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)
Affilliated to K.N.R. University of Health Sciences, Warangal (T.S)
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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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