INSTITUTIONAL ETHICS COMMITTEE

NIZAM'S INSTITUTE OF MEDICAL SCIENCES
PANJAGUTTA
HYDERABAD
INDIA

Protecting Patients Guiding Doctors

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GENERAL INFORMATION

I. IEC INFORMATION

INSTITUTIONAL ETHICS COMMITTEE
NIZAM'S INSTITUTE OF MEDICAL SCIENCES, HYDERABAD.

IEC GENERAL INFORMATION

This document
for
Institutional Ethics Committee
Of
Nizam's Institute of Medical Sciences
Is
Prepared by
Dr.M.U.R.Naidu and Dr.P.Usha Rani
Department of Clinical Pharmacology and Therapeutics

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Composition of IEC

IEC will have a chairman , the member secretary and members nominated by the Director.

IEC will have minimum eight (8) members including:

* 2 medical scientists ,

* 2 non medical scientists,

* 1 nonscientist (lay person,)

* 1 legal expert or retired judge.

Responsibilities of the IEC

1. To protect and safeguard the dignity, rights, safety and well being of all actual or potential research participants.

2. To consider the principle of justice, that the benefits and burdens of research be distributed fairly among all groups and classes in society taking into account age, gender, economic status, culture and ethic consideration.

3. To provide advise to the researchers on all aspects of the welfare and safety of research participants after ensuring the scientific soundness of the proposed research.

To

The Director,
Nizam's Institute of Medical Sciences,
HYDERABAD- 500 082.

Sub: Consent to be a member of IEC

* * * *

Sir,

I accept the invitation to become a member of IEC of Nizam's Institute of Medical Sciences. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.

I shall be willing to publicize my full name, profession and affiliation.

I shall made available to the public on request, all reimbursement for work and expenses if any related to IEC.

I shall not keep any literature or study related document with me after the discussion and final review.

I shall maintain all the research project related information confidential and shall not reveal the same to any one other than project related personnel.

I herewith enclose my CV.

Thanking You,

Yours sincerely,

Signature ----------

Name of Member.---------- Date
Address and Telephone No:

Application for Ethical Review of Biomedical Research Proposal

To
The Chairman
Institutional Ethics Committee
Nizam's Institute of Medical Sciences,
Hyderabad.

Date:

Full name of applicant :_____

Designation:

Complete Postal Address:

Tel.No: (O) ®
(Fax)
e-mail:

Site of study:

Protocol NO. Version: Date:
Amendment No. Version: Date:

Title of Project:

Sponsor Name:
Address :

Name Signature:
Principal Investigator:
Co-investigator : 1)

2)

3)

Type of study: National / International

Type of Trial: Single center / multi center

Name & Signature of applicant Date:
(Application must be submitted along with all essential documents for the review in FORM I. FROM II)

List of documents to be submitted along with application for the IEC Review

Protocol No._____ Dated:

1) Signed and dated application form on prescribed format In (FROM I And II)
2) The protocol of the proposed research (clearly identified, numbered 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 (updated, signed and dated)
8) Material to be used (including advertisements) for the recruitment of 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 language(s) understood by the potential research participants and, when required, in other languages;
11) Informed consent form (clearly identified and dated) in the language(s) 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 or modified protocol) by other ECS or 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.

Institutional Ethics Committee
Nizam's Institute of Medical Sciences, Hyderabad

Acknowledgement

Date:

*** Study Proposal Registration No.NIMS - IEC/2002/0----------**

Received _____copies of study proposal.

Protocol No._____ Version Dated:

Amendment No.: Version : Dated:

Entitled:_____

_____

From Dr._____

Designation_____

Address_____

For ethical review:

* Name of IEC Staff receiving application:

* Signature:

* Date:

*** For official use only. Not to be filled by the applicant.**

(To filled by the applicant in duplicate)

Meeting requirements

* All the IEC meetings will be held regularly on scheduled dates that are announced and notified in advance.

* Additional review meetings can also be held with short notice as and when required.

* Meetings will be planned in accordance with the need of the work load.

* Member will be given 10 days time in advance to review study proposals and the relevant documents.

* Minutes of the IEC meetings, all the proceedings and deliberation will be documented.

* Signatures of all the members who have participated in the meeting will be obtained on the minutes of the meeting document.

* Applicant, sponsor or investigator may be invited to present the proposal or elaborate on specific issues.

* Independent expert may be invited to the meeting or to provide written comment, subject to applicable confidentiality agreement.

Elements For Review

Following are the element to be reviewed by the IEC members

Scientific design and conduct of the Study.

1) The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants.
2) The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;
3) The justification for the use of control arms;
4) Criteria for prematurely withdrawing research participants;
5) Criteria for suspending or terminating the research as a whole
6) The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring committee (DSMC).
7) The adequacy of the site, including the supporting staff, available facilities and emergency procedures;
8) The manner in which the results of the research will be reported and published..

