAE at the site)

Name of the Principal Investigator:

Department:

MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee Protocol No:

Protocol Title:

Patient ID:_____ Event / SAE term:_____

_____ Report Date:

☐ ☐ _____ Date of Onset of SAE: _____

Initial Follow-up No. of Follow-up ☐

Attach a narrative for details of SAE, history of the case and relevant laboratory findings and treatment given:

Outcome of SAE: ☐ resolved ☐ on-going

Seriousness:	Relation to Drug Device
☐ Death	☐ study procedure
☐ Life threatening	☐ Not related
☐ Hospitalization – initial ☐ prolonged ☐	☐ Possibly
☐ Disability / Incapacity	☐ Probably
☐ Congenital Anomaly	☐ Definitely related
☐ Any Other… _____	☐ Unknown
	Whether study drug withheld: Yes ☐ No ☐
	~~If yes, since when:~~ _____

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Details of compensation:

Who has paid for medical treatment?
Whether compensation given to participant in case of study related injury?

Signature of the Principal Investigator:

Date: _____

Acknowledged/ Reviewed by

Name of Member Secretary_____Sign and Date _____

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Annexure - 13: Serious Adverse Event (SAE) Analysis Report

(For SAE at the site)

Sr.	Details		
1	Country (Name of the country should be specified)		
2	SAE report of death or other than death, Please tick (✓)	Death	Other than Death
		Yes /No	Page No.
3	In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box		
4	Protocol Title		
5	Protocol Study No./ ID /Code		
6	Copy of Clinical Trial permission obtained from CDSCO		
7	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8	Sponsor (Address with contact no and Email)		
9	CRO (Address with contact no and Email)		
10	Initial / Follow-up (FU)		
11	In case of follow-up: Date & Diary no of Initial or recently submitted report information		
12	Patient Details		
a	Initials & other relevant identifier (Hospital /OPD record number etc.)		
b	Gender		
c	Age and/or date of birth		
d	Weight		
e	Height		
13	Suspected Drug(s)		
a	Generic name of the drug.		
b	Indication(s) for which suspect drug was prescribed or tested.		
c	Dosage form and strength.		
d	Daily dose and regimen (specify units -e.g., mg, ml, mg/kg).		
e	Route of administration.		
f	Starting date and time of day.		
g	Stopping date and time, or duration of treatment		
14.	Other Treatment(s)		
	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s).		
15.	Details of the events		
a	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
b	Start date (and time) of onset of reaction.		
c	Stop date (and time) or duration of reaction.		
d	Dechallenge and rechallenge information.		
e	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16	Outcome		

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Sr.	Details		
a	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b	For a fatal outcome, cause of death and a comment on itspossible relationship to the suspected reaction; any post- mortem findings.		
c	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug oralcohol abuse; family history; findings from special investigations etc.		
17.	Details about the Investigator		
a	CT Site Number, if any		
b	Name		
c	Address		
d	Telephone/Mobile Number & Email		
e	Profession (specialty)		
f	Date of reporting the event to Licensing Authority:		
g	Date of reporting the event to Ethics Committee overseeing the site:		
h	Signature of the Investigator		
18.	Details about the Ethics Committee		
a	Name & Address		
b	Name of Chairman & Address		
c	Telephone/Mobile Number		
d	Email		
19.	Adverse Event Term / Details of SAE		
20.	Causality Assessment Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a	Duly filled SAE Form as per Appendix XI of Schedule Y		
b	Laboratory investigations report/Discharge summary (if available and applicable)		
c	Post-mortem report (if applicable)/ Any additional documents)		

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Annexure - 14: Checklist for Research Involving Children

IEC protocol no._____Name of Principal Investigator _____

Risk Determination	Benefit Assessment	IEC Action
Minimal	With or without direct benefit	Approvable
Greater than minimal risk	Potential to child	Approvable
Greater than minimal risk	**No direct benefit to individual offer general knowledge about the child's condition or disorder.**	Approvable on case to case basis

i. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.
ii. Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.
iii. Approval to proceed with this category of research must be made by the Administrator of the IEC, with input from selected experts.

	Yes	No	NA
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes: Is the inclusion of normal volunteers justified?			
Are the studies conducted on animals and adults, appropriate and justified?			
If No: Is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?			
If Yes: Are the conditions acceptable?			
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
Are provisions made to protect subjects' privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor MGM Dental College and Hospital, Kamothe Navi Mumbai Institutional Ethics Committee member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve a which has implications for other			

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	Yes	No	NA
family member ? (for example, genetic risk , HIV infection , Hepatitis C) If Yes: Are there adequate mechanisms in place to deal with other members of the family? Are parents being required to be present during the conduct of the research? Are proposed subjects to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?			

Comments:

Name & Signature
Primary Reviewer Sign and Date

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Annexure - 15: Checklist for Research Involving Pregnant Women & Foetus

IEC protocol no._____

Name of Principal Investigator _____

Section 1: This Research Involves Pregnant Women or Fetuses Prior to Delivery	Yes	No	NA
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non- pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and foetus;			
The risk to the foetus is not greater than minimal, or any risk to the foetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the foetus;			
Any risk is the least possible for achieving the objectives of the research;			
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions , unless altered or waived in accord with 45 CFR			
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the foetus or resultant child;			
If the research involves children as defined in 45 CFR 46.402(a) who are pregnant, assent and permission will be obtained in accord with the provisions of subpart D of that part;			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and			
Individuals engaged in the research will have no part in determining the viability of a foetus.			

If the response to any of the above is No, the research is not approvable by the IEC, MGM Dental College & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee.

Section 2: This research involves fetuses after delivery	Yes	No	NA
Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to foetuses;			
The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the research on the foetus or resultant child;			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate pregnancy;			

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Individuals engaged in the research will have no part in determining the viability of a foetus.

AND

This research involves Foetuses of uncertain viability	Yes	No	NA
Does the **research** hold out the prospect of enhancing the probability of survival of the particular foetus to the point of viability, and any risk is the least possible for achieving the objectives of the **research; OR**			
The purpose of the **research** is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the foetus resulting from the **research**;			
The legally effective informed consent of either parent of the foetus or , if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.			

AND/OR

This research involves Non-viable foetuses	Yes	No	NA
Vital functions of the foetus will not be artificially maintained;			
There will be no risk to the foetus resulting from the research;			
The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; **AND**			
The legally effective informed consent of both parents of the foetus will be obtained in accord with the subpart A of 45 CFR 46, except that the waiver and alteration provisions of and (d) do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a non-viable foetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable foetus will not suffice to meet the requirements of this paragraph.			

If the response to any of above is No, the research is not approvable by the MGM DentalCollege & Hospital, Kamothe, Navi Mumbai Institutional Ethics Committee .

Section 3: This research can be conducted only after:

a) The Institutional Ethics Committee, MGM Dental College & Hospital, Kamothe, Navi Mumbai finds that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women or foetus and,

b) The secretary, after consultation with a panel of experts in pertinent disciplines(for examples: science, medicine, ethics, law) is satisfied that.

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a. The research presents a reasonable opportunity to further the understanding,prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or foetus;
b. The research will be conducted in accord in sound ethical principles; and
c. Informed consent will be obtained in accord with prevailing regulations.

Comments:

Primary Reviewer Name & signature _____ Date _____

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Annexure - 16: Checklist for Research Involving Cognitively Impaired Adults

IEC protocol no. _____

Name of Principal Investigator _____

The purpose of this checklist is to provide support for the Institutional Ethics Committee members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects.

1. For review using the expedited procedure this checklist is to be completed by the Designated Reviewer to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
2. For review during the convened IEC meeting to document determinations required by theregulations and protocol specific findings justifying these determinations.

1. Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject (All items must be "Yes")		
One of the following is true (Check the box that is true) • The risk to the subjects is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. • More than minimal risk to subjects is presented by monitoring procedure that is likely to contribute to the subjects well – being.	Yes	No
The risk is justified by the anticipated benefit to the subjects.	Yes	NoThe
relation of anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.	Yes	No
The proposed plan for the assessment of the capacity to consent is adequate.	Yes	No
Assent is required of: (One of the following must be **"Yes")** of the following is true **(please tick)** All Subjects All Subjects capable of being consulted. None of the subjects	Yes	NoOne
The consent document includes a signature line for a legally authorized representative.	Yes	No
2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be"Yes")		
The proposed plan for the assessment of the capacity to consent is adequate.	Yes	No
The objectives of the trial cannot be met by means of study of subjects who can give consent personally.	Yes	No
The foreseeable risks to the subjects are low.	Yes	No
The negative impact on the subject's well-being is minimized and low.	Yes	No
The trial is not prohibited by law.	Yes	No
Subjects have a disease or condition for which the procedures in the research are intended.	Yes	No

Primary Reviewer Name & signature _____ Date _____

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Annexure - 17: Checklist for Research Involving Students, Employees or Residents

IEC protocol no. _____

Name of Principal Investigator _____

Subjects who are students, employees or residents require special considerations.

Does the employer or supervisor of the research subject need to be aware of theresearch project?	No	Yes
Is there a letter of support and/ or internal services checklist?	No	Yes
Have the subjects been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	No	Yes
Have the risks to subjects been minimized?	No	Yes
Have subjects been assured that participation is voluntary (no signs of coercion)?	No	Yes
Have subjects been assured that confidentiality will be protected or maintained?	No	Yes

Comments:

Primary Reviewer Name & signature _____ Date _____

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Annexure - 18: Checklist for Genetic Research

IEC protocol no. _____

Name of Principal Investigator _____

	Yes	No
Will the samples be made anonymous to maintain confidentiality? If yes, stop here		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
Has the appropriateness of the various strategies for recruiting subjects and their family members been considered?		
Does the proposed study population comprise family members?		
Will family members be implicated in the studies without consent?		
Will the samples be destroyed in the future?		
Is genetic counseling being offered?		

Comments:

Primary Reviewer Name & signature _____ Date _____

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Annexure - 19: Site Monitoring Visit (SMV) Report

(To be completed by IEC monitor)

IEC Protocol No.				Date of the Visit:
Study Title:				
Principal Investigators:				
Department:				
Total number of participants enrolled:		Total participants ongoing:		
No. of participants completed:		No. of drop outs including reasons:		
Sr		**Yes**	**No**	**Comment**
1	Are the present study team membersas per the list approved by the IEC			
2	Are site facilities appropriate?			
3	Is recent version of Informed ConsentDocument (ICD) used?			
4	Is it approved by the IEC?			
5	Whether consent has been taken fromall patients?			
6	Whether appropriate vernacular consent has been used?			
7	Any other findings noted about theICDs			
8	Is recent version of protocol used?			
9	Is it approved by the IEC?			
	Any adverse events found?			
11	Any SAEs found?			
12	Were the SAEs informed to IEC within24 hours?			
13	Any there any protocol non-compliance deviations/violations?			
14	Have the protocol non- compliance deviations/violations been informed to IEC			

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15	Are all Case Record Forms up to date?			
16	Are storage of data and investigating products locked?			
17	Any safety concern for study participants?			
18	Audio Video Recording of Informed Consent review (If Applicable)			
19	Interview of PI, Study Team member, study Participants (If Applicable)			
20	Any outstanding tasks or results of visit?			
21	Duration of visit:_____hours	Started From		Finished To
22	Name and signs of IEC members and representatives who attended the monitoring visit:	1		
		2		
		3		

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Final Decision at the IEC meeting held on:

Chairperson, IEC
Signature with date

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Annexure - 20: Application Form for Requesting Waiver of Consent

1) Principal Investigator's name: _____
2) Department:
3) Title of project:
4) Names of other participating staff and students:
5) Request for waiver of informed consent:

   Please check the reason(s) for requesting waiver (Please refer the back of thisannexure for criteria that will be used by IEC to consider waiver of consent).

   - ☐ Research involves 'not more than minimal risk'
   - ☐ There is no direct contact between the researcher and participant in emergency situations as described in ICMR Guidelines (ICMR 2006 Guidelines- http://www.icmr.nic.in/ethical_guidelines.pdf)
   - ☐ Any other (please specify) ……..
6) Statements assuring that the rights of the participants are not violated
7) State the measures described in the Protocol for protecting confidentiality of data and privacyof research participant

---

Principal Investigator's signature with date:

Final decision at full board meeting held on: ……./……/……

Waiver granted: Yes / No.

If not granted, reasons: ……

……

Signature of the Chairperson with Date:

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Type of research projects which may qualify for consent waiver:

A request to waive written informed consent must be accompanied by a detailed explanation.

The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants.

The following criteria (ICMR GCP guidelines) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to participants. (*ICMR GCP guidelines)* e.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life].

2. When it is impractical to conduct research since confidentiality of personally identifiable information must be maintained throughout research as maybe required by the sensitivity of the research objective. *(ICMR GCP guidelines)* E.g. *conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS/conducting phone interviews with homosexuals.*

The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the IRB.

[In case of telephonic interviews, waiver of written informed consent may be requested butthis does not mean that verbal consent cannot be utilized].

The following points need to be considered.

3. The following documents need to be submitted for the IRB review. A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.

4. The interview schedule (questions to be asked???) will confirm that the interview is a simple 5 minute call and that no questions are asked that compromise a person's confidentiality or position.

5. Normally, investigators will be asked to keep a log of those who were approached about the study, and offered verbal consent. A simple chart can indicate the participants as participant 1, participant 2, and participant 3. A column can indicatethat verbal consent was given and a date. Since a specific number of study participants are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more participants than they originally requested.

6. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies. (ICMR 2017) guidelines

7. Research on anonymized biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from

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repositories or registries etc. (ICMR GCP guidelines)

8. In emergency situations when no surrogate consents can be taken. (ICMR GCP guidelines) when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IRB can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he/she gains consciousness or to relative/ legal guardian when available later.

References:

1. Ethical Guidelines for Biomedical research on Human Participants, ICMR 2006 http://www.icmr.nic.in/ethical_guidelines.pdf.

2. 45CFR Title 45 Public Welfare (45 CFR 46) Protection of human subjects, Department of Health and Human Services, revised June 23, 2005. Website http://www.hhs.gov/ohrp/humansubjects/guidance/45 CFR 46.htm, paragraph 46.116- 'General Requirements for Informed Consent'.

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Annexure - 21: IEC Self-Assessment Tool

Institutional Ethics Committee (IEC), MGM Dental College & Hospital, Kamothe, Navi Mumbai

Total Maximum Score – 50

(Please give Score 1 for Response 'Yes' and 0 for Response 'No')

Sr.	Sections	Response			
		Yes	No	Score	Comments *(If any)*
Section I: Organizational Aspects					
1	Whether IEC is established under the highest authority of the Institute i.e. Head of Institute and availability of documented evidence to support it?				
2	Whether IEC have documented policy to ensure its independency in functioning and decision making?				
3	Does the IEC have documented evidence to confirm appointment of Chairperson and all IEC members by Head of Institute?				
4	Does the IEC have a policy for signing Confidentiality Agreement for all members at time of appointment and documented evidence to support it?				
5	Does the institution/organization regularly evaluate the operations of the IEC (e.g., budgetary needs, adequacy of material resources, adequacy of policies and procedures and practices, the training requirements of the IEC members				
Section II: Membership, Qualification And Training					
6	Does the current membership of IEC comply with quorum requirements as per applicable rules and regulations?				
7	Does IEC maintain updated educational records (i.e Curriculum Vitae, Medical registration certificate or any other supporting documents etc.) of all members?				
8	Do all the members of IEC attend ICH-GCP training or ICH- GCP refresher training at least once in every 2 years?				
9	Do all members of IEC attend updated SOPs training and can provide SOP training records?				
Section III: Managing Conflict Of Interest					
10	Does the IEC have a policy for disclosure and management of potential conflicts of interest for members of the research team?				
11	Does IEC ask all members to declare written conflict of interest at time of appointment?				
12	Does IEC chairperson ask all members to declare written conflict of interest for study projects to be discussed at start of every meeting?				
13	Do the minutes reflect that members were asked whether they had a conflict of interest regarding any of the protocols to be discussed and indicate that such members did not participate in the decision making process of the relevant protocols?				

