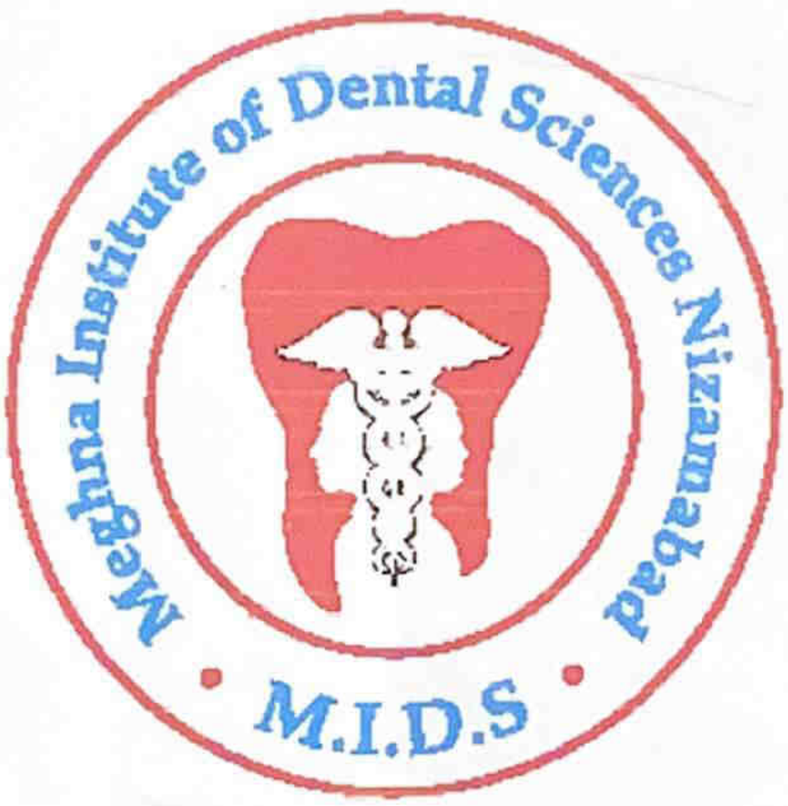
Standard Operating Procedures

For

Institutional Ethics Committee



Meghna Institute of Dental Sciences

Mallaram (V), Nizamabad

Prepared by:

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APPENDIX

PRINCIPAL
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I. Short title and Scope:

The following may be called as "Standard Operating Procedure" for the Institutional Ethics Committee [IEC] of Meghna Institute of Dental Science (MIDS), Nizamabad. The present SOP covers functioning of ethics committee reviewing all research on human subjects done at MIDS as well as those done at other locations under the aegis of a Principle investigator / co-investigator/ employed at MIDS

II. Name of the Ethics committee:

Institutional Ethics Committee [IEC], Meghna Institute of Dental Sciences, Nizamabad

Address of the office of the ethics committee:

The Member Secretary

Institutional Ethics Committee

Meghna Institute of Dental Sciences, Nizamabad, 503230.

Phone no: 9505445456

Email ID: mids_nizamabad@yahoo.co.in

III. Objective:

The objective of this standard operating procedure of the Institutional Ethics Committee [IEC], of MIDS, Nizamabad is to maintain effective functioning of the IEC-MIDS and to ensure quality and technical excellence and consistent ethical review of all the submitted health and biomedical research proposals and ongoing approved research studies involving human participants in accordance with ICMR ethical guidelines for biomedical research on human subjects.

IV. Terms of Reference:

The ethics committee is mandated to examine research proposals where research is to be wholly or partially carried out at MIDS to ensure that research is carried out in accordance with ethical principles.

To ensure that the research projects carried out at MIDS

- Are sound in design, have statistical validity and are conducted according to ICMR and ICH/GCP Guidelines .
- Do not compromise safety of the patients or volunteers.
- Are conducted under the supervision of medical persons with the required expertise.
- Include solely, patients who have given voluntary and informed consent.

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V. Authority under which the ethics committee has been constituted, membership requirements, the term of reference, conditions of appointments and the quorum required

1. Authority under which the ethics committee has been constituted: The chairman, of Meghna Institute of Dental Sciences, Nizamabad, is the competent authority for constitution of the IEC among. The principal is authorized to nominate members in consultation with the chairperson of the IEC among those who possess the qualifications and experience as per the norms prescribed under drugs and cosmetic rules.

2. Membership requirements:

Institutional Ethics Committee will be constituted with the following:

i. Chairperson, nominated by the principal, an expert from outside the Institute.

ii. Member secretary – Institutional, 1 member

iii. Basic Medical scientists -1 member

iv. Subject expert - 4 members

v. Non-medical: social scientist /philosopher /ethicist/theologian-01 member

vi. Legal expert-01 member

vii. Lay person-01 member

viii. Additional member[s] in any of the above categories as required.

Presence of atleast one woman on the committee is compulsory

Medical scientists shall hold a postgraduate degree in Medicine/Dentistry of MD/MS/PHD. The Non-Medical Scientific members are required to have a PhD in Life Sciences/Veterinary Sciences. Legal expert is required to be an advocate with qualification of B.L. All members are required to have good moral character and should not have been convicted for any offence.

