Annexure-XII

Application for Permission for Animal Experiments

Form B (per rule 8(a)* for Submission of Research Protocol(s)

Application to be submitted to the CPCSEA, New Delhi after approval of Institutional Animal Ethics Committee (IAEC)

Section -I

1.	*Name and address of establishment	
2.	*Registration number and date of registration.	
3.	Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C	
4.	Place where the animals are presently kept (or proposed to be kept).	
5.	Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)	
6.	Date and Duration of experiment.	
7.	Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)	

Signature

Name and Designation of Investigator

Date: Place:

*Applicable only for application to be submitted to CPCSEA

Section -II

Protocol form for research proposals to be submitted to the Institutional Animal Ethics Committee/ CPCSEA, for new experiments or extensions of ongoing experiments using animals.

1. Project / Dissertation / Thesis Title:

2. Principal Investigator / Research Guide / Advisor:

    a. Name
    b. Designation
    c. Dept / Div/ Lab
    d. Telephone No.
    e. E-mail Id
    f. Experience in Lab animal experimentation

3. List of all individuals authorized to conduct procedures under this proposal.

    a. Name
    b. Designation
    c. Department
    d. Telephone No.
    e. E-mail Id
    f. Experience in Lab animal experimentation

4. Funding Source / Proposed Funding Source with complete address (Please attach the proof)

5. Duration of the animal experiment.

    a. Date of initiation (Proposed)
    b. Date of completion (Proposed)

6. Describe details of study plan to justify the use of animals (Enclose Annexure)

7. Animals required

    a. Species and Strain
    b. Age and Weight
    c. Gender
    d. Number to be used (Year-wise breakups and total figures needed to be given in tabular form)
    e. Number of days each animal will be housed.

8. Rationale for animal usage
   a. Why is animal usage necessary for these studies?
   b. Whether similar study has been conducted on *in vitro* models? If yes, describe the leading points to justify the requirement of animal experiment.
   c. Why are the particular species selected?
   d. Why is the estimated number of animals essential?
   e. Are similar experiments conducted in the past in your establishment?
   f. If yes, justify why new experiment is required?
   g. Have similar experiments been conducted by any other organization in same or other *in vivo* models? If yes, enclose the reference.

9. Describe the procedures in detail:

   a. Describe all invasive and potentially stressful non-invasive procedures that animals will be subjected to in the course of the experiments)
   b. Furnish details of injections schedule Substances: Doses :
      Sites :
      Volumes :
   c. Blood withdrawal Details: Volumes :
      Sites :
   d. Radiation (dosage and schedules):
   e. Nature of compound/Broad Classification of drug/NCE:

10. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures? If yes, justify.

11. Will survival surgery be done?

   If yes, the following to be described.

   a. List and describe all surgical procedures (including methods of asepsis)
   b. Names, qualifications and experience levels of personnels involved.
   c. Describe post-operative care
   d. Justify if major survival surgery is to be performed more than once on a single animal.

12. Describe post-experimentation procedures.

   a. Scope for Reuse :

   b. Rehabilitation (Name and Address, where the animals are proposed to be rehabilitated) :

c. Describe method of Euthanasia (If required in the protocol) :

d. Method of carcass disposal after euthanasia. :

13. Describe animal transportation methods if extra-institutional transport is envisaged.

14. Use of hazardous agents (use of recombinant DNA-based agents or potential human pathogens requires documented approval of the Institutional Biosafety Committee (IBC). For each category, the agents and the biosafety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified).

If, your project involved use of any of the below mentioned agent, attach copy of the approval certificates of the respective agencies:

(a) Radionucleotides (AERB)
(b) Microorganisms / Biological infectious Agents (IBSC)
(c) Recombinant DNA (RCGM)
(d) Any other Hazardous Chemical / Drugs

Investigator's declaration.

1. I certify that the research proposal submitted is not unnecessarily duplicative of previously reported research.

2. I certify that, I am qualified and have experience in the experimentation on animals.

3. For procedures listed under item 10, 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 IAEC/ CPCSEA before initiating any changes in this study.

5. I certify 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).

6. I certify that I will submit appropriate certification of review and concurrence for studies mentioned in point 14.

7. I shall maintain all the records as per format (Form D) and submit to Institutional Animal Ethics Committee (IAEC).

8. I certify that, I will not initiate the study before approval from IAEC/ CPCSEA received in writing. Further, I certify that I will follow the recommendations of IAEC/ CPCSEA.

9. I certify that I will ensure the rehabilitation policies are adopted (wherever required).

Signature

Name of Investigator

Date:

Certificate

This is to certify that the project proposal no ..... entitled …… submitted by Dr./ Mr. / Ms. …….. has been approved/recommended by the IAEC of……(Organization) in its meeting dated……. and has been sanctioned……(animals) under this proposal for a duration of next..... months.

Authorized by	**Name**	**Signature**	**Date**
Chairman:	…….	……	……..
Member Secretary:	…….	……	……..
Main Nominee of CPCSEA:	…….	……	……..

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)