Recruitment of research participants:

1) The characteristics of the population from which the research participants will be drawn(including gender, age, literacy, culture, economic status and ethnicity).
2) The means by which initial contact and recruitment is to be conducted.
3) The means by which full information is to be conveyed to potential research participants or their representatives.
4) Inclusion criteria for research participants
5) Exclusion criteria for research participants.

Care and protection of research participants

1. The suitability of the investigator(s)'s qualifications and experience for the proposed study;
2. Any plans to withdraw or withhold standard therapies for the purpose of the research and the justification for such action;
3. The medical care to be provided to research participants during and after the course of the research;
4. The adequacy of medical supervision and psycho-social support for the research participants.
5. Steps to be taken if research participants voluntarily withdraw during the course of the research.
6. The criteria for extended access to the emergency use of and/or the compassionate use of study products;
7. The arrangements, if appropriate for informing the research participants general practitioner (family doctor), including procedures for seeking the participant's consent to do so.
8. A description of any plans to make the study product available to the research participants following the research;
9. A description of any financial costs to research participants.
10. The rewards and compensations for research participants (including money, services, and /or gifts).
11. The provisions for compensation/treatment in the case of the injury disability/ death of a research participant attributable to participation in the research.
12. The insurance and indemnity arrangements.

Protection of research participant confidentiality

1. A description of the persons who will have access to personal data of the research participants, including medical records and biological samples.

2. The measures taken to ensure the confidentiality and security of personal information concerning research participants.

Informed consent process

1. A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent;

2. The adequacy, completeness, and understandability of written and oral information to be given to the research participants and when appropriate, their legally acceptable representative(s).

3. Clear justification for the intention to include in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals;

4. Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation (including their rights, safety and well-being).

5. The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

Community Considerations

1) The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn.
2) The steps taken to consult with the concerned communities during the course of designing the research;
3) The influence of the community on the consent of individuals.
4) Proposed community consultation during the course of the research
5) The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research and the ability to respond to public health needs;
6) A description of the availability and affordability of any successful study product to the concerned communities following the research.
7) The manner in which the results of the research will be made available to the research participants and the concerned communities.

Quorum requirements
1. Minimum 5 members are required to compose the quorum 2. No quorum should consist entirely of members of one profession. Quorum will include at least one member as non scientific(lay person), at least one who is independent of the Nizam's institute of medical sciences and at least one medical scientist. 3. For expedited review, minimum of 3 members are required of which one must be expert in the area of research proposal.

Institutional Ethics Committee

Nizam's Institute of Medical Sciences,
Hyderabad, India

"Protecting Patients, Guiding Doctors"

Review letter No. IEC/NIMS/_____ Date:

To

Ethics Committee of Nizam's Institute of Medical Sciences, Hyderabad, India, in its____ Meeting held on_____ at_____ hours in the meeting room---------- reviewed and discussed the study proposal with Protocol No.
Version dated . Amendment No. version _____ dated _____
Entitled"_____
_____
_____
.
Submitted by Dr._____,

Members present:			Members Absent:		
Name	Affiliation	Gender	Name	Affiliation	Gender
1.			1.		
2.			2.		
3.					
4.					
5.					
6.					

Members reviewed the following documents:

1 Protocol ( ) 2. Amendment ( ) 3. Written informed consent ( )

4. Investigator's Brochure ( ) 5. Available safety information ( )

6. Subject recruitment procedure ( ) 7. Payments and compensation to subject ( )

8. Subject information sheet ( ) 9. Investigator's C.V. ( ) 10.Others ( )

The members present, presented a quorum, being atleast 50% plus one of all the members, and having atleast on medically qualified person and atleast one layperson present from outside the institute.

Issues discussed and reviewed:

Of members present, ____ voted of approval, _____ voted against and ____ were absent.

After consideration, the committee has decided to approve / not to approve/ suggested resubmmission after required modification / subject to_____. The present approval is valid only for one year, investigator must take the reapproval after one year.

The investigator is requested to submit the progress report after 6 months to IEC for review. Any change, modification or deviation in the protocol, or any adverse event must be informed to ethics committee. Any protocol modification or amendment must receive IEC approval. Investigator should conduct the study as per the recommended GCP guidelines.

Chairman
Institutional Ethics Committee

Name:

Signature:

Date:

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 published to the Institutional Ethics Committee Office, Room. No. 13, Opp. to Dean's Office in prescribed proforma in 11 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. All the Proformae are available at IEC Office and Principal Investigators are requested to copy the proformae in their floppy.

The new projects will be taken up on first come first basis.

NIZAM' S INSTITUTE OF MEDICAL SCIENCES
(A UNIVERSITY ESTABLISHED UNDER STATE ACT)
PANJAGUTTA : : : HYDERABAD – 500 082.

