**NIEC Forms**

* Proforma – I
* Proforma – II
* Amendment Form
* Appendix-V
* Appendix – **A**
* Appraisal

**Note:** The members are requested to submit 3 sets with all the above documents and 5 study synopsis. The covering letter forwarded by the HOD, should attach to all the sets including synopsis. Addressed to the Member Secretary, NIEC, NIMS

**NIMS-IEC/AP-01 PROFORMA – I**

**INSTITUTIONAL ETHICS COMMITTEE (IEC) NIZAM’S INSTITUTE OF MEDICAL SCIENCES PANJAGUTTA , HYDERABAD – 500 082**

PROTOCOL SUBMISSION FORM IEC Project Registration No: Date:

**1. Title of the Project, Protocol Number, Version & Date:**

**2. Principal Investigator:**

2.1 Name of the Investigator:

2.2. Qualifications

MD DM MS MCh PhD

Others

2.3 Faculty Resident other

2.4 Designation:

2.5 Department :

**3. Co-Investigators or Guides / Co-Guides:**

**3.1.1. Name of the Co- Investigator 1 Guides / Co-Guide**

3.1.2 Qualifications

MD DM MS MCh PhD

Others

3.1.3 Department :

3.1.4 Name of the Institution:

**3.2.1. Name of the Co- Investigator 2, Guides / Co-Guide**

3.2.2 Qualifications

MD DM MS MCh PhD

Others

3.2.3 Department :

3.1.4 Name of the Institution:

**3.3.1. Name of the Co- Investigator 3, Guide or Co-Guide;**

3.3.2 Qualifications

MD DM MS MCh PhD

Others

3.3.3 Department :

3.3.4 Name of the Institution:

**3.4.1. Name of the Co- Investigator 4, Guide or Co-Guide;**

3.4.2. Qualifications

MD DM MS MCh PhD

Others

3.4.3 Department :

3.4.4 Name of the Institution:

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

**4. Level of review required:**

|  |  |  |
| --- | --- | --- |
|  | Full Expedited | Amendmentcademic Projects). |
| **5.**5.1 | **Funding source:**Internal Funding (Only for A |
| 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 Under review Not applicable

**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 at Nizam’s

Institute of Medical Sciences, Hyderabad.

8.1 Proposed number of research participants required / randomised:

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

8.2 Age Range

1-6 yrs. 7-17 yrs

18-60 yrs >60 yrs

8.3 Types of subjects

Inpatients

Out patients

Healthy Volunteers

Others: Specify:

8.4 Will the study be formed on both genders?

Yes No

If No justify

8.5 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 Elderly subjects (>70 yrs)

Others (specify:

8.6 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 Referral 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 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

11.2 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.)

12.1 Does the research involve the use of any drugs?

Yes No

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

12.2 Does the research involve the use of any device?

Yes No

If yes, Please submit the device information Brochure

12.3 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: )

12.4 Does the study involve blood drawing, bioipsy 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 personal information that will be collected about study subjects during the participation in this study

Name Address Age / Date of birth

Legally accepted representative’s Name and Address

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 N/A

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

Yes No N/A

If yes, provide their details.

15.7 Describe the procedures for subject withdrawal.

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**

Will the subjects be paid or otherwise compensated for participation?

Yes No

If yes, what incentives, compensation, travel money, or other reimbursement will be given to the subjects? Is there clause on compensation due to study related injury 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 Nizam’s Institute of

Medical Sciences of the conduct of the trial. I here by declare.

 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** | **Name** | **Signature** | **Date** |
| Principal Investigator |  |  |  |
| Co-Investigator 1/ Guide/ Co-Guide |  |  |  |
| Co-Investigator 2/ Guide/ Co-Guide |  |  |  |
| Co-Investigator 3/ Guide/ Co-Guide |  |  |  |
| Co-Investigator 4 / Guide/ Co-Guide |  |  |  |

