# APPLICATION PROCEDURE

All Principal Investigators are requested to submit (not more than 3) new project proposals for the review of Ethics Committee on or before schedule date as indicated by the Member/Secretary of the Institutional Ethics Committee in the prescribed proforma in 3 sets for consideration.

Application should be sent along with duly filled Proforma I and II. Principal Investigators are requested to provide the information in this Proforma - I for review along with protocol proposal. Principal Investigator must fill the relevant information in proforma II and enclose for Ethics committee meeting.

## PROFORMA – I

**INSTITUTIONAL ETHICS COMMITTEE (IEC)**
**UNIVERSITY OF HYDERABAD**
**HYDERABAD – 500 046**

## PROTOCOL SUBMISSION FORM

IEC NO:-
Date:

**1. Title of the Project,**

**Protocol Number,**
**Version & Date:**

**2. Principal Investigator:**

2.1 Name of the Investigator:

2.2. Qualifications

2.3 Designation:

2.4 Department :

**3. Co-Investigators:**

**3.1.1. Name of the Co- Investigator 1;**

3.1.2 Qualifications

3.1.3 Department :

3.1.4 Name of the Institution:

**3.2.1. Name of the Co- Investigator 2;**

3.2.2 Qualifications

3.2.3 Depart ment :

3.2.4 Name of the Institution:

**3.3.1. Name of the Co- Investigator 3;**

3.3.2 Qualifications

3.3.3 Depart ment :

3.3.4 Name of the Institution:

**3.4.1. Name of the Co- Investigator 4;**

3.4.2. Qualifications

3.4.3 Department :

3.4.4 Name of the Institution:

**Note: If more co-investigators are involved, please photocopy this form and use**

**4. Level of review required:**

Full Expedited Amendment

**5. Funding source:**

5.1 Internal Funding (Only for Academic Projects).

5.2 External Funding

5.2.1 National International

5.2.2 National Agency CRO Industry

Other Specify
Name of the Funding Agency

Address and Contact Details of Funding Source

**6.0 Performance Sites:**

Has application been reviewed by any other hospital/ Institute / DCGI/ appropriate regulatory authority:

Yes No

**6.1 Additional Performance Sites / Collaborating Centers**

Any other sites are involved in the present study?

Yes No N/A

If yes, Please fill the following tables:

| **S.No.** | **List of other sites** |
|---|---|
| | |

7. **Purpose of the study:**
( Please summarize the purpose of the study using non-technical language)

8. **Description of Human Subject Population:**
Human subject means a living individual about whom an investigator
(whether professional or student) conducts research and obtains

a. Data through intervention on interaction with the individual, or
b. Identifiable private information (i.e, pathological specimens, medical records etc.,)

Please answer the questions below for the subject population to be enrolled:

Place at which they are enrolled :

8.1 Proposed number of trial subjects required:

8.2 Estimated total number of individuals who would be consented for the study to obtain the number of evaluable subjects.

8.3 Age Range

0-6 yrs. 7-17 yrs
18-58 yrs 59+ yrs

8.4 Types of subjects

Inpatients
Out patients
Healthy Volunteers
Others: Specify:_____

8.5 Will the study be formed on both genders?

Yes No

If No justify

8.6 Will special population be included in the research?

Yes No

If yes, complete the following:

Minor under age 18
Pregnant women
Fetus/fetal tissue
Prisoners
Economically disadvantaged
Individuals with mental retardation
Others (specify:_____)

8.7 Provide rational for using special population:

The groups listed in above section 8.6 are considered vulnerable and require special consideration by federal regulatory agencies and/or IEC.

9. **Recruitment Procedures:**

9.1 Will advertisement be used to recruit subjects?

Yes No

If yes, will the following:
Brochures
Newsletters
Flyers Posters
Radio
Television
Contact letters
Internet
Other (Specify :_____)

9.2 Describe who will make initial contact with the potential subject:

**10 Informed Consent:**

10.1. Will informed consent be obtained from the subjects participating in this Study?

Yes No

If No submit supplemental Waiver of content / Authorization

10.2 How will informed consent be obtained from potential study Participants?

Oral Written

10.3 Will be informed consent be translated in a local language?

Yes No

**11. Informed Consent Process:**

The following questions pertaining to the informed consent process have to be answered:
11.1 Will adult subjects have the capacity to give informed consent?

Yes No

If No, describe the likely range of impairment and explain how, and by whom their capacity to consent will be determined. Individuals who lack the capacity to consent may participate in research only if a legally authorized representative gives consent on their behalf.