Chairperson:

a. The chairperson of the committee should be from outside the institution to maintain the independence of the committee.

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b. The chairperson is responsible for conducting all committee meetings, and leads all discussions and deliberations pertinent to the review of research proposals.

c. The chairperson presides overall administrative matters pertinent to the committee's functions.

MEMBER SECRETARY

a. The member secretary should be a medical scientist who belongs to MIDS and should conduct the business of the committee.

b. In consultation with the chairperson, the member secretary will be responsible for the following functions.

- Receiving all research proposals.
- Forwarding all materials for review by the committee members
- Preparation and dissemination of agenda for all committee meetings [10 days prior to the meeting date]
- Inviting special attendees /expert, from relevant specialties to the scheduled meetings, if needed.
- Preparation and circulation of minutes [within 14 days of the meeting].
- Notification of the review outcome to principal investigator of research proposals.
- Retention and safekeeping of all records and documentation.
- Performance of other duties assigned by the chairperson.

Procedure for appointment of members:

The Principal after appointing the chairperson shall, in consultation with the chairperson, nominate the members of IEC, who have the qualification and experience to review and evaluate the science, medical aspect and ethics of the proposed study.

- The normal term for IEC member will be for 24 months.
- Principal in consultation with chairperson and member secretary can renew the appointment of the member on the basis of contribution.
- During the term, Principal in consultation with the chairperson and member secretary can disqualify any member if the contribution is not adequate and, or there is a long period of (member) non availability.
- Member can discontinue from membership of IEC after giving atleast one-month advance notice.
- Principal can replace the member of the IEC as and when required.
- Each member is required to sign the declaration and confidentiality agreement regarding IEC activities.
- Conditions of appointment: Non-Institutional committee members are paid and honorarium for each meeting.

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VI . The quorum required:

The quorum required shall be a minimum of five members. It should include both medical and non-medical members, with atleast one of the members present being not affiliated to MIDS.

The quorum for review of a clinical trial is bio availability are bio equivalence protocol and related documents shall be atleast five members with the following representations. (i) medical scientists (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.

VII. Type of clinical research reviewed by the committee (e.g. pharmaceuticals, devices, epidemiological retrospective, herbals, etc.,)

Drug trials, Prospective clinical Studies, on both dental and surgical patients and blood and pathology specimens, epidemiological studies, retrospective studies that are conducted by the students and the staff of Meghna Institute of Dental Sciences, Nizamabad.

VIII. Documents reviewed for every clinical trial protocol including informed consent documents.

(A) The appropriateness of the study design in relation to the objectives of the study, the statistical methodology, and the potential for reaching sound conclusions with the smallest number of research participants.
(B) Consent form in English and local language (TELUGU) case of studies on human subjects.
(C) Source of funding for the clinical trial.
(D) Description of ethical consideration involved in the research.
(E) Case report forms, diary cards, proformas and other questionnaires intended for research participants.
(F) Investigators curriculum vitae.
(G) A statement describing any compensations for study participation (including expenses and access to medical care) to be given to research participants.
(H) A description of arrangements for indemnity, if applicable.
(I) A description of arrangements for insurance coverage for research participates, if applicable.
(J) A statement of agreement to comply with ethical principles set out in relevant guidelines.
(K) All previous IEC's decision (eg. those leading to negative decisions or modified protocol) and by other regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reason for the previous negative decisions must be provided.
(L) Justifications of predictable risk and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
(M) The justification for use of controlled arms.
(N) Criteria for prematurely with drawing the research participants.
(O) Criteria for suspending or terminating the research as a whole.
(P) The adequacy of provisions made for monitoring and auditing the conduct of research including data safety monitoring committee .

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(Q) The adequacy of the site, including the supporting staff, available facilities and emergency procedures

(R) The manner in which the results of the research will be reported and published.

IX Procedure for submission of application for ethics review:

1) The principal investigator has to submit an application in a prescribed format along with study protocol for the review of the IEC
2) Application can be submitted to the office of the Chainman, IEC, Meghna Institute for Dental Sciences (MIDS), Nizamabad, on any working day.
3) All the proposals and documents must be submitted in English language, at least 3 weeks in advance from the schedule date of IEC meeting.
4) Eleven (11) copies of study proposal (with all documents) must be submitted along with application form duly signed and dated by the investigator(s)
5) On receipt the applications will be acknowledged with IEC registration number to be used for all future correspondence and reference.
6) Thesis of MDS Courses involving ethical issues also need IEC clearance.
7) Every application has to be routed through the concerned Head of the Department to the IEC.

X. The procedures (SOP) to be followed by the committee during meetings and while taking decisions:

(a) Meeting of the Ethics committee will be held mostly Applicant sponsor of investigator may be invited to make a slide presentation on the proposal or elaborate on specific issues.

(b) A decision will be taken only when sufficient time has been allowed to the Principal investigator for presentation of protocol and to the committee for review and discussion.

(c) The IEC will evaluate the possible risks to the subject with proper justifications the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.

(d) A decision will only be taken at meetings where the quorum is complete Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.

(e) Members will be given 10 days' time in advance to review study proposals and the relevant documents.

(f) IEC meetings will be minuted and all the proceedings and deliberation will be documented.