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Section IV: Initial Review of Projects					
14	Are the New study projects submitted to IEC as per the checklist provided in IEC SOPs				
15	Do the IEC members receive protocol and other study related documents (initial dossier) either as soft copy or hard copy at a specified time prior to IEC meeting?				
16	Does the IEC review the investigator's qualification and experience in clinical trials to conduct the study and check his/her ICH-GCP training records?				
17	Does the IEC review adequacy of study team including the supporting staff and facilities available to conduct the study at the site?				
18	Does the IEC perform the risk benefits assessment; evaluate the benefit against risks involved to the human subjects while participating in the research project?				
19	Does IEC review Clinical Trial Agreement including study budget for every clinical trial?				
20	Does the IEC consider whether the study sponsor/PI has adequate insurance to cover treatment of injury related to the study?				
21	Does IEC review English and other vernacular informed consent documents for adequate information provided to study participants?				
22	Does IEC confirm the presence of 24 hr contact details of Investigator in case of emergency and contact details of IEC in the Informed Consent Documents for research participants to raise any issue related to their rights, safety and integrity?				
23	Compensation of study related injury or death occurred during study periods in Informed Consent Documents?				
24	Does the IEC follow IEC SOP regarding the decisions for approval or disapproval for the study is made?				
25	Does the IEC follow IEC SOP for communicating the study decision to the investigator?				
26	Does the IEC ensure approval from regulatory body before issuing final IEC approval letter to Principal Investigator?				
27	Does the IEC mention approval duration and timeline for submission of periodic study reports in IEC approval letter?				
28	Does the IEC ensure final CTRI registration of Clinical trial which includes the name of PI, Site and IEC before enrollment of first subject at site?				
29	Does the IEC follow SOPs for reviewing research projects involving vulnerable participants and				
30	Does the IEC follow IEC SOP that lists conditions requiring wavier of ICF?				
Section V: Agenda and Minutes of Meetings					
31	Does the member secretary of IEC circulate agenda prior to Full board meeting as per timeline mentioned in SOPs to all members?				
32	Is the Required Quorum as per regulations met for all full Board meeting conducted by IEC?				

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33	Does the member secretary of IEC circulate agenda prior to Full board meeting as per timeline mentioned in SOPs to all members?				
34	Is the Required Quorum as per regulations met for all full Board meeting conducted by IEC?				
Section VI: Ongoing Review of Projects					
35	Does the IEC review continuing review reports andstudy completion report submitted by Principal Investigator in Full Board meeting?				
36	Does the IEC ensure submission of safety updates i.e list of adverse event occurred at site along with continuing review report?				
37	Does the IEC review Protocol deviation/Violation or non compliance submitted by PI?				
38	Does the IEC take required action against the investigator in case of violation, deviation, non compliance or in condition where patient safety has been compromised which has been identified during continuing review process?				
Section VII: Review of Serious Adverse Events					
39	Does the IEC follow strict timelines with regard to SAE Analysis (Initial and FU Review), Compensation Calculation and reporting to the licensing authority within the stipulated time?				
40	Does the IEC check whether compensation is paid to patient and whether amount is verified by IEC?				
41	Does the IEC verify whether adequate medical care is provided for serious adverse events as per applicable rules and regulations?				
Section VIII: Periodic Monitoring					
42	Does the IEC periodically monitor ongoing research project as per procedures defined in IEC SOPs?				
43	Are the Monitoring reports discussed in Full Board meeting and does the IEC communicate the follow up with the PI for closure of action items including preventive and corrective actions?				
Section IX: Research Participant's Rights					
44	Does the IEC ensure display of research participant's rights and responsibilities at research sites and IEC office?				
45	Does the IEC have a mechanism whereby enrolled research participants can file complaints or direct concerns regarding research participant's rights, safety and well being?				
Section X: Resources					
46	Does the IEC have its own yearly budget including budget for training of administrative staff and IEC members?				
47	Does the IEC have Full time administrative staff to mange administrative function on day to day basis?				
48	Does the IEC have resources/infrastructure i.e. Separate Office room, access to a meeting room, computer and printer, documents storage areas etc.?				

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Section XI: Storage And Archival					
49	Does the IEC store one hard copy and one soft copy of all documents and communications submitted to IEC of ongoing research projects under secure and protected place?				
50	Does the IEC archive documents (1 soft copy and 1 Hard copy) for at least 5 years from date of study closeout/ termination?				

SCORING

Section	Title	Maximum Score	Obtained Score
I	Organizational Aspects	5	
II	Membership, Qualification And Training	4	
III	Managing Conflict Of Interest	4	
IV	Initial Review Of Projects	17	
V	Agenda And Minutes Of Meetings	4	
VI	Ongoing Review Of Projects	4	
VII	Review Of Serious Adverse Events	3	
VIII	Periodic Monitoring	2	
IX	Research Participants Rights	2	
X	Resources	3	
XI	Storage And Archival	2	
	Total Score	**50**	

Six Monthly Performance of (IEC), MGM Dental College & Hospital, Kamothe, Navi Mumbai

Items	Period: From-to
Number of Full Board meetings	
Number of new protocols reviewed in full board meetings	
Number of protocols disapproved in full board meetings	
Number of Amended study protocols reviewed in Full Board	
Number of continuing review report/ study completion reports reviewed in Full Board	
Number of serious adverse Events (at site) reviewed	
Number of protocol deviation/Violation reviewed	
Number of Monitoring visits of ongoing studies	

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Period of Self-Assessment	From_____to_____	
Date of Self -Assessment:		
Duration		
Name of reviewer	Sign	Date
1.		
2.		
3.		
4.		
Presented in Full Board Meetingdated		
Sign and Date ofChairperson		

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Annexure - 22: Rights and Responsibilities of Research Participants

A. Rights of Research Participants

1. Right to information about Research study in an understandable language.
2. Right to informed consent before participation in any research study
3. Right to information on the expected cost of treatment, duration, alternative treatment available traveling or any other compensation provided for participation
4. Right to personal dignity, privacy and confidentiality
5. Right to get the information on plan of care
6. Right to uniform care for all classes of patients.
7. Right to information on how to voice a complaint against any violation in rightsand integrity (e.g. Ethics committee contact details)
8. Right to get 24 hours emergency contact details of Research doctor
9. Right to refusal of participation or withdrawal of participation any point ofstudy without disclosing any reason.
10. Rights to get information on medical management of any injury and compensationin case of any study related injury or death
11. Right to confidentiality of patient information/details recorded in the hospital.
12. Right to access clinical records.

B. Responsibilities of Research Participants

1. Provide complete and accurate information about:
   - Your health including present and past illness, hospitalization, medicationand allergies and surgeries.
   - Full name, address and other information.
   - Medical Insurance.
2. To follow the prescribed treatment plan, schedule and instructions given bydoctors carefully.
3. To ask question when he/she does not understand what the Doctors orother healthcare team members tells about diagnosis or treatment.
4. Not to take any medications without the knowledge of Doctor andhealthcare professional.
5. To accept the measures taken by the Hospital to ensure personal privacyand confidentiality of medical records.
6. To inform your study doctor immediately in case of any injury or development ofany new medical conditions.
7. Treat hospital staff, other patients and other visitors with courtesy.

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Annexure - 23: Risk-Benefit Assessment Tool

HIGH RISK /LOW BENEFIT (CLASS – A)	HIGH RISK / HIGH BENEFIT (CLASS – B)
BENEFITS	**RISKS**
• Completely new drug/formulation • Highly Toxic substances • Safety/Effectiveness not established through earlier studies • High incidence of SAEs/side effects in prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large no. Of participants • Violation legal/statutory regulations • Inadequate project documentation • Inadequate PI/Staff expertise • New/untried procedures	• Completely new drug/formulation • Highly Toxic substances • Safety/Effectiveness not established through earlier studies • High incidence of SAEs/side effects in prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large no. of participants • Violation legal/statutory regulations • Inadequate project documentation • Inadequate PI/Staff expertise • New/untried procedures
BENEFITS	**RISKS**
• Cost of treatment/drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No post trial alternatives	• Completely new cure • Preventive for life i.e. Vaccinations • Significant improvement over existing cures/treatments • Minimal side effects visa vis existing treatments • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs/mode (ex. Pelvis surgery) • Extension of benefits /availability of Treatment post trial • Benefits large no. of participants

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HIGH RISK /LOW BENEFIT (CLASS – C)	HIGH RISK / HIGH BENEFIT (CLASS – D)
BENEFITS	**RISKS**
• Proven/Acceptable toxicity • Proven safety and efficacy • Drug/formulation variation of approved drug/class of drugs • SAEs indicate minor/acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure/leakage possibilities • Minimal risk to legal/statutory regulations • Standard operating/surgical procedures	• Proven/Acceptable toxicity • Proven safety and efficacy • Drug/formulation a variation of approved drug/class of drugs • SAEs indicate minor/acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure/leakage possibilities • Minimal risk to legal/statutory regulations • Standard operating/ surgical procedures
BENEFITS	**RISKS**
• Cost of treatment/drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No post trial alternatives	• Completely new cure • Preventive for life i.e. Vaccinations • Significant improvement over existing cures/treatments • Minimal side effects visa vis existing treatments • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs/mode (ex. Pill vs surgery) • Extension of benefits / availability of treatment post trial • Benefits large no. of patients

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SOP Version 4 dt. January 2024
DCGI Registration # EC/RENEW/INST/2024/16844
SOP Version 4 dt. January 2024
DCGI Registration # EC/RENEW/INST/2024/16844

Annexure - 24: Undertaking by the Investigator

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there isno Principal Investigator)

2. Name and address of the medical college, hospital or other facility where the clinical trial will be conducted: Education, training & experience that qualify the Investigator for the clinical trial(Attach details including Medical Council registration number, and / or any other statement(s) of qualification(s))

   Medical Council Registration Number:.....

   CV Attached:.....

3. Name and address of all clinical laboratory facilities to be used in the study.

4. Name and address of the Review board that is responsible for approval and continuing reviewof the study.

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   Kamothe, Navi Mumbai
   District – Thane Pin: 410209, Maharashtra,
   INDIAPhone No: 022 27436604
   Mail: iercmgmdch@gmail.com or
   mgmdch@mgmmumbai.ac.inWeb Site:
   www.mgmdchnavimumbai.edu.in

5. Names of the other members of the research team (Co- or sub-Investigators) who willbe assisting the Investigator in the conduct of the investigation (s).

6. Protocol Title and Study number (if any) of the clinical trial to be conducted by the Investigator.
   "……
   ……
   ……"

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7. Commitments:

a. I have reviewed the clinical protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Review board and regulatory approvals have been obtained.
b. I agree to conduct the study in accordance with the current protocol. I will not\ implement any deviation from or changes of the protocol without agreement by the Sponsor and prior review and documented approval/ favorable opinion from the Review board of the amendment, except where necessary to eliminate an immediate hazard(s) to the trial Subjects or when the change(s) involved are only logistical or administrative in nature.
c. I agree to personally conduct and/or supervise the clinical trial at my site.
d. I agree to inform all subjects that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent and review board review and approval specified in the GCP guidelinesare met.
e. I agree to report to the Sponsor all adverse experiences that occur in the course ofthe investigation(s) in accordance with the regulatory and GCP guidelines.
f. I have read and understood the information in the Investigator's brochure,including the potential risks and side effects of the drug.
g. I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about their obligations in meeting their commitments in the trial.
h. I agree to maintain adequate and accurate records and to make those records available for audit / inspection by the Sponsor, Review board, Licensing Authority or their authorized representatives, in accordance with regulatory and GCP provisions. I will fully cooperate with any study related audit conducted by regulatory officials or authorized representatives of the Sponsor.
i. I agree to promptly report to the Review board all changes in the clinical trial activities and all unanticipated problems involving risks to human Subjects or others.
j. I agree to inform all unexpected serious adverse events to the Sponsor as well asthe Review board within seven days of their occurrence.
k. I will maintain confidentiality of the identification of all participating study patientsand assure security and confidentiality of study data.
l. I will not enroll any subject prior to registration of this study at the clinical trialregistry of India (www.ctri.nic.in).
m. I agree to comply with all other requirements, guidelines and statutory obligations as applicable to clinical Investigators participating in clinical trials.

Signature of Investigator with Date

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Annexure - 25: Format for Communication of IEC decision to the Investigator

<Date>

To,
<Investigator Name>
<Designation, Address>
<Contact Details>

Reference: *<Protocol title with version & date>*

Dear Dr._____

The Institutional Ethics Committee (IEC) of MGM Dental College & Hospital, Kamothe, NaviMumbai has reviewed and discussed your application to conduct the clinical study entitled *<Protocol title with version & date>* on

<date>.The following documents were

reviewed:

a) Study-protocol synopsis
b) Study Protocol (including protocol amendments), dated_____ Version No(s)_____
c) Participant Information Sheet (PIS) and Informed Consent Form (ICF) including updates ifany in English and/ or vernacular language.
d) Investigator's Brochure (IB), dated_____ Version No._____
e) Official prescribing information for products which are marketed in India/other countries /scientific literature of the drug substance or product supporting the use of the drug in thesaid indication.
f) Regulatory status of the new drug in India and developed countries.
g) Approval of the DCGI no._____ dt._____ (if applicable).
h) Proposed methods for patient accrual including advertisement (s) etc. proposed to be usedfor the purpose.
i) Principal Investigator's current CV.
j) Insurance Policy / Compensation for participation and for serious adverse eventsoccurring during the study participation.
k) Investigator's Agreement with the Sponsor/CRO.
l) Details of research grant (if any)
m) Investigator's Undertaking (Annexure – 24).

The following members of the review board were present at the meeting held on (date, time, andplace) and voted:

1. _____Chairman of the Review board
2. _____Member secretary of the Review board
3. _____Name of each member with designation

None of the study team members including principal investigator were a part of the voting procedure.

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DECISION

- The IEC hereby approves the study to be conducted in its presented form. – The validity of this approval is for the duration of the study period.
- Applicable mandatory regulatory and other permissions to be obtained prior tocommencement of the study.
- The investigator team members should be trained on the protocol & protocol related proceduresand the Good Clinical Practices (GCP) Guidelines prior to commencing the study.
- The study to be registered at the "Clinical Trials Registry – India (CTRI)" at "http://ctri.nic.in"before commencement of study subjects (first patient in (FPI)).
- Participating subjects should not be put to additional financial burden due to participation inthe study.
- The IEC is required to be informed about the following:
    1. Periodic safety update reports (PSUR).
    2. Any other safety related information received by the PI from sponsor/CRO/anyother source to be communicated to the IEC immediately.
    3. Any SAE occurring during the study to be communicated within 24 hours ofinformation to the IEC and the sponsor/CRO.
    4. Progress of the study to be reported annually to the IEC.
    5. Any amendments/changes in the protocol and/or patient information / informedconsent document.
    6. To provide an abridged copy of the final report after completion of the study.

Yours sincerely,

Chairperson / Member

SecretaryIEC

<Seal of IEC>

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Annexure - 26: IEC Review process fees

Projects	Type of submission	IEC Fees
Investigator initiated Academic Projects	Any submission	Rs. 1000/-
Government sponsored projects	Initial submission	INR 20,000/- plus taxes
	Study protocol document amendments (if full meeting required)	INR 10,000/- plus taxes
Industries sponsored projects	Regular submission	INR 50,000/- plus taxes
	Expedited submission	INR 80,000/- plus taxes
	Amendment to Protocol or study documents	INR 10,000/- plus taxes

Mode of payment : Cheque/DD/NEFT
Bank Details:
Savings A/C # 0183104000108263

IDBI Bank,
CBD – Belapur, Sec – 11,
Navi Mumbai
RTGS/ NEFT IFCS code – IBKL0000183

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Annexure - 27: IEC Re-registration certificate with DCGI

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MAHATMA GANDHI MISSION'S DENTAL COLLEGE & HOSPITAL
(Accredited by NAAC with A++ Grade)
INSTITUTIONAL ETHICS COMMITTEE
Junction of NH-4 and Sion Panvel Expressway,
Sector-1, Kamothe, Navi Mumbai- 410 209
E-Mail ID :iercmgmdch@gmail.com

MGMDCH/IEC/026 /2024

Date: 20/6/2024

IEC Circular No.26 /2024

This is to inform you that an Institutional Ethics Committee (IEC) meeting has been scheduled for Monday, June 24, 2024, at 10:00 a.m. to discuss the following agenda points:

1. Confirmation of minutes of the previous IEC meeting.
2. Presentation, discussion, and scrutiny of the research protocol of a PhD student at MGM Dental College.
3. Any other point

For,

Dr. Shilpa Patel
Member Secretary
IEC MGMDCH

CC to:

- Co-Chairman (IEC)
- Members (IEC)
- Dean (MGMDCH)

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Kamothe, Navi Mumbai- 410 209
E-Mail ID: mgmdch@mgmmumbai.ac.in

Tel: 022- 27436604
Fax: 91-22-27433185

Record of attendance at Meeting

Meeting of: IERC MGMDCH

Subject: Scrutiny of PhD thesis & one external study.

Venue: Conference room MGMDCH Date: 24/6/2024 Time: 10 am to 11 am.

Sr. No	Name	Designation	Signature
1.	Himanshi Jindal	BDS, Student MSc GUH.	Himanshi
2.	Dr. Agraja Patil	PhD scholar (Periodontology)	Patil
3.			
4.			
5			
6.			
7.			
8.			
9			
10			
11.			
12.			
13.			
14.			
15.			

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Dean

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Tel: 022- 27436604
Fax:-91-22-27433185

Record of attendance at Meeting

Meeting of: IERC MGMDCH

Subject: scrutiny of PhD thesis.