**NIMS-IEC/AP-02 PROFORMA II**

**IEC Regn No: Protocol Title: Name of PI:**

Mark and comment on whatever items applicable to the study

|  |  |  |
| --- | --- | --- |
| 1 | Objectives of the Studyclear unclear | What should be improved? |
| 2 | Methodology:clear unclear | What should be improved? |
| 3 | Background Information and Datasufficient insufficient | Comment: |
| 4 | Risks and Benefits Assessmentacceptable unacceptable | Comment: |
| 5 | Inclusion Criteriaappropriate inappropriate | Comment: |
| 6 | Exclusion Criteriaappropriate inappropriate | Comment: |
| 7 | Discontinuation and Withdrawal Criteriaappropriate inappropriate | Comment: |
| 8 | Involvement of Vulnerable ParticipantsYes No | Comment: |
| 9 | Sufficient number of participants?Yes No | Comment: |
| 10 | Control Arms (placebo, if any)Yes No | Comment: |
| 11 | Contents of the Informed Consent | Comment: |

|  |  |  |
| --- | --- | --- |
|  | Documentclear unclear |  |
| 12 | Language of the Informed ConsentDocumentclear unclear | Comment: |
| 13 | Privacy & Confidentiality in InformedConsent DocumentYes No | Comment: |
| 14 | Inducement for ParticipationUnlikely Likely | Comment: |
| 15 | Provision for Medical Supportappropriate inappropriate | Comment: |
| 16 | Provision for Treatment of Study-RelatedInjuriesappropriate inappropriate | Comment: |
| 17 | Provision for Compensationappropriate inappropriate | Comment: |
| 18 | Study designappropriate inappropriate | Comment: |
| 19 | Randomisation and Blindingappropriate inappropriate | Comment: |
| 20 | Statistical analysisappropriate inappropriate | Comment: |

Any specific comments:

Name of the reviewer:

Signature: Date:

**SOP No.: NIMS-IEC-016 FORM – I**

Amendment Reporting Form

1. IEC project registration no:

2. Title of the Project:

3. Protocol Number, version & date:

4. Name of the Principal Investigator:

5. Mention Version No and date of amended Protocol/ Investigator brochure/ Addenum:

]

|  |
| --- |
| 6. Have you highlighted the amended portion in the document or tabulated details of changes. ( Enclose applicable documents) |
| 7. Does this amendment lead to any changes in trial patient information document (PID) and informed consent | Yes No |
| 8. If yes, is the amendment of PID and informed consent form enclosed | Yes NoIf No, reason for not submitting |

Signature of the Principal Investigator:

Name of PI : Date:

**NIMS-IEC/AP-03 APPENDIX V**

INFORMED CONSENT

1.Check list for study Subject’s informed consent document.

1.1 Essential Elements:

1. Statement that the study involves research and explanation of the purpose of the research.

2. Expected duration of the Subject’s participation.

3. Description of the procedures to be followed, including all invasive procedures.

4. Description of any reasonably foreseeable risks or discomforts to the Subject.

5. Description of any benefits to the Subject or others reasonably expected from research.If no benefit is expected Subject should be made aware of this.

6. Disclosure of specific appropriate alternative procedure or therapies available to the Subject.

7. Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject’s medical records.

8. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials).

9. Statement describing the financial compensation and medical management as under:

a. In the event of an injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.

b. In the event of a trial related injury or death, the Sponsor or the representative, whosoever has obtained permission from the LicensingAuthority for conduct of the clinical trial, shall provide financial compensation for the injury or death.

10. An explanation about whom to contact for trial related queries, rights of Subjects and in the event of injury.

11. The anticipated prorated payment, if any, to the Subject for participating in the trial.

12. Subject’s responsibilities on participation in the trial.

13. Statement that participation is voluntary, that the Subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled.

14. Any other pertinent information.

1.2 Additional elements, which may be required

a. Statement of foreseeable circumstances under which the Subject’s participation may be terminated by the investigator without the Subject’s consent.

b. Additional costs to the Subject that may result from participation in the study.

c. The consequences of a Subject’s decision to withdraw from the research and procedures for orderly termination of participation by Subject.

d. Statement that the Subject or Subject’s representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject’s willingness to continue participation will be provided.

e. A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or fetus, if the Subject is or may become pregnant), which are currently unforeseeable.

f. Appropriate number of Subjects enrolled in the study.