(g) At the end of each IEC meeting, signatures from each member who has participated will be obtained on the final draft of the minutes of meeting.

(h) Decision will be taken only after reviewing a complete application with all the required documents necessary for the proposal.

(i) Only members who participated in review and discussion will participate in decision.

(j) In case of conditional approval of a proposal the same will be communicated to the investigators, with clear suggestions for modifications and Re-review procedure.

(k) Negative decision will be supported clearly by stated reasons.

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XI Policy on protection of vulnerable population:

(a) Research on genetics should not lead to promotion of racial inequalities

(b) Persons who are economically or socially disadvantaged should not be used to benefit those who are better off than them.

(c) Rights and welfare of mentally challenged and mentally differently able persons who are incapable of giving informed consent or those with behavioral disorders must be protected.

(d) Adequate justification is required for the involvement of subjects such as prisoners, students, subordinates, employees, service personnel etc, who have reduced autonomy as research subjects.

XII Policy regarding training for new and existing committee members along with SOP's

The Member Secretary of the Ethics committee collects the information on Drugs and Clinical trails, notifications and supplementary amendments from time to time and informs the committee members. Formal training in Good Clinical Practice along with certification will be organized by MIDS at regular intervals.

XIII Procedure for communicating the decision of IEC to the applicant

The committee will give its opinion on the project in writing in one of the following ways;

- Approval
- Disapproval
- Modification before approval
- Discontinuation of previously approval project

The Chairperson of the committee may provisionally approve without calling a full meeting in cases where only administrative amendment has been made. The Chairperson will inform other members of the committee of the amendment and his decision. The decision will be ratified at the next full committee meeting and this will be minuted.

XIV Procedure for expedited review:

Only to be performed when there is no or minimum risk to the trial participants

1) Re-examination of a proposal already examined by the IEC.

2) Study of minor nature eg, examination of case records.

3) Similar study proposal for which IEC had already given approvals earlier.

4) An urgent proposal of national interest having minimum risk.

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5) Proposals with minimum risk to be reviewed when it may not be possible to convene main ethics committee meeting with quorum- as for example during natural disasters, lockdowns, epidemics etc

All expedited approvals will be given in a meeting with quorum of at least 3 members (Nominted by the Chairperson) of IEC Quorum must have one expert or scientist having scientific knowledge in the field of proposal. It should also include either the Member Secretary or the Chairperson or both.

Decision taken by the committee on expedited approval however will be brought to the notice of the main committee members for ratification.

XV Elements of Review:

Following are the elements to be reviewed by the IEC member.

A. Scientific design and conduct of the study:

1) The appropriateness of the study design in relation to the objectives of the study the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants

2) The appropriateness of clinical trial site in terms of facilities to conduct the intended research and to take clinical care of the patients as per their requirements. This shall include investigations, treatment facilities, supportive staff follow-up facilities etc

3) The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.

4) The justification for the use of control arms.

5) Criteria for prematurely withdrawing the research participants.

6) Criteria for suspending or terminating the research as a whole.

7) The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Committee (DSMC).

8) The manner in which the results of the research will be reported and published.

B. Requirement of research participants:

1. The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status and ethnicity).
2. The means by which initial contact and recruitment is to be conducted.

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3. The means by which full information is to be conveyed to potential research participants or their representatives.
4. Inclusion criteria for research participants.
5. Exclusion criteria for research participants.

C. Care and protection of research participants

1. Any plans to withdraw or withhold standard therapies for the purpose of justification

2.The medical care to be provided to research participants during and after the course of the research

3.The adequacy of medical supervision and psycho-social support for the research participants.

4.steps to be taken if research participants voluntarily withdraw during the course of the research.

5.The criteria for extended access to the emergency use of and/or the compassionate use of study products.

6.The arrangements if appropriate for informing the research participants general practitioner [family doctor]'including procedures for the participant's consent to do so.

7.A Description of any plans to make the study product available to the research participants following the research.

8. A description of any financial costs to research participants

9.The rewards and compensations for research participants [including money, services, and or gifts].

10.The provisions for compensation/treatment in the case of the injury disability /death of a research participant attributable to participation in the research.

11.The insurance and indemnity arrangements.

12.The ethics committee shall look into the details of the protocol for formation of a data and safety monitoring board. In the absence of any such provision in the protocol, the IEC may insist on the same prior to the approval or recommend to the principal MIDS to constitute a DSMB for monitoring the trial.

D. Protection of research participant confidentiality:

1.A description of the persons who will have access to personal data of the research participants ,including medical records and biological samples.

2. The measures taken to ensure the confidentiality and security of personal information concerning research participants.

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E. Informed consent process:

1.A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.

2.Consent form in English and local language [Telugu] in case of studies on human subjects will be reviewed.

3.The adequacy, completeness, and understandability of written and oral information to be given to the research participants and when appropriate, their legally acceptable representative[s].

4.Clear justification for the intention to include in the research individuals who cannot consent, and a full account of arrangements for obtaining consent authorization for the participation of such individuals.

5.Assurences that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being).

6.The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

F. Community consideration:

1) The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.

2) The steps taken to consult with the concerned communities during the course of designing the research.

3) The influence of the community on the consent of individuals.