Venue: Conference room Date: 24/6/2024 Time: 10 am to 11 am

Sr. No	Name	Designation	Signature
1.	Dr. Chandramani Patil		Patil
2.	Ms. Priyanka Sharma.		Priya
3.	Dr. VINEET KINI	Professor Periodontics	[illegible]
4.	Dr. Jyoti Nadpal	member	[illegible]
5.	Dr NIKHIL V BHANDARKAR	member	[illegible]
6.	Dr. Rupali Gujar	Member	[illegible]
7.	Dr. Deepak Langde	Chairman	[illegible]
8.	Dr. Nilesh. V. Joshi	member	[illegible]
9.	Dr. Shakeel Dhanjurwale	Basic medical member	Dhanjurwale 24/Jun/2024
10.	Dr Usha Asnani	Prof/member	Asnani
11.	Dr. Samantaini	member	[illegible]
12.	Dr Sheela S Hosamani	member	[illegible]
13.	Dr Shraddha Ghaisas		Ghaisas
14.			
15.			

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MAHATMA GANDHI MISSION'S DENTAL COLLEGE & HOSPITAL
INSTITUTIONAL ETHICAL COMMITTEE
Junction of NH-4 and Sion Panvel Expressway,
Sector-1, Kamothe, Navi Mumbai- 410 209
E-Mail ID: mgmdch@mgmmumbai.ac.in
IEC MEETING -24/06/2024

SR. NO.	IEC NUMBER	INVESTIGATORS	TITLE OF STUDY	COMMENTS
Department of Periodontology				
1.	MGM/DCH/IEC/159 /2024	Dr. Vaibhav Thakkar	Perspectives of Oral Health Care Providers on Adult Oral Health Promotion in Urban and Rural Settings in Mumbai Metropolitan Region - A qualitative study.	• Title may change.
Department of Public Health Dentistry				
2.	MGM/DCH/IEC/160 /2024	Dr. Agraja Patil	Development and Validation of a Periodontal tissue healing scale.	• Proposal found satisfactory.

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24/6/2024

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IEC MEETING -24/06/2024

SR. NO.	IEC NUMBER	INVESTIGATORS	TITLE OF STUDY	COMMENTS
Department of Periodontology				
1.	MGM/DCH/IEC/159 /2024	Dr. Vaibhav Thakkar	Perspectives of Oral Health Care Providers on Adult Oral Health Promotion in Urban and Rural Settings in Mumbai Metropolitan Region - A qualitative study.	- Revise sampling method - should be more specific. - How will you overcome biases.
Department of Public Health Dentistry				
2.	MGM/DCH/IEC/160 /2024	Dr. Agraja Patil	Development and Validation of a Periodontal tissue healing scale.	V. good presentation

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IEC MEETING -24/06/2024

SR. NO.	IEC NUMBER	INVESTIGATORS	TITLE OF STUDY	COMMENTS
			Department of Periodontology	
1.	MGM/DCH/IEC/159 /2024	Dr. Vaibhav Thakkar	Perspectives of Oral Health Care Providers on Adult Oral Health Promotion in Urban and Rural Settings in Mumbai Metropolitan Region - A qualitative study.	• Title & aim mismatch. • Modify ~~Title~~ & Aim & objective. • Sampling technique.
			Department of Public Health Dentistry	
2.	MGM/DCH/IEC/160 /2024	Dr. Agraja Patil	Development and Validation of a Periodontal tissue healing scale.	• NO ethical concerns.

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Dr NIKHIL BHANUSHALI
24/6/24

Dr. Nilesh. V. Joshi

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SR. NO.	IEC NUMBER	INVESTIGATORS	TITLE OF STUDY	COMMENTS
Department of Periodontology				
1.	MGM/DCH/IEC/159 /2024	Dr. Vaibhav Thakkar	Perspectives of Oral Health Care Providers on Adult Oral Health Promotion in Urban and Rural Settings in Mumbai Metropolitan Region - A qualitative study.	• In-depth interview settings. • • • • •
Department of Public Health Dentistry				
2.	MGM/DCH/IEC/160 /2024	Dr. Agraja Patil	Development and Validation of a Periodontal tissue healing scale.	• Is there any comparative index, if there • it is not mentioned. • • • •

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(Dr. Nilesh. V. Joshi).

Ms. Priyanka Sharma.
Member
24/6/24.

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SR. NO.	IEC NUMBER	INVESTIGATORS	TITLE OF STUDY	COMMENTS
			Department of Periodontology	
1.	MGM/DCH/IEC/159 /2024	Dr. Vaibhav Thakkar	Perspectives of Oral Health Care Providers on Adult Oral Health Promotion in Urban and Rural Settings in Mumbai Metropolitan Region - A qualitative study.	• Interview in Englis/Hindi ✓ • Consent / Validity / Reliability of both questionnaire ✓
			Department of Public Health Dentistry	
2.	MGM/DCH/IEC/160 /2024	Dr. Agraja Patil	Development and Validation of a Periodontal tissue healing scale.	• Images to be evaluated in which application? ✓ • Consent form for the patients, their images will be used for research? ✓ • Consent form for the patient perspective? ✓ - ~~Free~~

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- Dr. Shakeeb Dhorajiwala
- Basic Medical Scientist

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IEC MEETING -24/06/2024

SR. NO.	IEC NUMBER	INVESTIGATORS	TITLE OF STUDY	COMMENTS
Department of Periodontology				
1.	MGM/DCH/IEC/159 /2024	Dr. Vaibhav Thakkar	Perspectives of Oral Health Care Providers on Adult Oral Health Promotion in Urban and Rural Settings in Mumbai Metropolitan Region - A qualitative study.	(1) Please clarify sampling frame (2) How will you address the limitations since its been listed in the protocol. Give some measures to address limitations.
Department of Public Health Dentistry				
2.	MGM/DCH/IEC/160 /2024	Dr. Agraja Patil	Development and Validation of a Periodontal tissue healing scale.	Please elaborate procedure of training to be provided to implenters of scale (PG students, experts) to ensure uniformity of inference.

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IEC MEETING -24/06/2024

Dr. Deepak Langde

SR. NO.	IEC NUMBER	INVESTIGATORS	TITLE OF STUDY	COMMENTS
			Department of Periodontology	
1.	MGM/DCH/IEC/159 /2024	Dr. Vaibhav Thakkar	Perspectives of Oral Health Care Providers on Adult Oral Health Promotion in Urban and Rural Settings in Mumbai Metropolitan Region - A qualitative study.	• Revise title, aim, objective • – • – • Approved
			Department of Public Health Dentistry	
2.	MGM/DCH/IEC/160 /2024	Dr. Agraja Patil	Development and Validation of a Periodontal tissue healing scale.	• Validation - 3 months. ? Face/Content validity • Domain identification. → Data reduction • Sample size ?? • ROC • Approved

24/6/24

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E-Mail ID :iercmgmdch@gmail.com

MGMDCH/IEC/021 /2024 Date: 15/4/2024

IEC Circular No. 21 /2024

This is to inform that an Institutional Ethics Committee (IEC) full-board meeting has been scheduled on Thursday, 18th April, 2024 at 10:00AM to discuss the following agenda points:

1. Confirmation of minutes of previous IEC meeting.
2. Presentation, discussion and scrutiny of research protocols of MGM Dental College and Hospital.
3. Any other point

Dr. Shilpa Patel
Member Secretary
IEC MGMDCH

CC to:

- Co-Chairman (IEC)
- Members (IEC)
- Dean (MGMDCH)

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Kamothe, Navi Mumbai- 410 209
E-Mail ID: mgmdch@mgmmumbai.ac.in

Tel: 022- 27436604
Fax: 91-22-27433185

Record of attendance at Meeting

Meeting of: IEC.

Subject: Review of MGMDCH Protocols.

Venue: Conference room Date: 18/04/2024 Time: 10.00 A.M

Sr. No	Name	Designation	Signature
1.	Dr Deepak Langade	Chairman	
2.	Dr. Ashwin Jawdekar	Member	
3.	Dr. Shilpa. Patel	Member Secretary	
4.	Dr. VINEET KINI	Member	
5	Dr. Ravindranath V K	Member	
6.	Dr. Jyoti Vadjye	Member	
7.	Dr Usha Asnani	member	
8.	Ms. Priyanka Sharma	Member	
9	Dr. Deepali Gujar	Member-Social	
10.	Dr. Shaheeb Dhorajiwala	Basic Medical Scientist	18/04/2024
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E-Mail ID: mgmdch@mgmmumbai.ac.in

Tel: 022- 27436604
Fax: 91-22-27433185

Record of attendance at Meeting (Guide attendance)

Meeting of: IEC

Subject: Scrutiny of research protocols of MGMDCH

Venue: Conference room MGMDCH Date: 18/4/24 Time: 10:00am

Sr. No	Name	Designation	Signature
1.	Dr Signa Pathak	Prof & Guide	Pathak
2.	Dr. Kamlesh Dekate	PG guide Reader	[illegible]
3.	Dr. Sujeet V. Kuite	Reader	[illegible]
4.	Dr. Jyoti Nandpee	Prof & HOD	[illegible]
5	Ramindranath. V. [illegible]	Prof & HOD	[illegible]
6.	Dr. Anjali Ghewade.	prof.	[illegible]
7.	DR. VINEET KINI	PERIODONTICS Professor + HOD	[illegible]
8.	Dr Shilpa patel	Pg guide	[illegible]
9	Dr Devendra [illegible]	Professor	[illegible]
10.	Dr Srivalli	Dean & OM	[illegible]
11.	Dr usha Arora	member	[illegible]
12.			
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IEC MEETING -18/04/2024
ATTENDANCE SHEET

SR NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE	SIGN
1.	IN/DCH/106/04/2024	Dr. Misbah Kamble	Evaluation of Transforming Growth factor β receptor type II protein and mRNA expression in low –risk and high-risk oral leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	
2.	IN/DCH/107/04/2024	Dr. Manali Sawant	Molecular characterization of Transforming Growth Factor β in low and high- risk Oral Leukoplakia and Healthy Oral Mucosa- A Prospective cross-sectional study.	
3.	IN/DCH/108/04/2024	Dr. Mehwish Khan	Analysis of Genomic and Proteomic expression of Transforming Growth Factor β In Clinico -histopathologically diagnosed cases of Oral Leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	
4.	IN/DCH/109/04/2024	Dr. Saveen Mohod	Effectiveness of 0.1% Hyaluronic acid with 0.2% Chlorhexidine Mouthrinse or 0.2 % Chlorhexidine Mouthrinse alone as adjunct to scaling and root planning on clinical parameters and salivary AST marker in Periodontitis : a clinico biochemical in vivo study.	
5.	IN/DCH/110/04/2024	Dr. Tanvi Sanjay Satpute	Assessment of antibiotic prescription practices and factors for improper antibiotic prescription among dental practitioners in Navi mumbai	
6.	IN/DCH/111/04/2024	Dr. Singh Madhulika Shailesh	Comparative assessment of Antimicrobial Effect of Zinc Oxide (ZnO) Nanoparticle coated Titianium Mini Implant against Oral Pathogens : A Split Mouth Randomized Controlled Trial	
7.	IN/DCH/112/04/2024	Dr. Gaury Yogesh	Comparative Evaluation Of The Bone Regeneration With And Without	

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		Agrawal	Use Of 3D Scaffold Matrix In Adult Patients In Defects Following Intra-alveolar Extraction Of Mandibular Molars- A Single Blinded Prospective Randomized Control Study	
8.	IN/DCH/113/04/2024	Dr. Sayali Depak Tadas	Comparative evaluation of postoperative analgesia achieved using Bupivacaine and Ropivacaine administered by Suprazygomatic Maxillary Nerve Block following cleft palate repair: A Randomised Control Operator Blind Study.	
9.	IN/DCH/114/04/2024	Dr. Ritesh Chhatwani	Comparative Evaluation of Rate Of Mucolization Of Residual Raw Areas Post Palatoplasty With Or Without Use Of Buccal Fat Pad In Cleft Palate – A Prospective Randomised Clinical Study.	
10.	IN/DCH/115/04/2024	Dr. Rushikesh Bhamare	Comparative Evaluation Of Accuracy Of Reduction Of Unilateral Zygomatic Complex Fracture Following Open Reduction And Internal Fixation With Or Without Use Of Virtual Surgical Planning And 3D Printed Guide – A Randomised Clinical Study.	
11.	IN/DCH/116/04/2024	Priyanshi Chhajwani	Evaluation of knowledge and awareness on Nasoalveolar Moulding in newborns with Cleft lip and Cleft palate among Obstetricians-Gynecologists practicing in Mumbai metropolitan.	
12.	IN/DCH/117/04/2024	Dr. Leena Patil	Comparative evaluation of effect of two different ultrasonic scaler tips on the surface characteristics of titanium surfaces-An invitro profilometric study	
13.	IN/DCH/118/04/2024	Dr. Chinmayi Rajpurohit	Comparative evaluation of surface roughness of treated titanium surfaces after different implantoplasty protocols by either carbide burs or diamond points- an in vitro profilometric study	
14.	IN/DCH/119/04/2024	Dr. Vedika Joshi	Comparison of surface characteristics of titanium surfaces following air polishing with erythritol or glycine powders– An in vitro profilometric study.	
15.	IN/DCH/120/04/2024	Dr. Sneha Marke	Effect of two different particle sizes of aluminium oxide with air polishing powder on titanium surfaces- An in vitro profilometric study.	
16.	IN/DCH/121/04/2024	Dr. Krupa Patil	Effect of air polishing with either glycine or bioactive glass based powder on surface characteristics of titanium surfaces and biofilm removal: An invitro study	
17.	IN/DCH/122/04/2024	Dr. Divena Choudhary	Comparative evaluation of bacterial adherence inhibition and surface characteristics of diode laser irradiated graphene oxide-coated and non-coated titanium surfaces: An invitro study	

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18.	IN/DCH/123/04/2024	Dr. Sunny Rohida	Comparative Evaluation Of Remineralisation Potential Of Ginger Extract Fortified With Nano Particles And CPP- ACPF On Demineralised Human Enamel: An Invitro Study.	
19.	IN/DCH/124/04/2024	Dr.Prashant Bhasge	Comparative Evaluation Of Remineralisation Potential Of Neem Extract Fortified Nano Particles CPP- ACPF On Demineralised Human Enamel: An Invitro Study.	
20.	IN/DCH/125/04/2024	Dr. Vaibhavi Chaurasia	Comparative Evaluation of Implant Stability Quotient and Temperature Rise in Low Density Bone Using Conventional and Osseodensification Osteotomy Techniques with Two Different Implant Designs: An In-Vitro Study.	
21.	IN/DCH/126/04/2024	Dr. Aasif Tadvi	Comparative Evaluation of Internal Fit Between Conventional, Milling And 3D Printing Method for Fabrication of Cast Partial Denture Frameworks: An In-Vitro Study.	
22.	IN/DCH/127/04/2024	Dr. Tanushree Mohta	Comparative Evaluation of the Shear Bond Strength between Dual Cure Resin Cement Infused With Nano, Micro and Hybrid Bioactive Glass Particles for Bonding Lithium Di-Silicate Restorations : An In-Vitro Study	
23.	IN/DCH/128/04/2024	Dr. Bhagyashree Shinde	Influence of stimulated parafunctional forces on stress distribution at bone implant interface in endosseous bone level implant with internal and external hex: Finite Element Analysis study.	
24.	IN/DCH/129/04/2024	Dr. Ashte Swaraj Gopalrao	Comparative Assessment Of Cephalometric Measurements Obtained By Artificial Intelligence Software (AI) Vs Digital Software:A 2D Cephalometric Study	
25.	IN/DCH/130/04/2024	Dr. Smriti Surendrakumar Tiwari	Comparative Assessment of Corrosion on TiN Coated Mini Implants when Subjected To Three Fluoride Based Mouthwashes: An In Vitro Study	
26.	IN/DCH/131/04/2024	Dr. Pradnya Korwar	A retrospective survey to study the prevalence of maternal modifiable risk factors leading to cleft lip and/or palate in cases reporting to a tertiary care centre in Navi Mumbai.	

