

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

Application for Permission for Animal Experiments

Application to be submitted to the CCSEA, 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	10/Go/ReBiBt/S/99/CCSEA
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 CCSEA 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:

Section -II

Protocol form for research proposals to be submitted to the Institutional Animal Ethics Committee/CCSEA, 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 (the chemical characteristic detail of NCE and its likely reaction to the biological system and characteristic details of invitro study of that NCE have to be submitted by the establishment):

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)

Investigator's declaration.

1. I certify that there search 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/CCSEA 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 4.
7. Is hall 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/CCSEA received in writing. Further, I certify that I will follow the recommendations of IAEC/CCSEA.
9. I certify that I will ensure the rehabilitation policies are adopted (wherever required).

Signature

Name of Investigator

Date:

CHECK LIST (to be attached with Form-B)

S. No.	Document submitted	Response
1.	Have included a cover letter (Forwarded by HOD)	Yes/No
2.	Form B filed as per the CCSEA guidelines (Forwarded by HOD)	Yes/No
3.	Signature of PI and Co-PI on Form B with Stamp	Yes/No
4.	Source of funding proof (Attached)	Yes/No
5.	When was the project submitted for Institutional Bio-safety committee (IBSC) approval (give date of submission, or write 'NA' where not applicable)	
6.	When was the project submitted for Institutional Human Ethic Committee (IHEC) approval, if applicable (give date submission, or write 'NA' where not applicable)	
7.	When was the project submitted for IC-SCR (Stem Cell committee) approval, if applicable (give date of submission, or write 'NA' where not applicable)	
8.	Have you enclosed the final approval letter for the project from IBSC?	Yes/No
9.	Have you submitted the ongoing protocol Annual Progress Report of previous protocol.	Yes/No
10.	Have you submitted the 'Project Completion Report' for already approved project?	Yes/No
11.	Does the project involve use of survival surgical procedures?	Yes/No
12.	Does the project involve irradiating animals?	Yes/No
13.	Does the project involve in vivo imaging?	Yes/No
14.	Maintain records of carcass disposal of Laboratory animals (Species/Strains)	Yes/No
15.	Animal will be issued on Form -D only. After Completion of protocol Investigator must be submit the original copy of Form-D to CAF.	Yes/No
16.	Checklist has been included in the package	Yes/No

Note: - The project will not be considered without the Checklist attached.

Name of Principal Investigator
(With signature and stamp)