Rc.No:13/1/2007/A6 **Dt:**

CONSTITUTION OF INSTITUTIONAL ETHICS COMMITTEE

	Affillation	Gender
1.Chair Person: Justice Dr.K.Ramaswamy Designation: Former Justice	Supreme Court of India	Male
2.Member Secretary:Dr.S.Venkatratnam Desigantion: Medical Superintendent NIMS	Professor & Head Dept. of Radiation Oncology	Male
3.Member: Prof.V.Shantaram Designation: Emeritus Professor	NIMS	Male
4.Member:Prof.S.Manimala Rao Designation: Emeritus Professor	NIMS	Female
5.Member:Prof.P.L.Vishweshwar Rao Designation: Principal of Arts and Social Sciences & Prof. Of Journalism	Osmania University	Male
6.Member:Sri.P.Venkateswara Rao Designation: Journalist		Male
7.Member:Smt.D.Kanaka Durga Designation:Professor of English	Osmania University	Female
8.Member:Dr.M.Bhaskar Designation: Prof. Of Zoology	S.V.University, Tirupati	Male
9.Member:Dr.T.Ramesh Kumar Designation: Additional Professor of C.P & T	NIMS	Male
10.Member:Sri.G.Srinivasulu Designation: Executive Registrar	NIMS	Male

PROF.M.U.R.NAIDU
DEAN

PROFORMA – I

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

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

MD ☐ DM ☐ MS ☐ MCh ☐ PhD ☐
Others ☐

2.3 Faculty ☐ Resident ☐ other ☐

2.4 Designation: ☐

2.5 Department : ☐

3. Co-Investigators:

3.1.1. Name of the Co- Investigator 1;

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;

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;

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;

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 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 at Nizam's Institute of Medical Sciences, Hyderabad.

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

11.2 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 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 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	Signature	Date
Principal Investigator		
Co-Investigator 1		
Co-Investigator 2		
Co-Investigator 3		
Co-Investigator 4		
Co-Investigator 5		
Co-Investigator 6		

PROFORMA – II

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

REVIEW

I. Title of the Project *:

II. Protocol Number, version & date *:

III. Name of the Principal Investigator *:

For Official Use

IV. I reviewed the protocol and following are my observations:

S.NO.	Items to be Evaluated	Comment Yes	No
4.0	**Scientific Design and conduct of the study:**		
4.1	Is the design appropriate to the objectives of the study and the statistical methodology (including sample size calculation)?		
4.2	Will the data generated have potential conclusions with the patient population calculated		

ONLY, item No: I, II & III Should be filled by Investigator

4.3	Is the management of research related injuries (Adverse events) answered?		
4.4	Are the justification of predictable risks and inconveniences weighed against the anticipated benefits for the subject made?		
4.5	Is the Informed consent and patient Information sheet appropriate and in local language?		
4.6	Is the justification of control arm?		
4.7	Criteria for premature withdrawals defined?		
4.8	Are the Criteria for suspending or terminating the research as whole, defined?		
4.9	Are the adequate provisions for monitoring and auditing the conduct of the research?		
5.0	**Recruitment of Research Participants:**		
5.1	Are the characteristics (gender, age, literacy, culture, economic status) of the subject participating the research study?		
5.2	Are the means by which the initial contact and recruitment to be conducted adequate?		
5.3	Are the inclusion criteria for research participants defined?		
5.4	Are the exclusion criteria for research participants defined?		
6.0	**Care and protection of Research Participants:**		
6.1	Are the investigator's qualification and experience adequate for the proposed study?		

6.2	Are there any plans to withdraw or withhold standard therapies for the purpose of the research		
6.3	If yes, is adequate justification made?		
6.4	Is medical care provided to the subjects during and after the course of the research		
6.5	Are there adequate medical supervision and psychosocial support for the subjects?		
6.6	Are there adequate steps for voluntary withdrawl of research participants?		
6.7	Are there any plans to make the study product available to the research participants following the research?		
6.8	The detail description of any financial costs to research subjects made?		
6.9	Are rewards, incentives, etc provided?		
7.0	**Informed Consent:**		
7.1	A Full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent is made?		
7.2	Is there adequate completeness, and understandability of written and oral information to be given to the research participants made?		
7.3	Is there clear justification for the intention to include the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals made?		
7.4	Are there any provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project?		

8.0	**Community Considerations:**		
8.1	Are there any impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn?		
8.2	Are there necessary steps taken to consult the concerned communities during the course of designing the research?		
8.3	Is there any influence of community on the consent of individuals?		

Decision:

1. The proposed protocol can be considered for IEC meeting

   ☐ Yes ☐ No

2. The proposed protocol can be considered for IEC meeting only after further revision

   ☐ Yes ☐ NO

3. The protocol cannot be considered for IEC meeting.

   ☐ Yes ☐ No

Name of the Member:_____

Position in Ethics Committee_____

Signature: _____

Date:_____

PROFORMA – III

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

Amendment

Title of the Project:

Protocol Number, version & date:

Name of the Principal Investigator:

Herewith Iam enclosing for Amendment

Amendment No, Version & date:

The Content of Amendment:

I am also enclosing amendment for review

Signature of the Principal Investigator