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Dr. Shakeeb Dhorajiwala

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IEC MEETING -18/04/2024
RESEARCH PROTOCOLS

SR NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE	COMMENTS
1.	IN/DCH/106/04/2024	Dr. Misbah Kamble	Evaluation of Transforming Growth factor β receptor type II protein and mRNA expression in low –risk and high-risk oral leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	① • Sampling technique is not a non-probability type of sampling ? Yes then which one? ② Is CV of technician/pathology/CR required ? Yes Sol/U/P Professional Competence
2.	IN/DCH/107/04/2024	Dr. Manali Sawant	Molecular characterization of Transforming Growth Factor β in low and high- risk Oral Leukoplakia and Healthy Oral Mucosa- A Prospective cross-sectional study.	•
3.	IN/DCH/108/04/2024	Dr. Mehwish Khan	Analysis of Genomic and Proteomic expression of Transforming Growth Factor β In Clinico - histopathologically diagnosed cases of Oral Leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	• Recuse myself for having personal conflict of interest. Letter signed & dated
4.	IN/DCH/109/04/2024	Dr. Saveen Mohod	Effectiveness of 0.1% Hyaluronic acid with 0.2% Chlorhexidine Mouthrinse or 0.2 % Chlorhexidine Mouthrinse alone as adjunct to scaling and root planning on clinical parameters and salivary AST marker in Periodontitis : a clinico biochemical in vivo study.	•
5.	IN/DCH/110/04/2024	Dr. Tanvi Sanjay Satpute	Assessment of antibiotic prescription practices and factors for improper antibiotic prescription among dental practitioners in Navi mumbai	•

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6.	IN/DCH/111/04/2024	Dr. Singh Madhulika Shailesh	Comparative assessment of Antimicrobial Effect of Zinc Oxide (ZnO) Nanoparticle coated Titianium Mini Implant against Oral Pathogens : A Split Mouth Randomized Controlled Trial	•
7.	IN/DCH/112/04/2024	Dr. Gaury Yogesh Agrawal	Comparative Evaluation Of The Bone Regeneration With And Without Use Of 3D Scaffold Matrix In Adult Patients In Defects Following Intra-alveolar Extraction Of Mandibular Molars- A Single Blinded Prospective Randomized Control Study	•
8.	IN/DCH/113/04/2024	Dr. Sayali Depak Tadas	Comparative evaluation of postoperative analgesia achieved using Bupivacaine and Ropivacaine administered by Suprazygomatic Maxillary Nerve Block following cleft palate repair: A Randomised Control Operator Blind Study.	(1) • Dummy is who will be blinded? Kindly confirm
9.	IN/DCH/114/04/2024	Dr. Ritesh Chhatwani	Comparative Evaluation of Rate Of Mucolization Of Residual Raw Areas Post Palatoplasty With Or Without Use Of Buccal Fat Pad In Cleft Palate – A Prospective Randomised Clinical Study.	•
10.	IN/DCH/115/04/2024	Dr. Rushikesh Bhamare	Comparative Evaluation Of Accuracy Of Reduction Of Unilateral Zygomatic Complex Fracture Following Open Reduction And Internal Fixation With Or Without Use Of Virtual Surgical Planning And 3D Printed Guide – A Randomised Clinical Study.	• Need to rephrase Research question?
11.	IN/DCH/116/04/2024	Priyanshi Chhajwani	Evaluation of knowledge and awareness on Nasoalveolar Moulding in newborns with Cleft lip and Cleft palate among Obstetricians-Gynecologists practicing in Mumbai metropolitan.	•
12.	IN/DCH/117/04/2024	Dr. Leena Patil	Comparative evaluation of effect of two different ultrasonic scaler tips on the surface characteristics of titanium surfaces-An invitro profilometric study	
13.	IN/DCH/118/04/2024	Dr. Chinmayi Rajpurohit	Comparative evaluation of surface roughness of treated titanium surfaces after different implantoplasty protocols by either carbide burs or diamond points- an in vitro profilometric study	•

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14.	IN/DCH/119/04/2024	Dr. Vedika Joshi	Comparison of surface characteristics of titanium surfaces following air polishing with erythritol or glycine powders– An in vitro profilometric study.	•
15.	IN/DCH/120/04/2024	Dr. Sneha Marke	Effect of two different particle sizes of aluminium oxide with air polishing powder on titanium surfaces- An in vitro profilometric study.	•
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18.	IN/DCH/123/04/2024	Dr. Sunny Rohida	Comparative Evaluation Of Remineralisation Potential Of Ginger Extract Fortified With Nano Particles And CPP- ACPF On Demineralised Human Enamel: An Invitro Study.	•
19.	IN/DCH/124/04/2024	Dr.Prashant Bhasge	Comparative Evaluation Of Remineralisation Potential Of Neem Extract Fortified Nano Particles CPP- ACPF On Demineralised Human Enamel: An Invitro Study.	•
20.	IN/DCH/125/04/2024	Dr. Vaibhavi Chaurasia	Comparative Evaluation of Implant Stability Quotient and Temperature Rise in Low Density Bone Using Conventional and Osseodensification Osteotomy Techniques with Two Different Implant Designs: An In-Vitro Study.	•
21.	IN/DCH/126/04/2024	Dr. Aasif Tadvi	Comparative Evaluation of Internal Fit Between Conventional, Milling And 3D Printing Method for Fabrication of Cast Partial Denture Frameworks: An In-Vitro Study.	•
22.	IN/DCH/127/04/2024	Dr. Tanushree Mohta	Comparative Evaluation of the Shear Bond Strength between Dual Cure Resin Cement Infused With Nano, Micro and Hybrid Bioactive Glass Particles for Bonding Lithium Di-Silicate Restorations : An In-Vitro Study	•

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23.	IN/DCH/128/04/2024	Dr. Bhagyashree Shinde	Influence of stimulated parafunctional forces on stress distribution at bone implant interface in endosseous bone level implant with internal and external hex: Finite Element Analysis study.	•
24.	IN/DCH/129/04/2024	Dr. Ashte Swaraj Gopalrao	Comparative Assessment Of Cephalometric Measurements Obtained By Artificial Intelligence Software (AI) Vs Digital Software:A 2D Cephalometric Study	•
25.	IN/DCH/130/04/2024	Dr. Smriti Surendrakumar Tiwari	Comparative Assessment of Corrosion on TiN Coated Mini Implants when Subjected To Three Fluoride Based Mouthwashes: An In Vitro Study	•
26.	IN/DCH/131/04/2024	Dr. Pradnya Korwar	A retrospective survey to study the prevalence of maternal modifiable risk factors leading to cleft lip and/or palate in cases reporting to a tertiary care centre in Navi Mumbai.	•

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IEC MEETING -18/04/2024
RESEARCH PROTOCOLS

18/4/24

Dr Aaryaki Langade

SR NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE	COMMENTS
1.	IN/DCH/106/04/2024	Dr. Misbah Kamble	Evaluation of Transforming Growth factor β receptor type II protein and mRNA expression in low –risk and high-risk oral leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	•
2.	IN/DCH/107/04/2024	Dr. Manali Sawant	Molecular characterization of Transforming Growth Factor β in low and high- risk Oral Leukoplakia and Healthy Oral Mucosa- A Prospective cross-sectional study.	• PIS revision to include procedures. – Contact person sensi
3.	IN/DCH/108/04/2024	Dr. Mehwish Khan	Analysis of Genomic and Proteomic expression of Transforming Growth Factor β In Clinico histopathologically diagnosed cases of Oral Leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	•
4.	IN/DCH/109/04/2024	Dr. Saveen Mohod	Effectiveness of 0.1% Hyaluronic acid with 0.2% Chlorhexidine Mouthrinse or 0.2 % Chlorhexidine Mouthrinse alone as adjunct to scaling and root planning on clinical parameters and salivary AST marker in Periodontitis : a clinico biochemical in vivo study.	• Title – Design (RCT) – Observer blind study – PIS – randomization.
5.	IN/DCH/110/04/2024	Dr. Tanvi Sanjay Satpute	Assessment of antibiotic prescription practices and factors for improper antibiotic prescription among dental practitioners in Navi mumbai	Approved – Validate the survey Ques

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6.	IN/DCH/111/04/2024	Dr. Singh Madhulika Shailesh	Comparative assessment of Antimicrobial Effect of Zinc Oxide (ZnO) Nanoparticle coated Titianium Mini Implant ~~against Oral Pathogens~~ : A Split Mouth Randomized Controlled ~~Trial~~ Study	Title PIS Sterilization of coated implant coat material
7.	IN/DCH/112/04/2024	Dr. Gaury Yogesh Agrawal	Comparative Evaluation Of The Bone Regeneration With And Without Use Of 3D Scaffold Matrix In Adult Patients In Defects Following Intra-alveolar Extraction Of Mandibular Molars- A Single Blinded Prospective Randomized Control Study	Title Approved.
8.	IN/DCH/113/04/2024	Dr. Sayali Depak Tadas	Comparative evaluation of postoperative analgesia achieved using Bupivacaine and Ropivacaine administered by Suprazygomatic Maxillary Nerve Block following cleft palate repair: A Randomised Controlled ~~Operator~~ observer Blind Study.	Title
9.	IN/DCH/114/04/2024	Dr. Ritesh Chhatwani	~~Comparative Evaluation of~~ Rate Of Mucolization Of Residual Raw Areas Post Palatoplasty With Or Without Use Of Buccal Fat Pad In Cleft Palate – A Prospective Randomised ~~Clinical~~ Controlled Study.	Title. Objectives. (6 months.)
10.	IN/DCH/115/04/2024	Dr. Rushikesh Bhamare	Comparative Evaluation Of Accuracy Of Reduction Of Unilateral Zygomatic Complex Fracture Following Open Reduction And Internal Fixation With Or Without Use Of Virtual Surgical Planning And 3D Printed Guide – A Randomised Clinical Study.	Title
11.	IN/DCH/116/04/2024	Priyanshi Chhajwani	Evaluation of knowledge and awareness on Nasoalveolar Moulding in newborns with Cleft lip and Cleft palate among Obstetricians-Gynecologists practicing in Mumbai metropolitan.	Approved
12.	IN/DCH/117/04/2024	Dr. Leena Patil	Comparative evaluation of effect of two different ultrasonic scaler tips on the surface characteristics of titanium surfaces-An invitro profilometric study	Approved
13.	IN/DCH/118/04/2024	Dr. Chinmayi Rajpurohit	Comparative evaluation of surface roughness of treated titanium surfaces after different implantoplasty protocols by either carbide burs or diamond points- an in vitro profilometric study	Approved

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14.	IN/DCH/119/04/2024	Dr. Vedika Joshi	Comparison of surface characteristics of titanium surfaces following air polishing with erythritol or glycine powders– An in vitro profilometric study.	• Approved
15.	IN/DCH/120/04/2024	Dr. Sneha Marke	Effect of two different particle sizes of aluminium oxide with air polishing powder on titanium surfaces- An in vitro profilometric study.	•
16.	IN/DCH/121/04/2024	Dr. Krupa Patil	Effect of air polishing with either glycine or bioactive glass based powder on surface characteristics of titanium surfaces and biofilm removal: An invitro study	•
17.	IN/DCH/122/04/2024	Dr. Divena Choudhary	Comparative evaluation of bacterial adherence inhibition and surface characteristics of diode laser irradiated graphene oxide-coated and non-coated titanium surfaces: An invitro study	•
18.	IN/DCH/123/04/2024	Dr. Sunny Rohida	Comparative Evaluation Of Remineralisation Potential Of Ginger Extract Fortified With Nano Particles And CPP- ACPF On Demineralised Human Enamel: An Invitro Study.	•
19.	IN/DCH/124/04/2024	Dr.Prashant Bhasge	Comparative Evaluation Of Remineralisation Potential Of Neem Extract Fortified Nano Particles CPP- ACPF On Demineralised Human Enamel: An Invitro Study.	•
20.	IN/DCH/125/04/2024	Dr. Vaibhavi Chaurasia	Comparative Evaluation of Implant Stability Quotient and Temperature Rise in Low Density Bone Using Conventional and Osseodensification Osteotomy Techniques with Two Different Implant Designs: An In-Vitro Study.	• Approved
21.	IN/DCH/126/04/2024	Dr. Aasif Tadvi	Comparative Evaluation of Internal Fit Between Conventional, Milling And 3D Printing Method for Fabrication of Cast Partial Denture Frameworks: An In-Vitro Study.	•
22.	IN/DCH/127/04/2024	Dr. Tanushree Mohta	Comparative Evaluation of the Shear Bond Strength between Dual Cure Resin Cement Infused With Nano, Micro and Hybrid Bioactive Glass Particles for Bonding Lithium Di-Silicate Restorations : An In-Vitro Study	•

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23.	IN/DCH/128/04/2024	Dr. Bhagyashree Shinde	Influence of stimulated parafunctional forces on stress distribution at bone implant interface in endosseous bone level implant with internal and external hex: Finite Element Analysis study.	•
24.	IN/DCH/129/04/2024	Dr. Ashte Swaraj Gopalrao	Comparative Assessment Of Cephalometric Measurements Obtained By Artificial Intelligence Software (AI) Vs Digital Software:A 2D Cephalometric Study	•
25.	IN/DCH/130/04/2024	Dr. Smriti Surendrakumar Tiwari	Comparative Assessment of Corrosion on TiN Coated Mini Implants when Subjected To Three Fluoride Based Mouthwashes: An In Vitro Study	•
26.	IN/DCH/131/04/2024	Dr. Pradnya Korwar	A retrospective survey to study the prevalence of maternal modifiable risk factors leading to cleft lip and/or palate in cases reporting to a tertiary care centre in Navi Mumbai.	•

(Dr Deepak Langde)

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IEC MEETING -18/04/2024
RESEARCH PROTOCOLS

DR. ASHWIN JAWDEKAR

SR NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE	COMMENTS
1.	IN/DCH/106/04/2024	Dr. Misbah Kamble	Evaluation of Transforming Growth factor β receptor type II protein and mRNA expression in low –risk and high-risk oral leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	• Information sheet to be modified for the controlled group.
2.	IN/DCH/107/04/2024	Dr. Manali Sawant	Molecular characterization of Transforming Growth Factor β in low and high- risk Oral Leukoplakia and Healthy Oral Mucosa- A Prospective cross-sectional study.	•
3.	IN/DCH/108/04/2024	Dr. Mehwish Khan	Analysis of Genomic and Proteomic expression of Transforming Growth Factor β In Clinico - histopathologically diagnosed cases of Oral Leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	•
4.	IN/DCH/109/04/2024	Dr. Saveen Mohod	Effectiveness of 0.1% Hyaluronic acid with 0.2% Chlorhexidine Mouthrinse or 0.2 % Chlorhexidine Mouthrinse alone as adjunct to scaling and root planning on clinical parameters and salivary AST marker in Periodontitis : a clinico biochemical in vivo study.	• 'Randomized' study Details of randomization, blinding
5.	IN/DCH/110/04/2024	Dr. Tanvi Sanjay Satpute	Assessment of antibiotic prescription practices and factors for improper antibiotic prescription among dental practitioners in Navi mumbai	• Questionnaire validation is required.

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18/4/24

6.	IN/DCH/111/04/2024	Dr. Singh Madhulika Shailesh	Comparative assessment of Antimicrobial Effect of Zinc Oxide (ZnO) Nanoparticle coated Titianium Mini Implant ~~against Oral Pathogens~~ : A Split Mouth Randomized Controlled Trial	• Letter from manufacturer PICOS in the title
7.	IN/DCH/112/04/2024	Dr. Gaury Yogesh Agrawal	Comparative Evaluation Of The Bone Regeneration With And Without Use Of 3D Scaffold Matrix In Adult Patients In Defects Following Intra-alveolar Extraction Of Mandibular Molars- A Single Blinded Prospective Randomized Controlled Study	• Methods of randomization Flow chart ITT
8.	IN/DCH/113/04/2024	Dr. Sayali Depak Tadas	Comparative evaluation of postoperative analgesia achieved using % Bupivacaine and % Ropivacaine administered by Suprazygomatic Maxillary Nerve Block following cleft palate repair: A Randomised Controlled Operator Blind Study.	• Details of randomization
9.	IN/DCH/114/04/2024	Dr. Ritesh Chhatwani	Comparative Evaluation of Rate Of Mucolization Of Residual Raw Areas Post Palatoplasty ~~With Or Without~~ Using Buccal Fat Pad In Cleft Palate – A Prospective Randomised Clinical Study.	• Title ITT CONSORT flowchart details of randomization
10.	IN/DCH/115/04/2024	Dr. Rushikesh Bhamare	Comparative Evaluation Of Accuracy Of Reduction Of Unilateral Zygomatic Complex Fracture Following Open Reduction And Internal Fixation With Or Without Use Of Virtual Surgical Planning And 3D Printed Guide – A Randomised Clinical Study.	• modify title
11.	IN/DCH/116/04/2024	Priyanshi Chhajwani	Evaluation of knowledge and awareness on Nasoalveolar Moulding in newborns with Cleft lip and Cleft palate among Obstetricians-Gynecologists practicing in Mumbai metropolitan.	•
12.	IN/DCH/117/04/2024	Dr. Leena Patil	Comparative evaluation of effect of two different ultrasonic scaler tips on the surface characteristics of titanium surfaces-An invitro profilometric study	
13.	IN/DCH/118/04/2024	Dr. Chinmayi Rajpurohit	Comparative evaluation of surface roughness of treated titanium surfaces after different implantoplasty protocols by either carbide burs or diamond points- an in vitro profilometric study	•

