

SRI VENKATESWARA INSTITUTE OF MEDICAL SCIENCES

TIRUPATI - 517 507, ANDHRA PRADESH, INDIA

INSTITUTIONAL ETHICS COMMITTEE (IEC)

APPENDIX - IV: APPLICATION FOR ETHICS REVIEW OF BIOMEDICAL RESEARCH PROPOSAL

To _____ Date: _____
The Chairman
Institutional Ethics Committee
Sri Venkateswara Institute of Medical Sciences
Tirupati
Protocol No. (if any): _____
Amendment No.: _____

Full name of applicant: _____ Designation: _____

Complete Address: _____

Tel. No: _____ Fax No: _____ E-mail: _____

Site of Study: _____

Protocol No. Date: _____ Amendment No. Date: _____

Title of Project:

Type of study: ☐ Local ☐ National ☐ International Type of Trial: ☐ Single centre ☐ Multi centre

Sponsor's Name: _____

Address: _____

Role	Name	Signature
Principal Investigator		
Co-Investigator 1		
Co-Investigator 2		
Co-Investigator 3		

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

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APPENDIX - VII

PROFORMA TO BE FILLED BY THE PRINCIPAL INVESTIGATORS SUBMITTING RESEARCH PROPOSALS
THROUGH SVIMS FOR CONSIDERATION OF THE ETHICS COMMITTEE

TITLE OF THE PROJECT:

PRINCIPAL INVESTIGATOR:.....

DESIGNATION & DEPT.:.....

PART – I (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:

Suffering from illness

☐ Yes ☐ No

Normal individuals

☐ Yes ☐ No

3. Whether the project involves:

3.1 Clinical trial with new drug(s) / device(s) approved by DCGI

☐ Yes ☐ No

3.2 Clinical trial with existing drug(s) / device(s) approved by
DCGI

☐ Yes ☐ No

3.3 Clinical trial with traditional medicines from Ayurvedic /
Unani / Homoeopathy / Tribal systems

☐ Yes ☐ No

3.4 None of the above

☐ Yes ☐ No

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

If answer to 3.1 is yes, kindly furnish evidence of experimental and clinical safety of the drug (*Use separate sheets*).

4. Whether the project involves:

4.1 Any invasive procedure which would otherwise not be performed for the management of the patient ☐ Yes ☐ No

4.2 Use of in vivo radioactive material ☐ Yes ☐ No

4.3 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. If the human material to be collected is human tissue specify the tissue:

(.....)

It will be obtained by: ☐ Operation ☐ Biopsy ☐ Abortion ☐ Autopsy Other (Specify):

.....

6.2 Whether the procedure required to obtain the tissue is otherwise indicated for the management of the patient? ☐ Yes ☐ No

If answer to 6.2 is 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:

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

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

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PART – III (COLLECTION OF BLOOD)

8. Will it be collected in amounts in excess of which would otherwise be collected for the management of patients?

☐ Yes ☐ No

If answer to 8 is yes then specify the excess amount:

.....ml at a time

.....ml total

8.1 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 8.1 is yes then specify the total number of peripheral venous punctures:

(.....)

8.2 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 then specify the method: (.....)

PART – IV (DECLARATION BY THE PRINCIPAL INVESTIGATOR)

9. I hereby declare that:

1. Voluntary written informed consent of the human subject will be obtained.
2. In case of children and mentally handicapped subjects-voluntary written informed consent of the parents/ guardians will be obtained.
3. The probable risk involved in the project will be explained in full details to the subjects/parents/guardians.
4. Subjects/parent/guardians will be at liberty to opt out of the project at any time.
5. 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.

DEPARTMENT:

PRINCIPAL INVESTIGATOR

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PART – V (DECLARATION BY THE PRINCIPAL INVESTIGATOR / HEAD OF THE DEPT.)

1. Is the Dept./Institution ready to undertake the responsibility of the human subjects in case of injury?	☐ Yes ☐ No
* 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 to avoid 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.