**Annexure-6**

## 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

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(for IHEC usage)

Proposal Number :

Date first received :

Date received after modification (if any) :

Approval date :

Expiry date :

Name of IAHC :