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14.	IN/DCH/119/04/2024	Dr. Vedika Joshi	Comparison of surface characteristics of titanium surfaces following air polishing with erythritol or glycine powders– An in vitro profilometric study.	•
15.	IN/DCH/120/04/2024	Dr. Sneha Marke	Effect of two different particle sizes of aluminium oxide with air polishing powder on titanium surfaces- An in vitro profilometric study.	•
16.	IN/DCH/121/04/2024	Dr. Krupa Patil	Effect of air polishing with either glycine or bioactive glass based powder on surface characteristics of titanium surfaces and biofilm removal: An invitro study	•
17.	IN/DCH/122/04/2024	Dr. Divena Choudhary	Comparative evaluation of bacterial adherence inhibition and surface characteristics of diode laser irradiated graphene oxide-coated and non-coated titanium surfaces: An invitro study	•
18.	IN/DCH/123/04/2024	Dr. Sunny Rohida	Comparative Evaluation Of Remineralisation Potential Of Ginger Extract Fortified With Nano Particles And CPP- ACPF On Demineralised Human Enamel: An Invitro Study.	•
19.	IN/DCH/124/04/2024	Dr.Prashant Bhasge	Comparative Evaluation Of Remineralisation Potential Of Neem Extract Fortified Nano Particles CPP- ACPF On Demineralised Human Enamel: An Invitro Study.	•
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21.	IN/DCH/126/04/2024	Dr. Aasif Tadvi	Comparative Evaluation of Internal Fit Between Conventional, Milling And 3D Printing Method for Fabrication of Cast Partial Denture Frameworks: An In-Vitro Study.	•
22.	IN/DCH/127/04/2024	Dr. Tanushree Mohta	Comparative Evaluation of the Shear Bond Strength between Dual Cure Resin Cement Infused With Nano, Micro and Hybrid Bioactive Glass Particles for Bonding Lithium Di-Silicate Restorations : An In-Vitro Study	•

18/4/24

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23.	IN/DCH/128/04/2024	Dr. Bhagyashree Shinde	Influence of stimulated parafunctional forces on stress distribution at bone implant interface in endosseous bone level implant with internal and external hex: Finite Element Analysis study.	•
24.	IN/DCH/129/04/2024	Dr. Ashte Swaraj Gopalrao	Comparative Assessment Of Cephalometric Measurements Obtained By Artificial Intelligence Software (AI) Vs Digital Software:A 2D Cephalometric Study	•
25.	IN/DCH/130/04/2024	Dr. Smriti Surendrakumar Tiwari	Comparative Assessment of Corrosion on TiN Coated Mini Implants when Subjected To Three Fluoride Based Mouthwashes: An In Vitro Study	•
26.	IN/DCH/131/04/2024	Dr. Pradnya Korwar	A retrospective survey to study the prevalence of maternal modifiable risk factors leading to cleft lip and/or palate in cases reporting to a tertiary care centre in Navi Mumbai.	•

12/4/24

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IEC MEETING -18/04/2024
RESEARCH PROTOCOLS

SR NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE	COMMENTS
1.	IN/DCH/106/04/2024	Dr. Misbah Kamble	Evaluation of Transforming Growth factor β receptor type II protein and mRNA expression in low –risk and high-risk oral leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	• take consent of healthy participants.
2.	IN/DCH/107/04/2024	Dr. Manali Sawant	Molecular characterization of Transforming Growth Factor β in low and high- risk Oral Leukoplakia and Healthy Oral Mucosa- A Prospective cross-sectional study.	• "
3.	IN/DCH/108/04/2024	Dr. Mehwish Khan	Analysis of Genomic and Proteomic expression of Transforming Growth Factor β In Clinico - histopathologically diagnosed cases of Oral Leukoplakia and normal healthy mucosa- A prospective cross-sectional study.	• "
4.	IN/DCH/109/04/2024	Dr. Saveen Mohod	Effectiveness of 0.1% Hyaluronic acid with 0.2% Chlorhexidine Mouthrinse or 0.2 % Chlorhexidine Mouthrinse alone as adjunct to scaling and root planning on clinical parameters and salivary AST marker in Periodontitis : a clinico biochemical in vivo study.	• – use the word "Study" not "trail". –
5.	IN/DCH/110/04/2024	Dr. Tanvi Sanjay Satpute	Assessment of antibiotic prescription practices and factors for improper antibiotic prescription among dental practitioners in Navi mumbai	•

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10.	IN/DCH/115/04/2024	Dr. Rushikesh Bhamare	Comparative Evaluation Of Accuracy Of Reduction Of Unilateral Zygomatic Complex Fracture Following Open Reduction And Internal Fixation With Or Without Use Of Virtual Surgical Planning And 3D Printed Guide – A Randomised Clinical Study.	• Prospective randomised controlled study
11.	IN/DCH/116/04/2024	Priyanshi Chhajwani	Evaluation of knowledge and awareness on Nasoalveolar Moulding in newborns with Cleft lip and Cleft palate among Obstetricians-Gynecologists practicing in Mumbai metropolitan.	•
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25.	IN/DCH/130/04/2024	Dr. Smriti Surendrakumar Tiwari	Comparative Assessment of Corrosion on TiN Coated Mini Implants when Subjected To Three Fluoride Based Mouthwashes: An In Vitro Study	•
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MGMDCH/IEC/ 001 /2024 Date:30/01/2024

IEC Circular No. 001 /2024

This is to inform that an Institutional Ethics Committee (IEC) full-board meeting has been scheduled on Saturday, 03rd February, 2024 at 10:30AM to discuss the following agenda points:

1. Confirmation of minutes of previous IEC meeting
2. Presentation, discussion and scrutiny of research protocols of MGM School of Biomedical Sciences
3. Presentation, discussion and scrutiny of research protocols of MGM Dental College and Hospital
4. Scrutiny of research protocols of MGM College of Physiotherapy
5. Any other point

Dr. Shilpa Patel
Member Secretary
IEC MGMDCH

Dr. Shilpa Patel
Member Secretary
IEC, MGMDCH

CC to:

- Co-Chairman (IEC)
- Members (IEC)
- Dean (MGMDCH)

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Tel: 022- 27436604
Fax: 91-22-27433185

Record of attendance at Meeting

Meeting of: IEC (Institutional ethics committee).

Subject: MGMSBS & MGMDCH Protocols

Venue: Conference room MGMDCH Date: 03-02-24 Time: 10:30 a.m.

Sr. No	Name	Designation	Signature
1.	Dr. Deepak Sangade	Chairman	3/2/24
2.	Dr. Prakash Khandelwal	Co chairman	3/2/24
3.	Dr. Shilpa patil.	Member Secretary	
4.	Dr. Rupali Gujar	Social.	
5.	Dr. Sheela S Hosamani	Legal expert	
6.	Ms. Priyanka Sharma	Lay person	Priyal
7.	Dr. Shakeeb Dhorajiwala	Basic Medical Scientist	03/Feb/2024
8.	Dr. Sumathini. M.	Member	
9.	Dr. Usha Armani	Member	
10.	Dr. Vaibhav. T	Member	
11.	Dr. Rohit Gadda	Member	
12.	Dr. Chandramani Pathak	Scientific Member	
13.	Dr. Isha Misra		
14.	Dr. Shraddha Chaisas		
15.			

Dean

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DR. DEEPAK

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IEC MEETING -03/02/2024
RESEARCH PROTOCOLS

SR NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE	COMMENTS
1.	IN/SBS/26/01/2024	Dr. Mini Mol	Impact of COVID-19 on Semen Parameters : An Observational Study	• Retrospective study
2.	IN/SBS/27/01/2024	Dr. Mini Mol	An Observational Study on Semen Analysis According to WHO Reference Values: A Key Predictor of IUI	• Title revision - outcomes. - objectives
3.	IN/SBS/28/01/2024	Dr. Mini Mol	Impact of Pyospermia on Semen Quality : A Retrospective Study	• Inclusion/exclusion criteria - title, objectives.
4.	IN/SBS/29/01/2024	Dr. Mini Mol	Effect of Trophectoderm (TE) Biopsy on Implantation Rates - An Observational Study.	• title, objectives analysis
5.	IN/SBS/30/01/2024	Dr. Mini Mol	Impact of Seminal Fluid on Implantation Rate: An Observational Study	• Same as above
6.	IN/SBS/31/01/2024	Dr. Mini Mol	Impact of Tobacco and Alcohol Consumption on Sperm DNA Fragmentation Index (DFI), Semen Parameters, and Their Relation with Assisted Reproductive Technology (ART) Outcomes: An Observational Study	• Same as above
7.	IN/SBS/32/01/2024	Dr. Mini Mol	Effects of Testicular Biopsy on ICSI Outcome: An Observational Study.	• Same as above - Sample size.

All retrospective studies need to have ① waiver of consent. ② Undertaking to maintain confidentiality.

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				- Exclusion → vs AIDS / Steroids - Rescue
8.	IN/SBS/33/01/2024	Dr. Mini Mol	Harmonizing and Exploring the Therapeutic Effect of Heartfulness Meditation on Dysmenorrhea	• Biomarkers - Randomization. - Sample size.
9.	IN/SBS/34/01/2024	Dr. Anjali Sabnis	Analysis of BRCA Somatic Mutation Variants in Indian Population by NGS based assay.	• Title - PIS - simplify
10.	IN/SBS/35/01/2024	Dr. Anjali Sabnis	Comparative Study of Prenatal Diagnosis of Common Chromosomal Aneuploidies using QF PCR and Karyotyping	- Title - objective
11.	IN/SBS/36/01/2024	Dr. Anjali Sabnis	Profile of DNA Mutation and Fusion Transcripts Associated with Myeloid Disorders using Next Generation Sequencing.	• title - objective
12.	IN/SBS/37/01/2024	Dr. Anjali Sabnis	Impact of Maternal Cell Contamination in Patients Studied for Chromosomal Abnormalities in Product of Conception using Array Comparative Genomic Hybridization	• title, objectives
13.	IN/SBS/38/01/2024	Dr. Anjali Sabnis	Profiling of BRCA1 and BRCA2 Variants in Young Women with Ovarian Cancer by Next Generation Sequencing.	• Same as Sub # 9
14.	IN/SBS/39/01/2024	Dr. Anjali Sabnis	NGS based High-resolution HLA Typing to Decipher Common Immunogenetic Variants in the Indian Population.	- • Title objective - Inclusion / Exclusion
15.	IN/SBS/40/01/2024	Dr. Anjali Sabnis	To Study the Chromosomal Evaluation of Patients with Infertility	• Inclusion, Exclusion.
16.	IN/SBS/50/01/2024	Dr.Mugdha Thakur	Study of Valvular Heart Disease in Adult Pateints in Tertiary Care Hospital	Revise - PIS, title

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17.	IN/SBS/51/01/2024	Mr. Rohit.I.Gupta	Impact of Soft Contact Lens Hands-On Training Program on Knowledge and Approach of College Going Students Towards Soft Contact Lens	• Inclusion - Sampling - Advertisement
18.	IN/SBS/52/01/2024	Dr. S.Faraaz Hussain	Comparison of Foveal Foveal Test of Cuppers with Tangent Scale and Visuoscopy using Direct Ophthalmoscope for Measuring Eccentric Fixation.	• - PIS - Title
19.	IN/SBS/53/01/2024	Mr. Rohit.I.Gupta	Evaluation of Convergence Insuffiency among College Going Students and Effectiveness of Exercise Implementation	• Approved
20.	IN/SBS/54/01/2024	Mr. Rohit.I.Gupta	Comparison of Visual Skills among Athletes Across Different Sports and Non-Athletes	• Approved.
21.	IN/SBS/55/01/2024	Dr. S.Faraaz Hussain	Comparison of Disc-foveal Angle Measurement using Fundus Camera and Indirect Ophthalmoscope in Torsional Strabismus	• Approved - PIS ascribia
22.	IN/SBS/56/01/2024	Dr. Aditya Nayak	Factors Influencing the Patient's Decision while Choosing Kidney Tranplantation Versus Maintenance Dialysis Therapy	• Approved
23.	IN/SBS/57/01/2024	Dr. Aditya Nayak	Health Literacy among Patients with Chronic Kidney Disease Undergoing Maintenance Hemodialysis	• Approved
24.	IN/DCH/01/01/2024	Dr. Ashok Dhoble	Evaluation of efficacy and acceptability of herbal toothpaste in the reduction of plaque and gingival inflammation in healthy adult population – A Multicentric ~~clinical~~ pilot study.	• CTRI required Approved
25.	IN/DCH/02/01/2024	Dr. Ashok Dhoble	To evaluate the efficacy and acceptability of the fluoridated toothpaste in its anti-plaque and anti-gingivitis properties in a pediatric population in the age group of 6 to 12 years – A randomized ~~control~~ non-active clinical trial.	• - CTRI req. - Approved
26.	IN/COP/59/01/2024	Dr. Shruti Nair	Efficacy of facilitating reflecting practices on reflective capacity, learning and clinical competency of under-graduate physiotherapy students : a longitudinal study	Approved

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DR. PRAKASH.

MAHATMA GANDHI MISSION'S DENTAL COLLEGE & HOSPITAL
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Junction of NH-4 and Sion Panvel Expressway,
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IEC MEETING -03/02/2024
RESEARCH PROTOCOLS

SR NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE	COMMENTS
1.	IN/SBS/26/01/2024	Dr. Mini Mol	Impact of COVID-19 on Semen Parameters : An Observational Study	• Modify title. Attach copy of MOU IEC smoker quantity
2.	IN/SBS/27/01/2024	Dr. Mini Mol	An Observational Study on Semen Analysis According to WHO Reference Values: A Key Predictor of IUI	• Modify title, objective hypothesis.
3.	IN/SBS/28/01/2024	Dr. Mini Mol	Impact of Pyospermia on Semen Quality : A Retrospective Study	• Modify EC/IEC.
4.	IN/SBS/29/01/2024	Dr. Mini Mol	Effect of Trophectoderm (TE) Biopsy on Implantation Rates - An Observational Study.	• Modify title.
5.	IN/SBS/30/01/2024	Dr. Mini Mol	Impact of Seminal Fluid on Implantation Rate: An Observational Study	• Modify title.
6.	IN/SBS/31/01/2024	Dr. Mini Mol	Impact of Tobacco and Alcohol Consumption on Sperm DNA Fragmentation Index (DFI), Semen Parameters, and Their Relation with Assisted Reproductive Technology (ART) Outcomes: An Observational Study	• Modify title.
7.	IN/SBS/32/01/2024	Dr. Mini Mol	Effects of Testicular Biopsy on ICSI Outcome: An Observational Study.	• Modify title.

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8.	IN/SBS/33/01/2024	Dr. Mini Mol	Harmonizing and Exploring the Therapeutic Effect of Heartfulness Meditation on Dysmenorrhea	• Delete biomarker (PR) Modify E/C
9.	IN/SBS/34/01/2024	Dr. Anjali Sabnis	Analysis of BRCA Somatic Mutation Variants in Indian Population by NGS based assay.	• Title full form of BRCA PIS, Title objective
10.	IN/SBS/35/01/2024	Dr. Anjali Sabnis	Comparative Study of Prenatal Diagnosis of Common Chromosomal Aneuploidies using QF PCR and Karyotyping	• Modify title objective
11.	IN/SBS/36/01/2024	Dr. Anjali Sabnis	Profile of DNA Mutation and Fusion Transcripts Associated with Myeloid Disorders using Next Generation Sequencing.	• Remove S/E E/C
12.	IN/SBS/37/01/2024	Dr. Anjali Sabnis	Impact of Maternal Cell Contamination in Patients Studied for Chromosomal Abnormalities in Product of Conception using Array Comparative Genomic Hybridization	• Modify Aim
13.	IN/SBS/38/01/2024	Dr. Anjali Sabnis	Profiling of BRCA1 and BRCA2 Variants in Young Women with Ovarian Cancer by Next Generation Sequencing.	• Modify objective
14.	IN/SBS/39/01/2024	Dr. Anjali Sabnis	NGS based High-resolution HLA Typing to Decipher Common Immunogenetic Variants in the Indian Population.	• objective S/E E/C
15.	IN/SBS/40/01/2024	Dr. Anjali Sabnis	To Study the Chromosomal Evaluation of Patients with Infertility	• Modify S/E E/C
16.	IN/SBS/50/01/2024	Dr.Mugdha Thakur	Study of Valvular Heart Disease in Adult Pateints in Tertiary Care Hospital	• Title