11.2 In relation to the actual data gathering, when and where will consent be discussed and documentation obtained (for example, pre-operatively or several days before study procedures commence)?
Specific answer

11.3 How will you determine whether the subject understands the study?

By Questionnaire: Feed Back Others

**12. Description of Study**

12.1 Describe the procedures or tasks/tests the subjects will be asked to
Complete or undergo using non-technical language.

(Explain step by step what the subjects will be asked to do and distinguish those which are experimental from those comprising routine clinical care.)

12.2 Does the research involve the use of any drugs?

Yes No

If yes, please submit the Drug information Brochure / Investigator's Brochure

12.3 Does the research involve the use of any device?

Yes No

If yes, Please submit the device information Brochure

12.4 Does the research involve the following?

Any Surgical Procedure
Use of radioisotopes or radioactive agents (if so please submit detail
Information)
Invasive techniques
Changes in diet or exercise
Use of medical records
Deprivation of Physiological requirements such as nutrition or sleep.
Collection of personal or sensitive information

Others (Please specify :_____)

12.5 Does the study involve blood drawing, biopsy of tissue, marrow biopsy, etc? If yes, mention how much an how often the samples are drawn and also state the rational behind these sampling.

12.5 Will material be collected for genetic analysis?

Yes No

If yes, describe procedure involved for analysis and submit approval from the appropriate regulatory body.

**13. Protected Information:**

Indicate the information that will be collected about study subjects during the participation in this study
Name
Address
Employer's Name and Address
Relative's Name and Address
Dates
Age
Date of Birth
Telephone/Mobile/Fax/Email address numbers
Medical Record Numbers
Others (Please Specify:_____)

14. **Confidentiality:**

14.1 Where and how will the data be stored, and who will supervise access to the date to ensure that confidentiality is maintained?

14.2 Describe how, where and how long the data is stored?

If electronic data (eg. ECRF, audio or videotapes) are used how long they will be stored, and if they are meant for disposal how will they be disposed?

**15. Risks of the Research**

15.1 Identify the risks (current and potential) and describe the expected frequency, degree of severity, potential reversibility. Include any potential late effects.

15.2 Describe the precautions taken to minimize the risk

15.3 Please justify the risks in relation to the anticipated benefits to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result from the research

15.4 Describe the standard medical care provided to the subjects during and after the research period.

15.5 Will the investigational product be made available to the study subjects after the completion of the research?

Yes No

15.6 Is there any insurance coverage for trial subjects and trial participants?

Yes No

If yes, provide their details.

15.7 Describe the procedures for subject with drawl.

15.8 Describe the procedures for study suspension/termination.

15.9 Are there any plans for withholding the standard medication during the research? if yes, justify

Yes No

**16 Data and safety Monitoring Plan**

16.1 Is there a data safety monitoring board or committee to review this study for safety and adherence to the study protocol?

Yes No

16.2 Provide a general description of the data and safety-monitoring plan which must include, at a minimum, a description of the reporting mechanism of serious/unexpected adverse events to IEC, the sponsor and DCGI (if applicable)

16.3 Describe the procedures for managing the study related injuries (adverse Events)

**17 Benefits of Participation**

List any anticipated direct benefits of participation in this research project.

**18 Alternatives to Participation.**

List appropriate alternative clinical procedures of courses of treatment available to subjects.

**19. Compensation for Participation**

19.1 Will the subjects be paid or otherwise compensated for participation?

Yes No

If yes, Please answer 19.2 and if no, skip this section

19.2 What incentives, compensation, travel money, or other reimbursement will be given to the subjects?

Please provide the detailed information.

**20. Does the protocol require any issues to be answered by a specific community?**

Yes No

If yes, describe

**21. Details of contact persons of research team for any queries during research period.**

## 22. Investigator’s Assurance

I certify that the information provided by me is complete and correct.
I understand that as principal Investigator, I will take full responsibility for the protection of rights and welfare of all trial subjects including the conduct of study and ethical performance of the project.
I agree to comply will all rules and regulations of IEC and University of Hyderabad for the conduct of the study / trial.

I hereby declare that:

- Qualified personnel according to IEC will conduct the study.
- No change will be made in the protocol or consent form until approved by the IEC.
- Legally effective informed consent will be taken from Human subjects if applicable.
- Adverse events will be reported to IEC as per ICH GCP/DCGI Adverse event reporting policy.

I further certify that the proposed research is not currently being conducted and will not begin until IEC approval has been obtained.

| **Investigators** | **Signature** | **Date** |
|---|---|---|
| Principal Investigator | | |
| Co-Investigator 1 | | |
| Co-Investigator 2 | | |
| Co-Investigator 3 | | |
| Co-Investigator 4 | | |
| Co-Investigator 5 | | |
| Co-Investigator 6 | | |