2. Format of informed consent form for Subjects participating in a clinical trial. Informed Consent form to participate in a clinical trial

Study Title: Study Number:

Subject’s Initials: Subject’s Name: Date of Birth/ Age:

Address of the subject: Qualification:

Occupation: Student/ Self-employed / Service / Housewife / Others (Please tick as appropriate) Name and address of the nominee(s) and the relation to the subject: ------------------------------------ (for the purpose of compensation in case of trial related death)

Please initial box (subject)

(i) I confirm that I have read and understood the information sheet dated [ ]

for the above study and have had the opportunity to ask questions.

(ii) I understand that my participation in the study is voluntary and that I am free to [ ]

withdraw at any time, without my medical care or legal rights being affected.

(iii) I understood that the Sponsor of the clinical trial, others working on the Sponsor’s [ ] Behalf, the Ethies Committee and the regulatory authorities will not need my permission

to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access.However, I understand that my identity will not be revealed in any information released to third parties or published.

|  |  |  |
| --- | --- | --- |
| (iv) I agree not to restrict the use of any data or results that arise from this study provided | [ | ] |
| such a use is only for scientific purpose(s) |  |  |
| (v) I agree to take part in the above sudy | [ | ] |

Signature (or thumb impression) of the Subject/Legally Acceptable Representative:

Date: / \_/

Signatory’s Name:\_

Signature of the investigator:\_ Date: / /

Study Investigator’s Name:\_

Signature of the Witness: Date: / /

Name of the Witness:\_

(Copy of the Patient Information Sheet and duly filled informed Consent Form shall be handed over to the subject or his / her attendant)

NIZAMS’ INSTITUTE OF MEDICAL SCIENCES

PANJAGUTTA: : : : HYDERABAD -500 082.

(SPONSORED RESEARCH CELL)

**APPRAISAL FORM**

1. Title of the project:

2. Name & Department of principal Investigator:

3. Number of projects as principal Investigator:

4. Number of project as Co- Investigator:

5. Name of Co- investigator & Department:

6. Project type: Academic/ Government Funded/ Sponsored

7. Any other Institute involved in the Project (total sites):

8. Aim, (Hypothesis) Relevance & Justification for Proposed Project:

9. Number of trail subject to be recruited :

10. Cost per subject :

11. Total Budget :

12. Number of hours to be spent per week on this project:

 a) Principal Investigator :

 b) Co-Investigator :

13. Human Resource requirement (Positions, Number &Duration):

14. What will be the likely outcome of this Project:

15. Ethical issues to be taken care:

16. Brief summary of the Project in 100 words/

 3 slides for Presentation:

Signature of Co- Investigator :

Signature of Principal Investigator :

Date:

**APPENDIX-A**

**STUDY PROTOCOL**

1. Title of the project
2. Clear research objectives, rationale and hypothesis for undertaking the study in the light of existing knowledge.

Objectives:

Rationale:

Hypothesis:

1. Participant recruitment procedures
2. Inclusion and exclusion criteria for entry of participants.
3. Precise description of methodology of the proposed research, including

sample size (with justification), type of study design (observational, experimental, pilot, randomized, blinded et c.), intended intervention, dosages of drugs, route of administration, duration of treatment and details of invasive procedures if any. In case of laboratory departments type of investigations, methodology, with justifications.

1. Plan to withdraw or withhold standard therapies in the course of research.
2. Plan for statistical analysis of the study.
3. Procedure for seeking and obtaining informed consent. Attach sample of patient information sheet and informed consent forms in English and local languages-i.e. Telugu, Hindi.\*
4. Safety of proposed intervention, including results of relevant laboratory, animal and human research, if applicable
5. For research involving more than minimal risk, an account of management of such risk or injury.
6. Proposed management of research related and unrelated injury/ illness during and after research period if applicable.
7. An account of maintenance of all data collected during the study.
8. Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants.
9. A statement on probable ethical issues and steps taken to tackle the same
10. Details of other relevant documents related to the study protocol
11. Details of Funding agency and fund allocation if applicable
12. A statement on conflict-of-interest (COI), if any.
13. Attach recent curriculum vitae of the student researcher guide and co-guide(s) indicating qualification and experience.\*

**Signatures:**

Student Researcher

Guide Co-Guide Co-Guide

Reviewer 1 Reviewer 2

\*-Forms to be enclosed along with study protocol submission