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17.	IN/SBS/51/01/2024	Mr. Rohit.I.Gupta	Impact of Soft Contact Lens Hands-On Training Program on Knowledge and Approach of College Going Students Towards Soft Contact Lens	• Sampling.
18.	IN/SBS/52/01/2024	Dr. S.Faraaz Hussain	Comparison of Foveal Foveal Test of Cuppers with Tangent Scale and Visuoscopy using Direct Ophthalmoscope for Measuring Eccentric Fixation.	• Title
19.	IN/SBS/53/01/2024	Mr. Rohit.I.Gupta	Evaluation of Convergence Insuffiency among College Going Students and Effectiveness of Exercise Implementation	• Approved
20.	IN/SBS/54/01/2024	Mr. Rohit.I.Gupta	Comparison of Visual Skills among Athletes Across Different Sports and Non-Athletes	• Approved
21.	IN/SBS/55/01/2024	Dr. S.Faraaz Hussain	Comparison of Disc-foveal Angle Measurement using Fundus Camera and Indirect Ophthalmoscope in Torsional Strabismus	• Approved
22.	IN/SBS/56/01/2024	Dr. Aditya Nayak	Factors Influencing the Patient's Decision while Choosing Kidney Tranplantation Versus Maintenance Dialysis Therapy	• Approved
23.	IN/SBS/57/01/2024	Dr. Aditya Nayak	Health Literacy among Patients with Chronic Kidney Disease Undergoing Maintenance Hemodialysis	• Approved
24.	IN/DCH/01/01/2024	Dr. Ashok Dhoble	Evaluation of efficacy and acceptability of herbal toothpaste in the reduction of plaque and gingival inflammation in healthy adult population – A Multicentric ~~clinical~~ Pilot study.	• Approved
25.	IN/DCH/02/01/2024	Dr. Ashok Dhoble	To evaluate the efficacy and acceptability of the fluoridated toothpaste in its anti-plaque and anti-gingivitis properties in a pediatric population in the age group of 6 to 12 years – A non-randomized active control clinical trial.	• Approved
26.	IN/COP/59/01/2024	Dr. Shruti Nair	Efficacy of facilitating reflective practices on reflective capacity, learning and clinical competency of under-graduate physiotherapy students: a longitudinal study	Approved as per letter of NUHS & Recommendations of IEC. Approved

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1.	IN/SBS/26/01/2024	Dr. Mini Mol Angelica D'almeida	Impact of COVID-19 on Semen Parameters: An Observational Study	
2.	IN/SBS/27/01/2024	Dr. Mini Mol Aditi Kadam	An Observational Study on Semen Analysis According to WHO Reference Values: A Key Predictor of IUI	AKadam
3.	IN/SBS/28/01/2024	Dr. Mini Mol Shaista Patel	Impact of Pyospermia on Semen Quality : A Retrospective Study	Patel
4.	IN/SBS/29/01/2024	Dr. Mini Mol Shruti Savla	Effect of Trophectoderm (TE) Biopsy on Implantation Rates - An Observational Study.	Shruti
5.	IN/SBS/30/01/2024	Dr. Mini Mol Jidnyasa Raut	Impact of Seminal Fluid on Implantation Rate: An Observational Study	Raut
6.	IN/SBS/31/01/2024	Dr. Mini Mol Manasi Bhavsar	Impact of Tobacco and Alcohol Consumption on Sperm DNA Fragmentation Index (DFI), Semen Parameters, and Their Relation with Assisted Reproductive Technology (ART) Outcomes: An Observational Study	Bhavsar
7.	IN/SBS/32/01/2024	Dr. Mini Mol Juhi singh	Effects of Testicular Biopsy on ICSI Outcome: An Observational Study.	Juhi

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8.	IN/SBS/33/01/2024	Dr. Mini Mol Maseera Khurshed	Harmonizing and Exploring the Therapeutic Effect of Heartfulness Meditation on Dysmenorrhea	
9.	IN/SBS/34/01/2024	Dr. Anjali Sabnis Gauri Dhumal	Analysis of BRCA Somatic Mutation Variants in Indian Population by NGS based assay.	
10.	IN/SBS/35/01/2024	Dr. Anjali Sabnis Swapnali Bhagat	Comparative Study of Prenatal Diagnosis of Common Chromosomal Aneuploidies using QF PCR and Karyotyping	
11.	IN/SBS/36/01/2024	Dr. Anjali Sabnis	Profile of DNA Mutation and Fusion Transcripts Associated with Myeloid Disorders using Next Generation Sequencing.	
12.	IN/SBS/37/01/2024	Dr. Anjali Sabnis Mrunmayi Jadhav.	Impact of Maternal Cell Contamination in Patients Studied for Chromosomal Abnormalities in Product of Conception using Array Comparative Genomic Hybridization	
13.	IN/SBS/38/01/2024	Dr. Anjali Sabnis Vaishnavi Koulave	Profiling of BRCA1 and BRCA2 Variants in Young Women with Ovarian Cancer by Next Generation Sequencing.	
14.	IN/SBS/39/01/2024	Dr. Anjali Sabnis Shaniya Raghav.	NGS based High-resolution HLA Typing to Decipher Common Immunogenetic Variants in the Indian Population.	
15.	IN/SBS/40/01/2024	Dr. Anjali Sabnis Leena Taide	To Study the Chromosomal Evaluation of Patients with Infertility	
16.	IN/SBS/50/01/2024	Dr.Mugdha Thakur Sagar Sonawane	Study of Valvular Heart Disease in Adult Pateints in Tertiary Care Hospital	
17.	IN/SBS/51/01/2024	Mr. Rohit.I.Gupta Aditi maurya	Impact of Soft Contact Lens Hands-On Training Program on Knowledge and Approach of College Going Students Towards Soft Contact Lens	
18.	IN/SBS/52/01/2024	Dr. S.Faraaz Hussain Ruchira G.	Comparison of Foveal Foveal Test of Cuppers with Tangent Scale and Visuoscopy using Direct Ophthalmoscope for Measuring	

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			Eccentric Fixation.	
19.	IN/SBS/53/01/2024	Mr. Rohit.I.Gupta Shivam Singh	Evaluation of Convergence Insuffiency among College Going Students and Effectiveness of Exercise Implementation	Shivam
20.	IN/SBS/54/01/2024	Mr. Rohit.I.Gupta Fardeen Khan	Comparison of Visual Skills among Athletes Across Different Sports and Non-Athletes	
21.	IN/SBS/55/01/2024	Dr. S.Faraaz Hussain Ummesalma Khan	Comparison of Disc-foveal Angle Measurement using Fundus Camera and Indirect Ophthalmoscope in Torsional Strabismus	
22.	IN/SBS/56/01/2024	Dr. Aditya Nayak Heet Kenia	Factors Influencing the Patient's Decision while Choosing Kidney Tranplantation Versus Maintenance Dialysis Therapy	
23.	IN/SBS/57/01/2024	Dr. Aditya Nayak Sayali Mirgar	Health Literacy among Patients with Chronic Kidney Disease Undergoing Maintenance Hemodialysis	
24.	IN/DCH/01/01/2024	Dr. Ashok Dhoble	Evaluation of efficacy and acceptability of herbal toothpaste in the reduction of plaque and gingival inflammation in healthy adult population – A Multicentric clinical study.	
25.	IN/DCH/02/01/2024	Dr. Ashok Dhoble	To evaluate the efficacy and acceptability of the fluoridated toothpaste in its anti-plaque and anti-gingivitis properties in a pediatric population in the age group of 6 to 12 years – A randomized control clinical trial.	
26.	IN/EOP/59/01/24	Dr. Sheetli Nair	Efficacy of facilitating Reflective Practices on reflective capacity, learning and clinical competency of under-graduate Physiotherapy students : a longitudinal study.	3/2/24

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1.	IN/SBS/26/01/2024	Dr. Mini Mol	Impact of COVID-19 on Semen Parameters : An Observational Study	• Needs to be quantified. - Attach MOU of appolo. - topic should include restrepective.
2.	IN/SBS/27/01/2024	Dr. Mini Mol	An Observational Study on Semen Analysis According to WHO Reference Values: A Key Predictor of IUI	• Range for motility - title inappropriate / modify (outcome)
3.	IN/SBS/28/01/2024	Dr. Mini Mol	Impact of Pyospermia on Semen Quality : A Retrospective Study	• - Inclusion criteria (Rewse). - Control group needs to be revised.
4.	IN/SBS/29/01/2024	Dr. Mini Mol	Effect of Trophectoderm (TE) Biopsy on Implantation Rates - An Observational Study.	- Embryo before/after. - Primary implantation needs to be compared.
5.	IN/SBS/30/01/2024	Dr. Mini Mol	Impact of Seminal Fluid on Implantation Rate: An Observational Study	•
6.	IN/SBS/31/01/2024	Dr. Mini Mol	Impact of Tobacco and Alcohol Consumption on Sperm DNA Fragmentation Index (DFI), Semen Parameters, and Their Relation with Assisted Reproductive Technology (ART) Outcomes: An Observational Study	• - Change the title.
7.	IN/SBS/32/01/2024	Dr. Mini Mol	Effects of Testicular Biopsy on ICSI Outcome: An Observational Study.	• Include in defination. - Outcome (3),

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MGMDCH/IEC/ 003 /2024 Date: 29 / 02 /2024

Action taken report against minutes of Institutional Ethics Committee held on 03/02/24

Sr. No.	Subject	Action taken	Action Completed Yes/No
1.	Confirmation of minutes of previous IEC meeting	Reviewed and Confirmed	Yes
2.	Presentation, discussion and scrutiny of research protocols of MGM School of Biomedical Sciences	23 protocols were discussed. Revisions were suggested by the chairman and IEC members. The investigators were informed to submit the amended protocols within 7 working days.	Yes
3.	Presentation, discussion and scrutiny of research protocols of MGM Dental College and Hospital	2 protocols of the IDA multicentric study were discussed. Revisions were suggested by the chairman and IEC members. The investigators were informed to submit the amended protocols within 7 working days. They were also asked to submit the IEC approval letters from all the centers.	Yes
4.	Scrutiny of research protocols of MGM College of Physiotherapy	1 protocol was scrutinized and resubmitted with modified title as per MUHS suggestions.	Yes
5.	Any other point	The new IEC SOP version 4 was reviewed and a proposal to increase the application fees for scrutiny and approval of protocols from 500/- to 1000/- INR was made and approved.	Yes

Dr. Deepak Langade
Chairman
IEC MGMDCH

Dr. Shilpa Patel
Member Secretary
IEC MGMDCH

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8.	IN/SBS/33/01/2024	Dr. Mini Mol	Harmonizing and Exploring the Therapeutic Effect of Heartfulness Meditation on Dysmenorrhea	• avoid using "bio-marker" word. -
9.	IN/SBS/34/01/2024	Dr. Anjali Sabnis	Analysis of BRCA Somatic Mutation Variants in Indian Population by NGS based assay.	• – Use full form. – title change.
10.	IN/SBS/35/01/2024	Dr. Anjali Sabnis	Comparative Study of Prenatal Diagnosis of Common Chromosomal Aneuploidies using QF PCR and Karyotyping	• – Embryotic fluid specify.
11.	IN/SBS/36/01/2024	Dr. Anjali Sabnis	Profile of DNA Mutation and Fusion Transcripts Associated with Myeloid Disorders using Next Generation Sequencing.	•
12.	IN/SBS/37/01/2024	Dr. Anjali Sabnis	Impact of Maternal Cell Contamination in Patients Studied for Chromosomal Abnormalities in Product of Conception using Array Comparative Genomic Hybridization	• Change title
13.	IN/SBS/38/01/2024	Dr. Anjali Sabnis	Profiling of BRCA1 and BRCA2 Variants in Young Women with Ovarian Cancer by Next Generation Sequencing.	•
14.	IN/SBS/39/01/2024	Dr. Anjali Sabnis	NGS based High-resolution HLA Typing to Decipher Common Immunogenetic Variants in the Indian Population.	• – inclusion/exclusion criteria. – define study population
15.	IN/SBS/40/01/2024	Dr. Anjali Sabnis	To Study the Chromosomal Evaluation of Patients with Infertility	•
16.	IN/SBS/50/01/2024	Dr.Mugdha Thakur	Study of Valvular Heart Disease in Adult Pateints in Tertiary Care Hospital	•

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17.	IN/SBS/51/01/2024	Mr. Rohit.I.Gupta	Impact of Soft Contact Lens Hands-On Training Program on Knowledge and Approach of College Going Students Towards Soft Contact Lens	• Announcement needs to be approved here. (IEC)
18.	IN/SBS/52/01/2024	Dr. S.Faraaz Hussain	Comparison of Foveal Foveal Test of Cuppers with Tangent Scale and Visuoscopy using Direct Ophthalmoscope for Measuring Eccentric Fixation.	•
19.	IN/SBS/53/01/2024	Mr. Rohit.I.Gupta	Evaluation of Convergence Insuffiency among College Going Students and Effectiveness of Exercise Implementation	•
20.	IN/SBS/54/01/2024	Mr. Rohit.I.Gupta	Comparison of Visual Skills among Athletes Across Different Sports and Non-Athletes	•
21.	IN/SBS/55/01/2024	Dr. S.Faraaz Hussain	Comparison of Disc-foveal Angle Measurement using Fundus Camera and Indirect Ophthalmoscope in Torsional Strabismus	•
22.	IN/SBS/56/01/2024	Dr. Aditya Nayak	Factors Influencing the Patient's Decision while Choosing Kidney Tranplantation Versus Maintenance Dialysis Therapy	•
23.	IN/SBS/57/01/2024	Dr. Aditya Nayak	Health Literacy among Patients with Chronic Kidney Disease Undergoing Maintenance Hemodialysis	•
24.	IN/DCH/01/01/2024	Dr. Ashok Dhoble	Evaluation of efficacy and acceptability of herbal toothpaste in the reduction of plaque and gingival inflammation in healthy adult population – A Multicentric ~~clinical~~ pilot study.	•
25.	IN/DCH/02/01/2024	Dr. Ashok Dhoble	To evaluate the efficacy and acceptability of the fluoridated toothpaste in its anti-plaque and anti-gingivitis properties in a pediatric population in the age group of 6 to 12 years – A non-randomized active control clinical trial.	•

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Sheela Hosman

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2.	IN/SBS/27/01/2024	Dr. Mini Mol	An Observational Study on Semen Analysis According to WHO Reference Values: A Key Predictor of IUI	• has to modify the title.
3.	IN/SBS/28/01/2024	Dr. Mini Mol	Impact of Pyospermia on Semen Quality : A Retrospective Study	• Criteria has to be revised.
4.	IN/SBS/29/01/2024	Dr. Mini Mol	Effect of Trophectoderm (TE) Biopsy on Implantation Rates - An Observational Study.	•
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8.	IN/SBS/33/01/2024	Dr. Mini Mol	Harmonizing and Exploring the Therapeutic Effect of Heartfulness Meditation on Dysmenorrhea	• She has to revise the work.
9.	IN/SBS/34/01/2024	Dr. Anjali Sabnis	Analysis of BRCA Somatic Mutation Variants in Indian Population by NGS based assay.	She has to add full form of BRCA change the title.
10.	IN/SBS/35/01/2024	Dr. Anjali Sabnis	Comparative Study of Prenatal Diagnosis of Common Chromosomal Aneuploidies using QF PCR and Karyotyping	•
11.	IN/SBS/36/01/2024	Dr. Anjali Sabnis	Profile of DNA Mutation and Fusion Transcripts Associated with Myeloid Disorders using Next Generation Sequencing.	•
12.	IN/SBS/37/01/2024	Dr. Anjali Sabnis	Impact of Maternal Cell Contamination in Patients Studied for Chromosomal Abnormalities in Product of Conception using Array Comparative Genomic Hybridization	• Change the title
13.	IN/SBS/38/01/2024	Dr. Anjali Sabnis	Profiling of BRCA1 and BRCA2 Variants in Young Women with Ovarian Cancer by Next Generation Sequencing.	•
14.	IN/SBS/39/01/2024	Dr. Anjali Sabnis	NGS based High-resolution HLA Typing to Decipher Common Immunogenetic Variants in the Indian Population.	• modify the object
15.	IN/SBS/40/01/2024	Dr. Anjali Sabnis	To Study the Chromosomal Evaluation of Patients with Infertility	•
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Dr. Rupali Gryan

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2.	IN/SBS/27/01/2024	Dr. Mini Mol	An Observational Study on Semen Analysis According to WHO Reference Values: A Key Predictor of IUI	•
3.	IN/SBS/28/01/2024	Dr. Mini Mol	Impact of Pyospermia on Semen Quality : A Retrospective Study	• Revise.
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5.	IN/SBS/30/01/2024	Dr. Mini Mol	Impact of Seminal Fluid on Implantation Rate: An Observational Study	•
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10.	IN/SBS/35/01/2024	Dr. Anjali Sabnis	Comparative Study of Prenatal Diagnosis of Common Chromosomal Aneuploidies using QF PCR and Karyotyping	•
11.	IN/SBS/36/01/2024	Dr. Anjali Sabnis	Profile of DNA Mutation and Fusion Transcripts Associated with Myeloid Disorders using Next Generation Sequencing.	•
12.	IN/SBS/37/01/2024	Dr. Anjali Sabnis	Impact of Maternal Cell Contamination in Patients Studied for Chromosomal Abnormalities in Product of Conception using Array Comparative Genomic Hybridization	• Revise Title
13.	IN/SBS/38/01/2024	Dr. Anjali Sabnis	Profiling of BRCA1 and BRCA2 Variants in Young Women with Ovarian Cancer by Next Generation Sequencing.	•
14.	IN/SBS/39/01/2024	Dr. Anjali Sabnis	NGS based High-resolution HLA Typing to Decipher Common Immunogenetic Variants in the Indian Population.	•
15.	IN/SBS/40/01/2024	Dr. Anjali Sabnis	To Study the Chromosomal Evaluation of Patients with Infertility	•
16.	IN/SBS/50/01/2024	Dr.Mugdha Thakur	Study of Valvular Heart Disease in Adult Pateints in Tertiary Care Hospital	•