4) Proposed community consultation during the course of the research.

5) The extent to which the research contributes to capacity building such as the enhancement of local health care, research and the ability to respond to public health needs.

6) A description of the availability on affordability of any successful study product to the concerned community following the research.

7) The manner in which the results of the research will be made available to the research participants and the concerned communities.

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G. Selection of special groups as research subjects

i) **Children:** Before undertaking trial in children the investigator must ensure that-

a. Children will not be involved in research that could be carried out equally well with the adults.
b. The purpose of research is to obtain knowledge relevant to health needs of the children. For clinical evaluation of new drug the study in children should always be carried out after the phase III clinical trials in adults. It can be studied earlier only if the drug has a therapeutic value in a primary disease of children.
c. A parent or a legal guardian of each child has given proxy consent.
d. The assent of the child should be obtained to the extent of the child's capabilities such as in case of mature minors, adolescents etc
e. Research should be conducted in settings in which the child and the parent can obtain adequate medical and psychological support.
f. Interventions intented to provide direct diagnostic, therapeutic or preventive benefit for the individual child subject must be justified in relation to anticipated risks involved in the study and anticipated benefits to society.
g. The child's refusal to participate in research must always be respected unless there is no medically acceptable alternative to the therapy provided/tested, provided the consent has been obtained from parents/guardian.
h. Interventions that are intended to provide therapeutic benefit likely to be atleast as advantageous to the individual child subjects as any available alternative interventions.
i. The risk presented by interventions not intended to benefit the individual child subject is low when compared to the importance of knowledge that is to be gained.

H) Appropriateness of investigator: The ethics committee shall review the CV of the investigator, including qualifications, current designations and experience to determine whether she/he has appropriate capability to undertake the research in question (including clinical trials).

XVI. Follow up procedure:

1.IEC will review the progress of all studies for which a positive decision has been reached from the time of decision till the termination of research.

2.Progress of all the research proposals will be followed at a regular intervals of atleast once in 6 months. But in special situations, IEC will conduct the follow up review at shorter intervals basing on the need, nature and events of research projects.

3.The committee shall seek from the investigators:

- A progress report on 6 monthly basis or more frequently as the committee feels it.
- A report of each serious event when observed during conduct of the study
- To be kept informed of amendments to any study related documents
- To be kept informed of study discontinuation with reasons.

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4.With regard to clinical trials, Data Safety Monitoring Board (DSMB) will be constituted by the principal MIDS or by the trial investigators to review the clinical trial notifications and to report the adverse events if any to the Institutional Ethics Committee. The board will review the clinical trial records for serious adverse events and report periodically to the IEC. Also the investigators have to communicate the observations DSMB to IEC periodically.

5.All the requirements and procedures for follow up review will be similar to that of initial and main review. Following instances and events will require the follow-up review

i. Protocol amendment, likely to affects, rights, safety or well-being of research subject in conduct of study.

ii. Serious or unexpected adverse reaction related to study or product, action taken by investigator, sponser and regulatory authority

iii. Any event or information that may affect benefit/risk ratio of the study

A decision of a follow up review will be issued and communicated to applicant indicating modification/suspension/termination/continuation of the project

Applicant must inform at the time of completion of study and must send the result summary to IEC.

IEC must receive a copy of final summary of study completed from the applicant.

XVII procedure for documentation and archiving;

1.All the documents and communications of IEC will be dated, filed and archived in a secured place

2.Only the person, who is authorized by the chairperson of IEC will have the access to the various documents.

3.All the documents related to research proposals will be archived for a minimum period of 5 years in the institute, following the completion of the study.

4.No documents (except agenda) will be retained by any IEC member.

5.At the end of each meeting every member will return all the research proposal documents to IEC office staff.

XVIII Review of performance of ethics committee;

The principal, MIDS who is the constituting authority of the IEC shall periodically assess the performance of IEC members in consultation with the chairperson and member secretary of the IEC, in terms of attendance, punctuality, participation in discussion and willingness to learn. The member secretary shall evaluate performance of the IEC itself in terms of time interval between submission of proposal and approval/rejection, maintenance of records, arrangements for meeting etc. and shall

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carry out corrective action. Records shall be maintained of the review and any corrective and preventive action.

XIX Amendment of SOP;

Guidelines in this document may be subjected to amendments as and when the need arises. The faculty/investigators from MIDS, or any other concerned citizen from public can suggest the need to add/delete, alter/amend certain clauses in this document. The MIDS ethics committee or a special committee constituted for that purpose shall discus the suggestions made before recommending for the same or otherwise. Member secretary will be responsible for tabling the amendments. Amended version of the document will be put before the executive board of MIDS for its consideration and approval.

XX Plagiarism

Plagiarism to be checked by plagiarism checking software Plag Scan and to be accepted if within 8%

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E-mail : info@meghnadentalcollege.ac.in Website : www.meghnadentalcollege.ac.in

APPENDIX-1

UNDERTAKING FROM PRINCIPAL INVESTIGATOR

Date:

Ref no:

Name and Address of the investigator [from MIDS]:

Chairperson/Member Secretary,

IEC-MIDS,

Meghna Institute Of Dental Sciences, Nizamabad

Sub: Ethical clearance for Research project entitled _____

UNDERTAKING

With respect to the above said Research/Clinical Trial/Thesis [strike off whichever is not relevant] protocol involving human subjects for which the ethical clearance being sought, I am to state that I have gone through IEC-MIDS guidelines and am aware of the rules governing the studies involving the human subjects. I am also aware that these guidelines are strictly to be followed while carrying out the above said research project involving human subjects.

