

FORM B

Form B (per rule 8(a)* for Submission of Research Protocol (s) Application for Permission for Animal Experiments

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	Yenepoya (Deemed to be University) Derlakatte Mangalore, Karnataka -575018 Telephone: +91-8242204668; Fax: +91- 8242204667 Email: pharmacology@yenepoya.edu.in
2.	Registration number and date of registration.	CPCSEA Reg.Number: 347/PO/ReBi-S/Rc-L/01/CPCSEA Date: 11.03.2022-10.03.2027
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).	Animal House, Department of Pharmacology, Yenepoya (Deemed to be University)
5.	Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)	Ethno pharmacology Lab, Department of Pharmacology, Yenepoya University. CPCSEA Reg.Number- 347/PO/ReBi-S/Rc-L/01/CPCSEA
6.	Date and Duration of experiment.	
7.	Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)	

Name & Signature of PI

Date:

Place: Mangalore

Name & Signature of Guide

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:

- a. Name:
- b. Designation:
- c. Dept / Div/ Lab :
- d. TelephoneNo:
- e. E-mail Id:
- f. Experience in Lab animal experimentation: .

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

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

5. Duration of the animal experiment. 6 months

- 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 :

e. Number of days each animal will be housed.

8. Rationale for animal usage

a. Why is animal usage necessary for these studies?

b. Why are the particular species selected required?

c. Why are the estimated numbers 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 is a new experiment required?

f. Have similar experiments been made by any other organization agency? If so, their results in your knowledge:

9. Description of procedures to be used:

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

11. 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):

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

13. Will survival surgery be done?

14. 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. :

d. Method of carcass disposal after euthanasia. :

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

16. 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 the performance of the experiment will be initiated only upon review and approval of scientific intent by an 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 the 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

Date:

Name of Investigator

Certificate

This is to certify that the project entitled “ title of the project ” by Name of the PI has been approved by the IAEC having IAEC approval

No.....

Authorized by	Name	Signature	Date
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Chairman:

Member Secretary:

Main Nominee of CPCSEA: