MEGHNA INSTITUTE OF DENTAL SCIENCES
(Managed by : VELS EDUCATION SOCIETY)
Permited by Govt. of India, Ministry of Health & F.W. (DE Section & DCI, New Delhi)
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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)		

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

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

(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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