Further, I also affirm that I will be responsible to keep the IEC informed of,

i. Any serious and unexpected adverse events and remedial steps taken to tackle them.

ii. Any new information that may influence the conduct of the study.

iii. Any changes made in the consent form.

iv. Under no circumstances, I/We deviate from the original approved protocol without prior consent from the IEC, in the event of need to amend the original protocol approved by the IEC, the proposed amendment shall be brought to the notice of IEC for its consideration and approval.

Date:

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Name and Signature of the Principal investigator

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APPENDIX -II

SPECIMEN CONCENT FORMs

Information to the participants:

This section should contain the information about the diagnosis made, if any, and also about the various modes of treatments available, subject needs to be given the free choice of selection of the treatments that are available, including the one which is being considered for the research study. Even if there is scope for slightest risk involved in the purposed mode of treatment/procedure, The same needs to be clearly informed to the participant and /or guardian of the person participating in the study. Participant in the proposed study be clearly informed about his/her right to withdraw from the study without any reason, if he/she desire so, and that would not effect in any way his/her treatment or of his/her ward/relative who is undergoing the treatment. Details regarding the scope of treatment in terms of duration, medications/procedures to be used and the clinical materials such as blood etc. that needs to be collected in terms of volume and periodicity be clearly stated in the information to be provided to the participants and/or the guardian. With this information made available to the participant in a language understandable to him/her it needs to be followed by the request and assurance as enumerated below from the investigator. i.e.

Undertaking by the investigator:

Your consent to participate in the above study is sought. you have right to refuse consent or withdraw the same during any part of the study without giving any reason in such an event, you will still receive best possible alternative treatment without any prejudice. if you have any doubts about the study, please feel free to clarify the same. Even during the study, you are free to contact any of the investigators for clarification if you so desire [investigators name with telephone no need to be furnished]. **All the information collected from you will be kept in strict confidence.**

Date:

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Name and signature of principal investigator

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Consent

I have been informed about the procedures of the study. The possible risks to have been explained to me as stated in the information. I have understood that I have the right to refuse my consent or withdraw it any time during the study without adversely affecting my/ my ward's treatment. I am aware that by subjecting to this investigation, I will have to give more time for assessments by the investigating team and that these assessments do not interfere with the benefits.

I _____, the under signed, give my consent to be a participant of this investigation /study program/clinical trial, entitled "_____

_____".

Signature of patient	Signature of the witness	Signature of the investigator:
Name of patient	Name of the witness	Name of the investigator
Place:	Place:	Place:
Date:	Date:	Date:

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PI. note:

(1) The above format is only a guideline, which may need to be altered according to the situation as to whether the participant is patient, or patient's guardian or a volunteer who may take part in studies involving the study of normal subjects, further where the participant is not proficient with English, he/she provided with a consent form in a language in which he/she is proficient.

(2) Informed Consent Form in min 3 languages viz. English, Hindi, Telugu and other languages where needed to be furnished.

(3) Suppose the study group deals with only English or any particular language speaking patient, then an undertaking required to be furnished.

(4) A certificate from the translator stating that the translated version of the informed consent form is the' true' translation of the original version of the informed consent form is required to be typed/ printed at the end of the each translated version of the document. Further, the translator has to append his signature, name and address below the certificate.

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MALLARAM (V), NIZAMABAD

CHAIRPERSON
Institutional Ethics Committee
Meghna Institute of Dental Science (IEC-MIDS)
NIZAMABAD-503001 (Telangana)

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APPENDIX III

IEC Membership Acceptance:

To,

The Principal,

Meghna Institute for Dental Sciences,

Nizamabad.

Sub: Consent to be a member of Institutional Ethics Committee.

******

Sir,

I accept the invitation to become a member of IEC of Meghna Institute of Dental Sciences, Nizamabad. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

- I shall be willing to publicize my full name, profession and affiliation
- I shall make available to the public on request, all reimbursement for work and expenses if any related to IEC
- I shall not keep any literature or study related document with me after the discussion and final review.
- I shall maintain the confidentiality regarding IEC activities.

Therewith enclose my CV.

Thanking you,

Yours sincerely.

Signature_____

Name of Member _____

Address

PRINCIPAL
Meghna Institute of Dental Sciences
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Date_____

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APPENDIX-IV

Application for Ethical Review of Biomedical Research Proposal

To Date:

The Chairperson,

Institutional Ethics Committee

Meghna Institute Dental Sciences,

Nizamabad

Full name of applicant:

Designation :

Complete Address

Tel No

E-mail:

Site of Study.

Protocol No.(if any) Date:

Amendment No Date:

Title of Project

Type of study.

