

Annexure-4

Form B (per rule 8(a)*)

APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

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

Part A

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 on which the experiment is to commence and duration of experiment.
7. Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)

Signature

Name and Designation of
Investigator

Date:

Place:

*The filled in Form B having above information / details / supporting documents (1 original + 14 copies and 1 soft copy in CD) should be sent to: -

The Member Secretary,
CPCSEA, Ministry of Environment & Forests,
8th floor, Jeevan Prakash Building,
25, Kasturba Gandhi Marg,
New Delhi-110 001

7. Animals required
 - a. Species / Common name
 - b. Age/ weight/ size
 - c. Gender
 - d. Number to be used (Year-wise breakups and total figures need to be given)
 - e. Number of days each animal will be housed.
 - f. Proposed source of animals.

8. Rationale for animal usage
 - a. Why is animal usage necessary for these studies?
 - b. Why are the particular species selected required?
 - c. Why is the estimated number of animals essential?
 - d. Are similar experiments conducted in the past? If so, the number of animals used and results obtained in brief.
 - e. If yes, why new experiment is required?
 - f. Have similar experiments been made by any other organization agency? If so, their results in your knowledge.

9. Description of the procedures to be used.

List and describe all invasive and potentially stressfull non-invasive procedures that animals will be subjected to in the course of the experiments.

Furnish details of injections schedule
 Substances :
 Doses :
 Sites :
 Volumes :
 Blood withdrawal
 Volumes :
 Sites :
 Radiation (dosage and schedules):

10. Please provide brief descriptions of similar studies from in vitro / in vivo (from other animal models) on same / similar test component or line of research. If, enough information is available, justify the proposed reasons.

11. Does the protocol prohibit use of anesthetic or analgesic for the conduct of painful procedures (any which cause more pain than that associated with routine injection or blood withdrawal)? If Yes, explanation and justification.

12. Will survival surgery be done?

If Yes, the following to be described.

- a. List and description of all such surgical procedures (including methods of asepsis)
- b. Names, qualifications and experience levels of operators
- c. Description of post-operative care
- d. Justification if major survival surgery is to be performed more than once on a single individual animal.

13. Methods of disposal post-experimentation

a. Euthanasia (Specific method):

b. Method of carcass disposal :

c. Rehabilitation :

14. Animal transportation methods if extra-institutional transport is envisaged.

15. 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)

- (a) Radionucleides
- (b) Microorganisms / Biological infectious Agents
- (c) Hazardous chemicals or drugs
- (d) Recombinant DNA
- (e) Any other (give name)

If, your project involved use of any of the above, attach copy of the minutes of IBC granting approval.

Investigator's declaration.

1. I certify that I have determined that the research proposal herein 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 11, 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 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 as per format (Form D)
8. I certify that, I will not initiate the study unless approval from CPCSEA received in writing. Further, I certify that I will follow the recommendations of CPCSEA.
9. I certify that I will ensure the rehabilitation policies are adopted.

Signature

Name of Investigator

Date:

Certificate

This is certify that the project title
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has been approved by the IAEC.

Name of Chairman/ Member Secretary IAEC:

Name of CPCSEA nominee:

Signature with date

Chairman/ Member Secretary of IAEC: _____ CPCSEA nominee:

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