SHIV NADAR
INSTITUTION OF EMINENCE DEEMED TO BE UNIVERSITY
DELHI NCR

APPLICATION FOR INSTITUTIONAL ETHICS COMMITTEE REVIEW

Proforma to be submitted to the Institutional Ethics Committee (Human studies)

1. Title of the Project :-
2. a) Name, Designation, Address, E mail ID and mobile no. of Principal Investigator :-
   b) Name, Designation(s) & Address(s), E mail ID and mobile no. of Co-investigators :-

3. Background information & purpose of study :- (include 4 - 6 relevant references and justify the reasons for undertaking the study, in 100 – 200 words)
4. Research Hypothesis :-
5. Aim and Objectives :-
6. Materials & Methods :-
   i. Whether, study involves humans, animals or both?
   ii. Type of study
   iii.
   - Inclusion criteria
   - Exclusion criteria

   iv. Number of groups studied
   v. Sample size in each group and method of determination of sample size
   vi. Interventions
   vii. Methodology
   viii. Methods of statistical analysis to be used
   ix. Relevant references Number of projects with the PI & Co investigator
7. Permission of Drug Controller of India (DGCI) (if applicable) - copy of permission to be attached.
8. Permission of any government or non-government organization – if their resources are being used: Copy of permission to be attached.
9. Ethical issues involved in the study :- (less than minimal risk / minimal risk / more than minimal risk to the study subjects) (please consult ICMR guidelines)
10. To attach consent forms parts 1 & 2 in English and local language

11. Conflict of interest for any other investigator(s) – if yes, please explain in
12. Declaration from PI regarding the risk factor of the study and the type of review recommended (See page 3)
13. Please provide a declaration regarding the usage of data collected incorporating data storage and security issues.

APPENDIX I

CHECKLIST FOR STUDY SUBJECT's INFORMED CONSENT DOCUMENTS

1.1 Essential Element:

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 procedures and
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 procedures or therapies available to the subject.
7. Statement describing the extent to which confidentially 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. Compensation and/or treatment(s)available to the subject in the event of trial-related injury
10. An explanation about whom to contact for trial related queries, rights of subjects and in the event of any 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 finding 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. Approximate number of subjects enrolled in the study

APPENDIX II

UNDERTAKING BY THE INVESTIGATOR

1. Full name, address and title of the Principal Investigator (or Investigator(s) when there is no Principal Investigator)
2. Name and address of the area where the study will be conducted: Education, training & experience that qualify the Investigator for the study
3. Name and address of all facilities to be used in the study.
4. Name and address of the Ethics Committee that is responsible for approval and continuing review of the study.
5. Names of the other members of the research team (Co-or sub-Investigators) who will assisting the Investigator in the conduct of the investigation (s).
6. Protocol Title and study number (if any)
7. Commitments:
   (i) I have reviewed the protocol and agree that it contains all the necessary information to conduct the study. I will not begin the study until all necessary Ethics Committee and regulatory approvals have been obtained.
   (ii) I agree to conduct the study in accordance with the current protocol. I will not implement any deviation from or changes of the protocol without agreement by the sponsor and prior review and documented approval / favorable opinion from the Ethics Committee of the amendment, expect where necessary to eliminate an immediate hazard(s) to the trial subjects or when the changes(s) involved are only logistical or administrative in nature.
   (iii) I agree to personally conduct and/or supervise the study
   (iv) I agree to report to the sponsor all adverse experiences that occur in the course of the investigation(s) in accordance with the regulatory guidelines
   (v) I agree to ensure that all associates, colleagues and employees assisting in the conduct of the study are suitably qualified and experienced and they have been informed about obligations in meeting their commitments in the study.
   (vi) I agree to maintain adequate and accurate records and to make those records available for audit/inspection by the sponsor, Ethics Committee, Licensing Authority or their authorized representative,, in accordance with regulatory provisions . I will fully cooperate with any

study related audit conducted by regulatory officials or authorized representatives of the sponsor.

(vii) I agree to promptly report to the Ethics Committee all changes in the clinical trial activities and all unanticipated problems involving risk to human subjects or others.

(viii) I agree to inform all unexpected serious adverse events to the sponsor as well as the Ethics Committee within seven days of their occurrence.

(ix) I will maintain confidentially of the identification of all participating study patients and assure security and confidentially of study data.

(x) I agree to comply with all other requirement, guidelines and statutory obligations as applicable

8. Signature of Investigator with date