Local /National/International

Type of trial: single centre/multi centre

Sponsor's Name:

Address

	Name	Signature
Principal Investigator :		
Co-Investigator: 1)		
2)		
3)		

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(Application must be submitted along with all essential documents for the review) (See list of Documents)

List of documents to be submitted along with application for the IEC Review:

1. Signed and dated application form on prescribed format.
2. The protocol of the proposed research (clearly identified and dated) together with supporting documents and annexes.
3. A summary (as far as possible in non-technical language), synopsis, or diagrammatic representation (flowchart) of the protocol.
4. A description (usually included in the protocol) of the ethical considerations involved in the research.
5. Case report forms, diary cards and other questionnaires intended for research participants.
6. In case the research involves a study product (such as a pharmaceutical or device under investigation), an adequate summary of all safety pharmacological, pharmaceutical and toxicological data available on the study product, together with a summary of clinical experience with the study product to date (e.g. recent investigator's brochure published data a summary of the product's characteristics); (Product information).
7. Investigator(s) curriculum vitae (update, signed and dated)
8. Material to be used (including advertisements) for the requirement & potential research participants.
9. A description of the process to be used to obtain and document consent.
10. Written and other forms of information for potential research participants (clearly identified and dated) in the languages understood by the potential research participants and, when required in other languages.
11. Informed consent form (clearly identified and dated) in the languages understood by the potential research participants and when required in other languages.
12. A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants.
13. A description of the arrangements for indemnity, if applicable.
14. A description of the arrangements for insurance coverage for research participants if applicable.
15. A statement of agreement to comply with ethical principles set out in relevant guidelines
16. All previous IEC's decisions (e.g. those leading to a negative decision of modified protocol) and by other regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol made on that account. The reasons for previous negative decisions must be provided.

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APPENDIX V

Institutional Ethics Committee

Meghna Institute for Dental Sciences (MIDS), Nizamabad

Acknowledgement

Date:

Received _____ Copies of study proposal.

Protocol No._____ Dated

Amendment No. Dated

Entitled:_____

_____

From Dr._____

Designation_____

Address_____

For ethical review.

_____

For official use only

- Study Proposal Registration No:
- Name of IEC Staff *Signature

Receiving application:

Date _____

(To be filled by the applicant in duplicate)

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APPENDIX VI

Institutional Ethics Committee

Meghna Institute for Dental Sciences (MIDS), Nizamabad

Review letter No. IEC/MIDS / Date:

To

The Ethics Committee of Meghna Institute for Dental Sciences (MIDS), Nizamabad, in its Meeting held on _____at _____hours in the meeting room _____ reviewed and discussed the study proposed with Protocol No _____ dated, _____

Entitled"_____

_____

_____

Submitted by Dr_____

Members:

	Name	Affiliation	Gender
1			
2			
3			
4			
5			

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Members reviewed the following documents (tick whichever is applicable):

1. Protocol ( )

2. Amendment ( )

3. Written informed consent ( )

4. Investigator's Brochure ( )

5 Available safety information: ( )

6 Subject recruitment procedure ( )

7. Payments and compensation to subject ( )

8. Subject information sheet ( )

9. Investigator's C.V. ( )

10. Others: Specify_____

The members present, represented the quorum and having at least one medically qualified person and at least one layperson present from outside the Institute.

All the issues presented in the study proposal were thoroughly discussed and reviewed. Members present, _____ voted for approval, _____ voted against and _____ were absent.

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After all considerations, the committee has decided to approve/ not to approve/ suggested resubmission after required modification/subject to

Please provide the following clarifications/documents for re review

1

2

3

4

The present approval is valid only for one year, investigator must take the re- approval after one year.

The investigator is requested to submit the progress report after 6 months to IEC for review. Any change, modification or deviation in the protocol, or any adverse event must be informed to ethics committee; Any protocol modification or amendment must receive IEC approval. Investigator should conduct the study as per the recommended GCP guidelines.

Signature :

Date :

Name :

Chairperson

Institutional Ethics Committee

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APPENDIX –VII

MEGHNA INSTITUTE OF DENTAL SCIENCES (MIDS) NIZAMABAD PROFORMA TO BE FILLED BY THE PRINCIPAL INVESTIGATORS SUBMITTING RESEARCH PROPOSALS THROUGH MIDS FOR CONSIDERATION OF THE ETHICAL COMMITTEE

TITLE OF THE PROJECT _____

_____

PRINCIPAL INVESTIGATOR _____

DESIGNATION & DEPT _____

PART-1

(In vivo experiments on human subjects)

1. Whether the human subjects are

Children (less than 15 years)	Yes/No
Elderly (More than 60 years)	Yes/No
Disabled (mentally or physically handicapped)	Yes/No
Prisoners/Restitutes	Yes/No
2. Whether the human subjects are	Yes/No
Suffering from illness	Yes/No
Normal individuals	Yes No
3. Whether the project involves	
Clinical trial with new drugs, device(s) approved by DCI	Yes/No
Clinical trial with existing drug(s) device(s) approved by DCI	Yes No
Clinical trial with traditional medicines from	Yes/No

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Ayurvedic /Homeopathy /Tribal system

None of the above Yes/No

CAUTION: NO DRUG/DEVICE IS TO BE USED UNLESS APPROVED BY DRUG CONTROLLER OF INDIA)

If answer to 3.1 is yes kindly finish evidence of experimental and clinical safety of the

drug (Use separate sheets)

4. Whether the project involves

Any invasive procedure which would otherwise not be

Performed for the management of the patient Yes/No

Use of invivo radioactive material Yes/No

Use of radiation Yes/No

If answer to any of 4.1 or 4.2 or 4.3 is yes then answer 5, below.