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17.	IN/SBS/51/01/2024	Mr. Rohit.I.Gupta	Impact of Soft Contact Lens Hands-On Training Program on Knowledge and Approach of College Going Students Towards Soft Contact Lens	•
18.	IN/SBS/52/01/2024	Dr. S.Faraaz Hussain	Comparison of Foveal Foveal Test of Cuppers with Tangent Scale and Visuoscopy using Direct Ophthalmoscope for Measuring Eccentric Fixation.	•
19.	IN/SBS/53/01/2024	Mr. Rohit.I.Gupta	Evaluation of Convergence Insuffiency among College Going Students and Effectiveness of Exercise Implementation	•
20.	IN/SBS/54/01/2024	Mr. Rohit.I.Gupta	Comparison of Visual Skills among Athletes Across Different Sports and Non-Athletes	•
21.	IN/SBS/55/01/2024	Dr. S.Faraaz Hussain	Comparison of Disc-foveal Angle Measurement using Fundus Camera and Indirect Ophthalmoscope in Torsional Strabismus	•
22.	IN/SBS/56/01/2024	Dr. Aditya Nayak	Factors Influencing the Patient's Decision while Choosing Kidney Tranplantation Versus Maintenance Dialysis Therapy	•
23.	IN/SBS/57/01/2024	Dr. Aditya Nayak	Health Literacy among Patients with Chronic Kidney Disease Undergoing Maintenance Hemodialysis	•
24.	IN/DCH/01/01/2024	Dr. Ashok Dhoble	Evaluation of efficacy and acceptability of herbal toothpaste in the reduction of plaque and gingival inflammation in healthy adult population – A Multicentric ~~clinical~~ pilot study.	•
25.	IN/DCH/02/01/2024	Dr. Ashok Dhoble	To evaluate the efficacy and acceptability of the fluoridated toothpaste in its anti-plaque and anti-gingivitis properties in a pediatric population in the age group of 6 to 12 years – A non-randomized control clinical trial.	•

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DR. SHAKEEL

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IEC MEETING -03/02/2024
RESEARCH PROTOCOLS

SR NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE	COMMENTS
1.	IN/SBS/26/01/2024	Dr. Mini Mol	Impact of COVID-19 on Semen Parameters : An Observational Study	• —
2.	IN/SBS/27/01/2024	Dr. Mini Mol	An Observational Study on Semen Analysis According to WHO Reference Values: A Key Predictor of IUI (Inserted)	• Title → IUI? → 2 tailed stud → Retrospective; ↳ unclear objective; Ques-Title ↳ hypothesis
3.	IN/SBS/28/01/2024	Dr. Mini Mol	Impact of Pyospermia on Semen Quality : A Retrospective Study	• Men ε; - comparator
4.	IN/SBS/29/01/2024	Dr. Mini Mol	Effect of Trophectoderm (TE) Biopsy on Implantation Rates - An Observational Study. → Retrospective	• —
5.	IN/SBS/30/01/2024	Dr. Mini Mol	Impact of Seminal Fluid on Implantation Rate: An Observational Study	• Null hypothesis → should state fund → ① waived consent ② embedded; - Appropriate test → 2 test for proportion → implantation rate; → Title → add controlled
6.	IN/SBS/31/01/2024	Dr. Mini Mol	Impact of Tobacco and Alcohol Consumption on Sperm DNA Fragmentation Index (DFI), Semen Parameters, and Their Relation with Assisted Reproductive Technology (ART) Outcomes: An Observational Study	• Add retrospective in Title → Conclusion
7.	IN/SBS/32/01/2024	Dr. Mini Mol	Effects of Testicular Biopsy on ICSI Outcome: An Observational Study. → Retrospective	• Statistics effect size very high → either recheck literature / discuss

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8.	IN/SBS/33/01/2024	Dr. Mini Mol	Harmonizing and Exploring the Therapeutic Effect of Heartfulness Meditation on Dysmenorrhea ? 2nd	• PG 9/Th → Fza → Etiology → too high → gynaecure → exclude NSAIDs copied → Recorded.
9.	IN/SBS/34/01/2024	Dr. Anjali Sabnis In vitro	Analysis of BRCA Somatic Mutation Variants in Indian Population by NGS based assay. Next generat sequencing	• → use full form in title → ~~explain~~ ~~include~~ which BRCA1 types will be
10.	IN/SBS/35/01/2024	Dr. Anjali Sabnis In vitro	Comparative Study of Prenatal Diagnosis of Common Chromosomal Aneuploidies using QF PCR and Karyotyping	•
11.	IN/SBS/36/01/2024	Dr. Anjali Sabnis In vitro	Profile of DNA Mutation and Fusion Transcripts Associated with Myeloid Disorders using Next Generation Sequencing.	•
12.	IN/SBS/37/01/2024	Dr. Anjali Sabnis In vitro	Impact of Maternal Cell Contamination in Patients Studied for Chromosomal Abnormalities in Product of Conception using Array Comparative Genomic Hybridization	• Aim has been mofamed → chromosomal abnormality seems to be causing MCC does not make sense. Rearrange words in Aims
13.	IN/SBS/38/01/2024	Dr. Anjali Sabnis	Profiling of BRCA1 and BRCA2 Variants in Young Women with Ovarian Cancer by Next Generation Sequencing.	•
14.	IN/SBS/39/01/2024	Dr. Anjali Sabnis	NGS based High-resolution HLA Typing to Decipher Common Immunogenetic Variants in the Indian Population.	• Use full form in Title & change Indian Population to dreamed population - study population
15.	IN/SBS/40/01/2024	Dr. Anjali Sabnis	To Study the Chromosomal Evaluation of Patients with Infertility	•
16.	IN/SBS/50/01/2024	Dr.Mugdha Thakur	Study of Valvular Heart Disease in Adult Pateints in Tertiary Care Hospital - Retrospective study	•

Outcome measure should be
- specific
- measurable

Exclusion cannot be complement of inclusion criteria

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17.	IN/SBS/51/01/2024	Mr. Rohit.I.Gupta	Impact of Soft Contact Lens Hands-On Training Program on Knowledge and Approach of College Going Students Towards Soft Contact Lens Questionnaire based	• ① Advertisement should be approved by ethics committee ② Grammatical error in title ~~Hands On~~ Hands-on
18.	IN/SBS/52/01/2024	Dr. S.Faraaz Hussain	Comparison of Foveal Foveal Test of Cuppers with Tangent Scale and Visuoscopy using Direct Ophthalmoscope for Measuring Eccentric Fixation.	• –
19.	IN/SBS/53/01/2024	Mr. Rohit.I.Gupta	Evaluation of Convergence Insuffiency among College Going Students and Effectiveness of Exercise Implementation	• –
20.	IN/SBS/54/01/2024	Mr. Rohit.I.Gupta	Comparison of Visual Skills among Athletes Across Different Sports and Non-Athletes	•
21.	IN/SBS/55/01/2024	Dr. S.Faraaz Hussain	Comparison of Disc-foveal Angle Measurement using Fundus Camera and Indirect Ophthalmoscope in Torsional Strabismus	• ~~PIS should explain~~
22.	IN/SBS/56/01/2024	Dr. Aditya Nayak	Factors Influencing the Patient's Decision while Choosing Kidney Tranplantation Versus Maintenance Dialysis Therapy	• –
23.	IN/SBS/57/01/2024	Dr. Aditya Nayak	Health Literacy among Patients with Chronic Kidney Disease Undergoing Maintenance Hemodialysis	• –
24.	IN/DCH/01/01/2024	Dr. Ashok Dhoble	Evaluation of efficacy and acceptability of herbal toothpaste in the reduction of plaque and gingival inflammation in healthy adult population – A Multicentric clinical study. 2nd	• – window period? – Travel reimbursement to participants? travel reimbursement!
25.	IN/DCH/02/01/2024	Dr. Ashok Dhoble	To evaluate the efficacy and acceptability of the fluoridated toothpaste in its anti-plaque and anti-gingivitis properties in a pediatric population in the age group of 6 to 12 years – A randomized control clinical trial. ① Dabur	① Is product approved → not PIII → marketed product ② PIII → safety/tolerability → effectiveness ③ Marketing authorization? ④ Pediatric? ⑤ Is it tried in adult/and healthy → vulnerable ⑥ Consent of consent? → other ethics committee approval

Is it
① PMS
② PIII
③ Outcomes research
④ Rights?

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① Novelty: Baseline → Retrospective → observational → operational defn: pack yr → mild smoker

→ anonymous

→ Scientific Administrative

improving / declining → sample of one pt → tested only once.

→ Sampling technique → universal sampling ?

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MGMDCH/IEC/03/2023 Date: 09/10/2023

IEC Circular No. 007/2023

This is to inform that Institutional Ethics Committee (IEC) full-board meeting has been scheduled on Friday 27th October, 2023 at 9.00 A.M. in the teleconference room to discuss the following agenda points:

1. Confirmation of minutes of previous meetings.
2. Presentation, Discussion and Scrutiny of non-dissertation research protocols of MGM Dental College & Hospital.
3. Any other point

Dr. Shilpa Patel
Member Secretary
IEC MGMDCH

CC to:

- Chairman (IEC)
- Members (IEC)
- Dean (MGMDCH)

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Tel: 022- 27436604
Fax: 91-22-27433185

Record of attendance at Meeting

Meeting of: Institutional Ethics Committee

Subject:

Venue: Conference Room MGMDCH Date: 27/10/23 Time: 9:00 AM

Sr. No	Name	Designation	Signature
1.	Dr Deepak Langadi	Chairman	
2.	Dr P. N Khandelwal	Co-chairman	
3.	Dr Shilpa patel.	Member Secretary	
4.	Dr. Sumanthini. M.V	member	
5	Dr usha Asrani	member	
6.	Dr. Jyoti Nandpal	member	
7.	Dr. VINEET KINI	Member	
8.	Dr. Sheela S Hosamani	Legal	
9	Dr. Rupali Gujar	Social	
10			
11.			
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15.			

Dean

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Record of attendance at Meeting

Meeting of: Institutional ethics committee

Subject: Guides.

Venue: Conference room MGMDCH Date: 27/10/23 Time: 9:00 am

Sr. No	Name	Designation	Signature
1.	DR. VINEET KINI	Professor and HoD Periodontics	
2.	Dr. Sumanthini. M.V	Prof. HoD	
3.	Dr. Sonka Shetty	Professor	
4.	Dr. Sujeet V. Kumbe	Reader	
5.	Dr Tigma Pathak	Professor	
6.	Dr. Jayeeta Verma	Reader	
7.	Dr. Antara Ghosh	Lecturer	
8.	Dr Divya Naik	Reader	
9.	Dr. Anuradha Patil	Professor	
10.	Dr. Chinmay Rao	Lecturer	
11.	Dr SUNIL SADANA	PROFESSOR	
12.	Dr. Janani Iyer	Professor	
13.	Dr. Anuradha Morik	Reader	
14.	Dr. Jyoti Nadgere	Prof. & HoD	
15.			

Dean

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IEC MEETING
NON-DISSERTATION PROTOCOLS OF MGM DENTAL COLLEGE AND HOSPITAL
DATE- 27/10/2023

SR. NO	IEC NUMBER	PRIMARY INVESTIGATOR	TITLE OF THE STUDY	COMMENT LIST
1.	MGM/DCH/IEC/IN/ DCH/147/09/23	Dr. Pradnya Chaure Dr. Sujeet Khiste	Effectiveness of Subgingival Irrigation with Probiotic Solution on Periodontal Healing Outcome in Patients with Moderate-to-Severe Periodontitis as Compared to Chlorhexidine Gluconate: A Clinical Study.	RCT split mouth design. Details of intervention ICF in proper format.
2.	MGM/DCH/IEC/IN/ DCH/148 /09/23	Dr. Karishma Lodaya Dr. Vineet Kini	Comparison of the effectiveness of bioactive glass as compared to glycine powder air polishing on surface characteristics of titanium surfaces: An invitro microscopic analysis	Approved.
3.	MGM/DCH/IEC/IN/ DCH/149 /09/23	Dr. Mudit Lodha Dr. Sarika Shetty	Assessment of Minimum Inhibitory Concentration of Pitavastatin against Periodontal Pathogen, Porphyromonas gingivalis : An In-Vitro Study	Approved
4.	MGM/DCH/IEC/IN/ DCH/150 /09/23	Dr Shreya Dalvi Dr. Kamlesh Dekate	Comparative evaluation of morphology of soft palate in patients with oral submucous fibrosis and healthy individuals, using digital cephalometrics: A cross sectional study	Age - 18 - 70 yrs. Cephalometric - PIS/ICF
5.	MGM/DCH/IEC/IN/ DCH/ 151 /09/23	Dr Anupama Warrier Dr. Jigna Pathak	Evaluation of the shape of uvula in clinical stages of oral submucous fibrosis – A cross sectional pilot study	Design - Include healthy sample. - Revise
6.	MGM/DCH/IEC/IN/ DCH/152 /09/23	Dr Rohit Magar	Effect of healing outcomes of pulpotomy compared with root canal treatment in patients	Sample size - ?? - ICF/PIS

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IEC MEETING
NON-DISSERTATION PROTOCOLS OF MGM DENTAL COLLEGE AND HOSPITAL
DATE- 27/10/2023

		Dr. Sumanthini M.V.	diagnosed with symptomatic irreversible pulpitis: A randomized controlled trial	
7. (8)	**MGM/DCH/IEC/IN/ DCH/153 /09/23**	Dr Vandana Yadav Dr. Divya Naik	Comparative evaluation of the effect of two different formulations of EDTA on the microhardness of restorative bulk-fill posterior composite resin - *An In vitro study*	Approved
8. (9)	**MGM/DCH/IEC/IN/ DCH/154 /09/23**	Dr Rutuja Rajput Dr. Sumanthini M.V.	Comparative evaluation of pericervical dentine reduction following the use of three different rotary file systems in the mesiobuccal root of the mandibular molar- *An In vitro study*	Approved.
9. (10)	**MGM/DCH/IEC/IN/ DCH/155 /09/23**	Amrita Agarwal Dr. Nitesh Patkar	Evaluation of the knowledge, awareness and practice of dental practitioners practising in Mumbai Metropolitan Region towards buffered local anesthetic solution: A cross sectional questionnaire-based study	Approved
10. (11)	**MGM/DCH/IEC/IN/ DCH/156 /09/23**	Dr. Mrunali Penkar Dr. Antara Ghosh	Comparative evaluation of effect of two different formulations of EDTA on solubility of a bulk-fill restorative composite resin: An In-Vitro Study	Approved
11. (12)	**MGM/DCH/IEC/IN/ DCH/157 /09/23**	Dr Snehal Kalsekar Dr. Anuradha Patil	Comparative evaluation of the effect of three different concentrations of sodium hypochlorite as a root canal irrigant on the solubility of bulk fill restorative composite resin: An in vitro study	Approved
12. (13)	**MGM/DCH/IEC/IN/ DCH/158 /09/23**	Dr. Neha Patil Dr. Jayeeta Verma	Comparative Evaluation of effect of 5% Sodium hypochlorite on the microhardness of	Approved

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IEC MEETING
NON-DISSERTATION PROTOCOLS OF MGM DENTAL COLLEGE AND HOSPITAL
DATE- 27/10/2023

			bulk-fill and Nano hybrid posterior composite resin : An In-Vitro Study	
13. (14)	MGM/DCH/IEC/IN/ DCH/159 /09/23	Dr. Saloni Shah Dr. Anuradha Mohite	Comparative Evaluation of The Accuracy and Dimensional Stability of Different Bite Registration Materials on Immersion in 2% Glutaraldehyde Disinfectant: An In-Vitro Study.	Approved
14. (15)	MGM/DCH/IEC/IN/ DCH/160 /09/23	Dr. Sohan Raje Dr. Jyoti Nadgere	Comparative Evaluation of the Effect of Two Adhesive Agents on the Peel Bond Strength of Room Temperature Vulcanizing Silicone Elastomer for Extraoral Maxillofacial Prosthesis: An-In-Vitro Study	Approved
15. (16)	MGM/DCH/IEC/IN/ DCH/161 /09/23	Dr.Manasi Bhanushali Dr. Janani Iyer	Comparative Evaluation of Impact Strength of Auto polymerizing Polymethyl Methacrylate Reinforced with 0.25% and 0.5% Graphene nanoparticles : An In-Vitro Study	Approved
16. (6)	MGM/DCH/IEC/IN/ DCH/162 /10/23	Dr Padmakar Baviskar Dr. Rohit Gadda Dr. Isha Mishra	Correlation of inferior alveolar nerve relation to pattern and angulation of impacted mandibular third molar – A radiographic retrospective analysis.	Approved
17. (17)	MGM/DCH/IEC/IN/ DCH/ 163/10/23	Dr Varad Saptarshi Dr. Chinmay Rao Dr. Srivalli Natarajan	Evaluation of patterns of road traffic accidents associated with maxillofacial trauma: A prospective cohort study.	Approved
18. (18)	MGM/DCH/IEC/IN/ DCH/ 164 /10/23	Dr Meghna Chandrachood	A questionnaire based study assessing the caregiver-reported outcome of speech and	Approved

