

Annexure-4

APPLICATION FOR PERMISSION FOR HUMAN EXPERIMENTS

(10 Copies Of Application to be submitted to Human Institutional Ethics Committee (IHEC)
Along With Synopsis)

Part-A

1. Place where the experiment is to be performed:
2. Date on which the experiment is to commence and duration of the experiment:

(The appropriate protocol form for the research proposal-Part B in the case of experiments using humans has to be duly filled in signed and appended to this form)

Signature

Name and Designation of
Chief Investigator

Date:
Place:

Applicable only for application to be submitted to Institutional Human Ethical
Committee

Address for Communication:

Form-B

Protocol form for research proposals to be submitted to the Institutional Human Ethics Committee for new experiments or extensions of ongoing experiments, using Human subjects

1. Project title :

2. Type of study

a. Drug Trial :

i. Phase-I

ii. Phase-II

iii. Phase-III

iv. Phase-IV

b. Vaccine Trial :

c. Surgical Procedure/
Medical Device :

d. Diagnostic agents- with
special reference to use of
radioactive materials/
X-rays :

e. Trials with herbal remedies :

3. Investigator's Curriculum Vitae

(One Medical Doctor to be mandatorily included as Co-Guide. If the topic is from other system of Medicine, expert from the respective system of medicine should be included as Co-Guide)

Chief Investigator:

a. Name :

b. Designation :

c. Qualification :

Others Investigators:

a. Name

b. Designation

c. Qualifications

4. Place where the experiment is to be performed:

5. Does the place of the experiment come under the jurisdiction of the IEC:

6. Research Objectives:

7. Rationale in undertaking the investigation in human subjects:

8. Subjects Recruitment Procedures:

9. Inclusion and Exclusion criteria for entry of subjects in the study:
10. Precise description of methodology of the proposed research including:
 - Intended dosages of drugs:
 - Planned duration of treatment
 - Details of invasive procedures
11. A description of plans to withdraw or withhold standard therapies in course of research:
12. Plans for statistical analysis of the study:
13. Procedure for obtaining informed consent forms in English and vernacular, (a copy has to be enclosed):
14. Safety of proposed interventions or drug/vaccine to be tested (please enclose results of relevant laboratory and animal research):
15. Does the study entail more than minimal risk? (If so give the account of plans to provide medical therapy for such risk or injury or toxicity due to over dosage):
16. Proposed compensation and reimbursement of incidental expenses:
17. Storage and maintenance of all data collected during the study:
18. Plans for publication of results positive or negative- (Privacy and confidentiality of the study participants should be maintained):
19. Statement of probable Ethical Issues and steps taken to tackle the same:
20. Relevant documents related to the study protocol including regulating clearances (Copies to be enclosed):
21. Indicate if you agree to comply with national and international GCP protocols:
22. Details of Funding Agency/sponsors and fund allocation for the proposed work:

INVESTIGATOR'S DECLARATION

1. I certify that I have determined that the research proposal herein is not unnecessarily duplicative of previous reported research
2. I certify that individuals working on this proposal, and experimenting have been trained and qualified physicians in their system of medicine
3. I certify that I have reviewed the pertinent scientific literature and have found no valid alternative to any procedure described herein which may cause less pain or distress.
4. I will obtain approval from the IHEC before initiating any significant changes in this study
5. Certified that performance of experiment will be initiated only upon review and approval of scientific intent by appropriate expert body (Institutional Scientific Advisory Committee/Funding agency/other body (to be named))
6. Institutional Biosafety Committee's (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens)
7. I shall maintain all the records

Signature

Date:

Name of the Investigator

(for IHEC usage)

Proposal Number :
 Date first received :
 Date received after modification (if any) :
 Approval date :
 Expiry date :
 Name of IAHC :