5.Do you think that the procedural risk or the cumulative risk of exposure is below safety

Limits Yes/No

PART-II

(COLLECTION OF HUMAN MATERIAL OTHER THAN NORMALLY EXCRETED URINE, STOOL, SALIVA, SWEAT, WHICH WOULD OTHERWISE NOT BE COLLECTED FOR THE MANAGEMENT OF THE PATIENT)

6. 1. If the human material to be collected is human tissue specify the tissue

(.....)

It will be obtained by Operation/Biopsy/Abortion/Autopsy

Other (Specify.....)

2. Whether the procedure required to obtain the tissue is otherwise indicated for the

management of the patient Yes/No

If answer to 6.2 if yes, please explain the full procedure and justify collection and use of material (Use separate sheets)

7. Any other human material (Specify Yes/No If answer to 7 is yes then answer 7.1 and 7.2 below)

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Specify the method of collection (.....)

Specify the amount to be collected (.....)

PART-III (COLLECTION OF BLOOD)

8. Will it be collected amounts in excess of which would otherwise be collected for the management of the patient Yes/No

if answer to 8 is yes, then specify the excess amount

_____ml at a time

_____ml total

1.Will it be collected by extra peripheral venous puncture which would otherwise, be required for the management of the patient Yes/No

If answer to 8. I is yes, then specify the total number of peripheral venous Punctures (_____)

2.Will it be collected by a method which would otherwise not be required for the management of the patient? Yes/No

If answer to 8.2 is yes on specify the method (_____)

PART-IV

(DECLARATION BY THE PRINCIPAL INVESTIGATOR)

9. I hereby declare that, Voluntary written informed consent of the human subject will be obtained. In case of children and mentally handicapped subjects-voluntary written informed consent of the parents/guardians will be obtained. The probable risk involved in the project will be explained in full details to the Subjects/parents/guardians. The Subjects/parent/guardians will be at liberty to opt out of the project at any time.

I will terminate the experiment at any stage, if I have probable cause to believe, in the exercise of the good faith, skill and careful judgment required for me that continuation of the experiment is likely to result in injury, disability of death to the experimental subject.

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PART V

(DECLARATION BY THE PRINCIPAL INVESTIGATOR'S HEAD OF THE DEPT)

1. Is the Dept Institution ready to undertake the responsibility of the human

   Subjects in case of injury Yes/No

   If yes then will it include

   Transportation charges Yes/No

   Hospitalization charges Yes/No

2. Do you think that the experiments are so designed that they would yield meaningful Results that could not be obtained by other methods. Yes/No
3. Do you think that the animal experiments carried out support the need for clinical experimentation. Yes/No
4. Do you think that the experiments would be conducted in a manner, in and all unnecessary physical and mental suffering and injury Yes/No
5. Do you think the experiments have been planned in a manner so that the degree of risk to be taken would never exceed that determined by the humanitarian importance of the problem to be solved by the experiment. Yes/No
6. Do you think that proper preparations would be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death. Yes/No
7. Do you think that safeguards have been taken to see that the experimentation would be conducted only by scientifically qualified persons who possess the requisite competence, experience and qualities to carry out the research Yes/No

PRINCIPAL INVESTIGATOR_____

HEAD OF THE DEPT_____

For drug trials the following are necessary before implementation;

1. Permission from DCG (I).
2. Memorandum of Understanding on Rs 100 Stamp paper (format given).
3. Indemnity agreement on Rs.100 Stamp paper (format given).

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APPENDIX-VIII

MEMORANDUM OF UNDERSTANDING

This Memorandum of understanding (hereinafter called MoU) between Meghna Institute for Dental Sciences, Nizamabad, India (herein after called MIDS) and the Second Party)_____(here after called _____) entered into _____ (day)_____ (month) _____ (year) Preamble

Whereas MIDS is a dental college and hospital, established by Vels Group of Institutions, as one of excellence for providing dental care education and research of high order and is chartered to function as an institute under this State Act.

Whereas (the Second Party)

Whereas MIDS and (the Second Party) _____

are willing to jointly participate in the development of_____

The coordinator of the project will be_____(name, designation of the faculty member responsible from MIDS, Nizamabad).

The other Coordinator of the project will be_____(name, and designation of person responsible for second party).

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Institutional Ethics Committee
Meghna Institute of Dental Science (IEC-MIDS)
NIZAMABAD-503001 (Telangana)

Scope of MoU

This MoU will cover the joint efforts of Meghna Institute of Dental Sciences (MIDS), Nizamabad, and (Second Party) in the area of

_____

_____

(Specify the area of work jointly to be done)

Furnish full details of the work to be done.

1.

2.

3.

4.

5.

Responsibilities of MIDS

1.

2.

3.

4.

Responsibilities of Second Party

1.

2.

3.

4.

5.