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27/10/23

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IEC MEETING
NON-DISSERTATION PROTOCOLS OF MGM DENTAL COLLEGE AND HOSPITAL
DATE- 27/10/2023

		Dr. Adil Gandevivala	social function among patients treated with palatoplasty in different age groups, using CLEFT-Q.	
19.	**MGM/DCH/IEC/IN/ DCH/165 /10/23**	Dr Meghna Chandrachood Dr. Adil Gandevivala	A questionnaire-based study assessing the caregiver-reported outcome measurement of lip and nose appearance among patients treated with Cheiloplasty at different age groups, using CLEFT-Q.	Approved
20.	**MGM/DCH/IEC/IN/ DCH/ 166 /10/23**	Dr Pranave P Dr. Adil Gandevivala	Comparative evaluation of esthetic and surgical outcomes for unilateral primary cleft rhinoplasty with or without septal cartilage graft: A prospective randomized clinical study.	PIS, ICF revision
21.	**MGM/DCH/IEC/IN/ DCH/ 167/10/23**	Dr Sayali More Dr. Sunil Sidana	Assessment of Incidence of gastrointestinal side-effects of ibuprofen and paracetamol in patients undergoing Intra-alveolar dental extractions: A cohort study	Design, NSAID with PPI / ± PPI ICF., Inclusion / exclusion
22.	**MGM/DCH/IEC/IN/ DCH/168 /10/23**	Dr Charlotte Saldanha Dr. Usha Asnani Dr. Sunil Sidana	Comparative evaluation of clinical outcomes in patients with controlled diabetes and non-diabetic patients undergoing intra-alveolar dental extractions without antibiotic prophylaxis: A cross- sectional clinical study.	Design, Remove Non-diabetics ICF, Inclusion / exclusion.
23.	**MGM/DCH/IEC/IN/ DCH/ 169/10/23**	Dr Shruti Potdukhe Dr. Jyoti Nadgere Dr. Janani Iyer	Evaluation of clinical outcomes between monolithic CAD/CAM grapheme and zirconia single crowns in the posterior region: A randomised control trial.	Randomization method Approved

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IEC MEETING
NON-DISSERTATION PROTOCOLS OF MGM DENTAL COLLEGE AND HOSPITAL
DATE- 27/10/2023

24.	MGM/DCH/IEC/IN/ DCH/121/11/22 Revise	Dr. Shardool Jagtap Dr. Chinmay Rao Dr. Vaibhav Thakkar	Assessment of reliability and concurrence of two different indices used to determine signs and symptoms of temporomandibular joint disorders in patients visiting the outpatient department in a tertiary healthcare hospital.	PI to be the Guide. Title should have indices. Sample size
25.	MGM/DCH/IEC/IN/ DCH/122/11/22 Revise	Dr. Kavita Jain Dr. Chinmay Rao Dr. Vaibhav Thakkar	Assessment of prevalence of temporomandibular joint diseases (TMDs) among the patients coming to the outpatient department of tertiary healthcare hospital.	Revise

27/10/23

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DATE- 27/10/2023

24.	**MGM/DCH/IEC/IN/ DCH/121/11/22**	Dr. Shardool Jagtap Dr. Chinmay Rao Dr. Vaibhav Thakkar	Assessment of reliability and concurrence of two different indices used to determine signs and symptoms of temporomandibular joint disorders in patients visiting the outpatient department in a tertiary healthcare hospital.	
25.	**MGM/DCH/IEC/IN/ DCH/122/11/22**	Dr. Kavita Jain Dr. Chinmay Rao Dr. Vaibhav Thakkar	Assessment of prevalence of temporomandibular joint diseases (TMDs) among the patients coming to the outpatient department of tertiary healthcare hospital.	

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		Dr. Adil Gandevivala	social function among patients treated with palatoplasty in different age groups, using CLEFT-Q.	
19.	MGM/DCH/IEC/IN/ DCH/165 /10/23	Dr Meghna Chandrachood Dr. Adil Gandevivala	A questionnaire-based study assessing the caregiver-reported outcome measurement of lip and nose appearance among patients treated with Cheiloplasty at different age groups, using CLEFT-Q.	
20.	MGM/DCH/IEC/IN/ DCH/ 166 /10/23	Dr Pranave P Dr. Adil Gandevivala	Comparative evaluation of esthetic and surgical outcomes for unilateral primary cleft rhinoplasty with or without septal cartilage graft: A prospective randomized clinical study.	
21.	MGM/DCH/IEC/IN/ DCH/ 167/10/23	Dr Sayali More Dr. Sunil Sidana	Assessment of Incidence of gastrointestinal side-effects of ibuprofen and paracetamol in patients undergoing Intra-alveolar dental extractions: A cohort study	
22.	MGM/DCH/IEC/IN/ DCH/168 /10/23	Dr Charlotte Saldanha Dr. Usha Asnani Dr. Sunil Sidana	Comparative evaluation of clinical outcomes in patients with controlled diabetes and non-diabetic patients undergoing intra-alveolar dental extractions without antibiotic prophylaxis: A cross- sectional clinical study.	
23.	MGM/DCH/IEC/IN/ DCH/ 169/10/23	Dr Shruti Potdukhe Dr. Jyoti Nadgere Dr. Janani Iyer	Evaluation of clinical outcomes between monolithic CAD/CAM grapheme and zirconia single crowns in the posterior region: A randomised control trial.	

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IEC MEETING
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			bulk-fill and Nano hybrid posterior composite resin : An In-Vitro Study	
13.	MGM/DCH/IEC/IN/ DCH/159 /09/23	Dr. Saloni Shah Dr. Anuradha Mohite	Comparative Evaluation of The Accuracy and Dimensional Stability of Different Bite Registration Materials on Immersion in 2% Glutaraldehyde Disinfectant: An In-Vitro Study.	
14.	MGM/DCH/IEC/IN/ DCH/160 /09/23	Dr. Sohan Raje Dr. Jyoti Nadgere	Comparative Evaluation of the Effect of Two Adhesive Agents on the Peel Bond Strength of Room Temperature Vulcanizing Silicone Elastomer for Extraoral Maxillofacial Prosthesis: An-In-Vitro Study	
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18.	MGM/DCH/IEC/IN/ DCH/ 164 /10/23	Dr Meghna Chandrachood	A questionnaire based study assessing the caregiver-reported outcome of speech and	

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		Dr. Sumanthini M.V.	diagnosed with symptomatic irreversible pulpitis: A randomized controlled trial	
7.	**MGM/DCH/IEC/IN/ DCH/153 /09/23**	Dr Vandana Yadav Dr. Divya Naik	Comparative evaluation of the effect of two different formulations of EDTA on the microhardness of restorative bulk-fill posterior composite resin - *An In vitro study*	
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2.	MGM/DCH/IEC/IN/ DCH/148 /09/23	Dr. Karishma Lodaya Dr. Vineet Kini	Comparison of the effectiveness of bioactive glass as compared to glycine powder air polishing on surface characteristics of titanium surfaces: An invitro microscopic analysis	
3.	MGM/DCH/IEC/IN/ DCH/149 /09/23	Dr. Mudit Lodha Dr. Sarika Shetty	Assessment of Minimum Inhibitory Concentration of Pitavastatin against Periodontal Pathogen, Porphyromonas gingivalis : An In-Vitro Study	
4.	MGM/DCH/IEC/IN/ DCH/150 /09/23	Dr Shreya Dalvi Dr. Kamlesh Dekate	Comparative evaluation of morphology of soft palate in patients with oral submucous fibrosis and healthy individuals, using digital cephalometrics: A cross sectional study	Ile. → Age. Hutton Cephalometric Parameters.
5.	MGM/DCH/IEC/IN/ DCH/ 151 /09/23	Dr Anupama Warrier Dr. Jigna Pathak	Evaluation of the shape of uvula in clinical stages of oral submucous fibrosis – A cross sectional pilot study	Modify Title.
6.	MGM/DCH/IEC/IN/ DCH/152 /09/23	Dr Rohit Magar	Effect of healing outcomes of pulpotomy compared with root canal treatment in patients	

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		Dr. Adil Gandevivala	social function among patients treated with palatoplasty in different age groups, using CLEFT-Q.	
19.	**MGM/DCH/IEC/IN/ DCH/165 /10/23**	Dr Meghna Chandrachood Dr. Adil Gandevivala	A questionnaire-based study assessing the caregiver-reported outcome measurement of lip and nose appearance among patients treated with Cheiloplasty at different age groups, using CLEFT-Q.	
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MGM INSTITUTE OF HEALTH SCIENCES

(DEEMED UNIVERSITY u/s 3 of UGC Act, 1956)
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Tel: 022-27432471 / 27432994, Fax: 022-27431094
Website: http://www.mgmuhs.com & http://www.mgmlibrary.com ; Email: universitylibrarian@mgmuhs.com

Our Ref: MGMIHS/LIB/22/

19 August 2022

To Whom It May Concern

It is certified that the Postgraduates, Ph.D. students, and Research Scholars of MGM Dental College and Hospital, Navi Mumbai, Maharashtra have been using OURIGINAL Plagiarism Software possessed by MGM Institute of Health Sciences (Deemed to be University) to assess the similarity assessment concerning to their research work as per norms and standards of University Grants Commission since 2018.

Dr. RP Dixit
University Librarian &
Coordinator

Countersigned by

Dr. Rajesh B Goel
Registrar
MGM Institute of Health Sciences
(Deemed to be University)
Sector-1, Kamothe, Navi Mumbai-410209

Dr. Rajesh B. Goel
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MEMORANDUM OF UNDERSTANDING

Between

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AND

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12th September 2019

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Dean
M. G. M. Dental College &

PREAMBLE:

As discussed in the IQAC meeting held on 10/9/2019, it was decided to have a Memorandum of Understanding between the **MGM Institute of Health Sciences (MGMIHS)**, Navi Mumbai and **MGM Dental College and Hospital,** Kamothe.

The MEMORANDUM OF UNDERSTANDING (MoU) made on **12th September 2019,** between the **MGM Institute of Health Sciences (MGMIHS)**, Navi Mumbai, a deemed to be University under section 3 of the University Grants Commission Act, 1956 having its office at – MGMIHS, Kamothe, Navi Mumbai and **MGM Dental College & Hospital** (MGMDCH), Kamothe, Navi Mumbai through Dr. Vanitha U. Shenoy, Dean and (hereinafter referred to as the party of the "**Second Part/ MGMDCH**" which expression shall, unless repugnant to the context thereof, include its, successors and assigns.) .

SCOPE AND OBJECTIVES OF MoU:

The scope and objectives of MoU are defined as:

MGMIHS AND MGMDCH agree to sign MoU for sharing academic, clinical training/internship, on job training, project work, student/faculty exchange and for collaborative research programmes to get the Mutual Benefits.

DURATION OF MoU

This MoU comes into effect from the date of its signing and will remain in force for a period of **FIVE YEARS.** Its validity can be extended by mutual agreement between both the parties.

RESPONSIBILITIES OF MGMIHS, KAMOTHE AND MGMDCH, KAMOTHE, NAVI MUMBAI:

Specific Roles of MGMIHS:

1. Provide academic, infrastructural support and research facilities including the MGMIHS Innovation and Incubation Centre facility for the faculty and students of MGMDCH.

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2. Exchange of information through lectures and practical's, relating to their activities in field of mutual interest.

3. Provide internship to the students.

4. Arrange observer-ship programs for the students.

Specific Roles of MGMDCH:

1. Provide academic and infrastructural support facility for the faculty and students of MGMIHS.

2. Exchange of information through lectures and practical's related to activities in field of mutual interest as per the National Medical Council.

Common Activities by Both the Parties

1. Both institutions agree to provide work space and technical facilities as applicable.

2. The consultancy and travel expenses related to the visits for lectures/sessions will be reimbursed by the host institute on mutually agreed terms.

3. Sharing of information for teaching and research periodically.

4. Either institute shall have the right to terminate this MoU upon 60 days prior notice period to the other Institute.

5. Both the institutes i.e. MGMIHS and MGMDCH will organize conferences, workshops, seminars etc. The faculty, students and staff shall be encouraged to participate in such activities, so as to interact with each other for their academic and professional growth; such programmes will be conducted by both the institutions with information to each other in advance, as and when required.

6. MGMIHS and MGMDCH mutually agree to exchange staff / students for their projects, clinical training/internship, on job training, project work, student/faculty exchange and for collaborative research programmes to get the Mutual Benefits and the charges will be borne by individual students as per the institutes rules and regulations.

Dr. Rajesh N. Goel
Registrar

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7. MGMIHS and MGMDCH mutually agree to help each other to establish and develop laboratories, research centers, etc. as and when required.

8. Faculty of MGMIHS and MGMDCH depending on their qualifications and experience can act as co-guides to the students pursuing the PG and Ph.D. programmes at MGMIHS and MGMDCH as the case may be.

9. Areas for faculty development shall be indentified and joint proposals shall be submitted to various funding agencies like ICMR, DST, BRNS, and RGSTC etc.

10. Both the institutes will participate in relevant government programs / schemes to take mutual benefits of Institute - Institute collaborations where ever possible.

11. MGMIHS and MGMDCH mutually agree that Publications of the joint research carried out will be done jointly by both the Institutes incorporating the names of all the contributors.

12. The regular health check up for MGMDCH students will be done by MGM Hospital and medical services will be provided to students, faculty and staff of MGMDCH. The dental check up will be done for students of MGMIHS and dental treatment will be provided to students, faculty and staff of MGMIHS.

13. One counselor will be assigned for the students of MGMDCH.

14. This document is in no way intended to create legal or binding obligations on either party. It serves only as a record of the parties' current intentions to enhance relationship of the Institute and Institute going forward.

General Conditions:

1. It will be ensured by both parties that the conduct of activities under the MoU will be smooth and achieve the objective of the MoU. The parties may further extend /renew the MoU on terms and conditions as mutually agreed. The MoU may be terminated only by mutual consent. Once the MoU is terminated no new activity will be conducted by and between the parties. However, the parties undertake to complete the activities, programs etc which have already been commenced or are in progress pursuant/under this MoU.

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2. The parties will jointly conduct yearly meetings to ensure that the activities/programs undertaken under this MoU by and between the parties are conducted in a proper manner and as per the schedule laid down.

NOTICES

Any notices given under this Agreement will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

MGMIHS :-

Address: Sector 1, Kamothe Navi Mumbai-410209, Tel No: 022-27432471/27432994
Fax: 022-27431094
Email: registrar@mgmuhs.com

MGMDCH :-

Address: Sector 1, Kamothe Navi Mumbai-410209, Tel.No:022-27436604, 27434946
Email. mgmdch@mgmmumbai.ac.in Website: www.mgmdchnavimumbai.edu.in

MISCELLANEOUS

a) Assignment

Neither party may assign this agreement or the rights their under without the prior written consent of the other party.

b) Severability

If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent/object of the parties under this MoU.

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences

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c) Order of Precedence.

In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated herein or any other document, correspondence or agreement concerning this Programme between the Parties and/or their employees, the terms of this Agreement will prevail.

d) Entirety.

This Agreement represents the entire agreement and understanding between the parties with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

e) Amendments.

The Amendments or changes to this Agreement must be in writing and signed by duly authorized representatives of both the parties. No amendment or modification of this MoU shall be valid unless the same is made in writing by both the parties or their authorized representatives and specifically stating the same to be an amendment of this agreement. The modification/changes shall be effective from the date on which they are made / executed unless otherwise agreed to.

f) Independent Entities.

MGMDCH and MGMIHS are independent parties and neither is an agent, joint venture partners, or partner of the other.

g) Dispute Resolution.

In event of dispute or claim between the parties concerning the interpretation of any provision of this agreement or the performance of any of the terms/obligations of/under this Agreement, such matter or matters in dispute shall be first settled amicably by mutual discussion between the Vice Chancellor / Registrar of MGMIHS and Dean of MGMDCH failing which through the Arbitration process.

Dr. Rajesh S. Goel
Registrar

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Both the parties after due discussion shall appoint an Arbitrator for resolving the dispute arising out of this Agreement.

Now, therefore, for and in consideration of the foregoing premises the parties have signed the Memorandum of Understanding on **12th September 2019**

PARTIES

Registrar **Dr. Rajesh B. Goel** **Registrar** **MGM Institute of Health Sciences** **Navi Mumbai - 410209** **MGM Institute Of Health Sciences,** **(Deemed University u/s 3 of UGC Act 1956)** Grade "A" Accredited by NAAC Sector 1, Kamothe Navi Mumbai - 410209	**Dean** Dean M. G. M. Dental College & Hospital Kamothe, Navi Mumbai - 410 209 **MGM Dental College & Hospital, Navi Mumbai,** Sector 1, Kamothe Navi Mumbai-410209

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