PRINCIPAL
Meghna Institute of Dental Sciences
MALLARAM (V), NIZAMABAD

CHAIRPERSON
Institutional Ethics Committee
Meghna Institute of Dental Science (IEC-MI
NIZAMABAD-503001 (Telangana)

Administration:

Overall responsibilities of the project will rest with Meghna Institute for Dental Sciences (MIDS), Nizamabad &

_____

_____

(Identify the Institution/Organization and name of the persons)

Financial Arrangements

Funds for the projects will be from _____(name the funding agency) and the proportion of the funds to be released to MIDS will be Rs. _____(specify the amount).

The following equipment/consumables/supplies will be provided to

MIDS by (Second Party)._____

(This is for MoU involving grant of

equipment/consumables/supplies)

1.

2.

3.

4.

5.

Intellectual Property Rights:

1. The R&D information generated shall be shared by both the collaborating Parties.

2. Any publication shall be by mutual consent of the coordinators

3. Patents and other benefits, arising out of the project if any, shall be shared between the collaborating parties.

4. For projects identified as having a distinct potential of generating, leading to commercial applications NRDC (National Research Development Corporation of India) Guidelines will be followed.

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NRDC GUIDELINES

1. To bring to the notice of the Investigator, prospective user of the technology being developed.

2. To do market research about the product and bring out a comprehensive study about the market potential for attending entrepreneur.

3. For effective coordination between the laboratory generating the know-how and the entrepreneur know

4. To take such other steps as may facilitate the communication of know-how.

5. NRDC will retain 40% of the royalty/premia and the remaining 60% will be sent to the Institution generating the know-how. The Maring of 40% between the Institute and the project investigator team may be decided by the Institute.

Duration of MOU

This MoU will be in force for a period of _____(Years) from the date of its signing)

Amendments to the MoU

Amendments if any, before the expiry of this MoU shall be made in writing by the Authorized representatives of MIDS and _____(second party) after mutual agreement.

Resolution of Dispute:

Any dispute or difference between the collaboration parties shall be amicably resolved by either through mutual consultation or arbitration

Seal of the Parties:

In witness thereof Parties hereto having signed this MoU on the day, month and your mentioned herein before

Parties:

Signed and delivered for

and behalf of MIDS

Signature

Name

Designation

Seal

PRINCIPAL
Meghna Institute of Dental Sciences
MALLARAM (V), NIZAMABAD

Signed and delivered for and

behalf of (Second Party)

Signature

Name

Designation

Seal

CHAIRPERSON
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APPENDIX-IX

INDEMNITY AGREEMENT

This indemnity agreement is between Meghna Institute of Dental Sciences (MIDS), Nizamabad, India (hereinafter MIDS)

and_____

_____

(Name of the second party/ sponsor)

(Herein after SPONSOR)

Whereas MIDS engages in Dental research that involves experimental and investigational products, drugs, devices or therapy and

Whereas SPONSOR owns or has right to such experimental or investigational products, drugs,

Devices specifically as it relates to this agreement, products, devices, drugs shall mean the

Following

1.

2

3.

4.

5.

Whereas MIDS and SPONSOR have agreed that MIDS will use SPONSOR'S experimental and investigational products, drugs, devices for research purpose.

Now therefore, the parties agree as follows

1. Undesirable side effects, injuries, illness or reactions.

The SPONSOR agrees to indemnify, protect, defend and hold harmless MIDS, its officers, employees against cost or expenses associated with the diagnosis and treatment of undesirable side effects, injuries, illness or reactions that arise specifically from SPONSOR's products, devices, and drugs

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2. Loss, Damage or Liability:

The SPONSOR agrees to indemnify, protect, defend and hold harmless MIDS, its officers, employees from any loss, damage or ability they may suffer or incur as a result of claim or demands made against them that arise specifically from research involving SPONSOR's products, devices, drugs

3. Insurance

The SPONSOR agrees to maintain in force at its sole cost and expense with reputable insurance companies, Insurance of a type and in amounts equal to at least

_____

_____pcr (specify the amount of money) occurrence combined single unit and _____annual (specify the amount of money)

MIDS shall have the right to request the appropriate certificates of insurance from SPONSOR for purposes of ascertaining the sufficiency of coverage.

4. Attorneys and legal coverage.

The SPONSOR agrees to provide, at its own expenses, attorneys to defend against any claims made or action filed against MIDS its officers, employees. The SPONSOR also agrees to pay any settlement amounts or judgments levied against MIDS or any losses or expenses incurred by MIDS resulting from such claims or action.

5. Cooperation of parties.

MIDS agrees to notify promptly, SPONSOR in writing when any undesirable side effect, injury, illness or reaction arises from research involving SPONSOR's products, devices, drugs, MIDS agrees to cooperate with SPONSOR in defending any claim or action covered by this agreement. The SPONSOR agrees to consult on a regular basis with MIDS regarding the defense or settlement of any claim or action. Neither party will compromise or settle any claim or action without prior written consent of the other party.

6. Other.

This indemnity agreement does not displace, supercede or in any way limit any other agreements between the parties MIDS

PRINCIPAL
Meghna Institute of Dental Sciences
MALLARAM (V), NIZAMABAD

Name

PRINCIPAL

Date

Seal

CHAIRPERSON
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