

GUIDELINES FOR FILLING FORM B AND YEARLY PROGRESS REPORT

The instructions given below have been recommended by IAEC committees of NCBS & INSTEM for all the PIs submitting research proposals for IAEC approval. Please read instructions carefully prior to filling in the forms.

For ease of managing the IAEC project submissions and to minimize corrections, ACRC has created google form for the submission of latest revised Form B and the yearly progress report. Please note an important point, the google form cannot be saved as draft and later continued, as Google does not support this feature. Therefore, have your files ready and use the document to copy paste in the google form. **PLEASE NOTE WE WILL NOT ACCEPT THE SUBMISSIONS DIRECTLY. USE THE GOOGLE FORM FOR SUBMISSION OF NEW PROJECT, MODIFIED OR RENEWAL PROJECTS AND YEARLY PROGRESS REPORT.**

1. IAEC approval in advance is mandatory for starting any research work on any live vertebrate animal or even for just collecting animal organ/tissue for research purpose.
2. Pilot studies also must be approved by IAEC.
3. Completely filled-in projects must be submitted to acrcinfo@ncbs.res.in at least a month before the proposed IAEC meeting date for consideration. Projects submitted after the dead line will not be forwarded to IAEC.
4. **ALL experimental procedures** to be done on or with animals whether **invasive** (surgeries, genotyping biopsy collection drug/component administration, organ/blood/fluid sampling etc...) or **non-invasive experimental assays** (from simple diet or environment change, to basic behaviour observation study, stress assays etc...) should be detailed in the project outline.
5. Breeder stocks/animals used for expansion colony/foundation colony shouldn't be considered as experimental animals and that number needn't reflect in form B.
6. No points in Form B must be left unanswered. If the point is not relevant in your study, mention as “**not applicable**”.

7. Principal investigator

- a. Main PI of the project must be a regular member of institution (faculty or scientific staff or Post-Doc – only in case of funding agency requirement).
 - b. In case of collaborative project, main PI must be an institutional member and collaborative PI has to be listed as Co-PI at Sl# 3 of Form B (section II).
 - c. Post doc can be listed as PI in cases where funding is solely in their name and they need IAEC certificate issued in their name. Here, Lab PI must be listed as co-PI.
 - d. Only one PI for a project, others may be listed as co-PI.
 - e. Main PI's name also must be listed along with other authorized individuals to conduct procedures in Section II, Sl. No. 3.
 - f. It is also mandatory to list name of institutional Veterinarian for all projects with invasive and/or stress/painful procedures on animals Section II, Sl. No. 3.
8. Look carefully for grammatical/formatting errors and proof read your document.
 9. The numbers of animals mentioned on Form B, progress report and on your PPT presentation slides should match.
 10. If it is a modified proposal, mention modifications in **BOLD letters** or **UNDERLINE**.
 11. Keep word format of Form B ready with you at the time of presentation in the meeting for corrections if suggested by the committee.
 12. Form B must be signed by the main PI only (Co-PI need not sign).
 13. Project title mentioned in Form B and IBSC certificate has to be same, if that is not possible for some reason, then IBSC approved protocol must be mentioned in the issued certificate.
 14. Read carefully and understand the Investigator's declaration before signing on Form B
 15. After circulation of comments of IAEC meeting by member secretary, the final corrected Form- B need to be submitted within 3-4 days.

In addition to the above general guidelines, we have given brief pointers to most of the points in Form B to help you in completing an animal research proposal.

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	National Centre for Biological Sciences (NCBS), TATA INSTITUTE OF FUNDAMENTAL RESEARCH (TIFR), GKVK campus, Bangalore – 65.
2.	Registration number and date of Registration	109/GO/ReBi/S/99/CPCSEA, Renewed on 21/07/2017
3.	Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C	National Centre for Biological Sciences (NCBS), TATA INSTITUTE OF FUNDAMENTAL RESEARCH (TIFR), GKVK campus, Bangalore – 65. 109/GO/ReBi/S/99/CPCSEA
4.	Place where the animals are presently kept (or proposed to be kept)	Animal Care and Resource Centre (ACRC), NCBS-TIFR, Bangalore – 65.
5.	Place where the experiment is to be performed (Please provide CPCSEA Reg. Number)	ACRC, NCBS-TIFR, Bangalore – 65. (109/GO/ReBi/S/99/CPCSEA)
6.	Date and Duration of experiment	
7.	Type of research involved (Basic Research / Educational/ Regulatory/ Contract Research)	Basic 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/ CPCSEA, for new experiments or extensions of ongoing experiments using animals.

1. Project / Dissertation / Thesis Title:

Sl. No. 1

Project title must be complete with name of animal species used in the project; no abbreviations allowed in the 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

Sl. No. 2

- Main PI of the project must be a regular member of institution (faculty or scientific staff or Post-Doc – only in case of funding agency requirement).
- In case of collaborative project, main PI must be an institutional member and collaborative PI has to be listed as Co-PI at Sl# 3 of Form B (section II).

Sl. No. 2f

Mention the number of years of experience in animal experimentation (no need for description).

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

Sl. No. 3

- Main PI's name also must be listed along with other authorized individuals to conduct procedures.
- It is also mandatory to list name of institutional Veterinarian for all projects with invasive and/or stress/painful procedures on animals.

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

Sl. No. 4

Mention full name of the funding source (NOT the budget code number), eg., NCBS/INSTEM core funds...and attach the proof in case of external grants.

5. Duration of the animal experiment.

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

Sl. No. 5a

Date of initiation (proposed) must be the month and year of IAEC meeting or any month after IAEC approval (DO NOT mention the days).

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

Sl. No. 6

Must be in easy to understand newspaper language

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)

12-month period (mm-yyyy)	Number of animals in each group				Total Animals required per year
	Experimental Groups				
	Control Group	Group 1	Group 2	Group 3	
Year 1 (mm-yyyy to mm-yyyy)	20	30	35	15	100
Year 2 (mm-yyyy to mm-yyyy)	25	30	35	10	100
Year 3 (mm-yyyy to mm-yyyy)	35	30	35	10	110

Sl. No. 7d – Example of table for experimental animals

- Please carefully define each of the experimental groups including the controls
- Don't mention range of numbers for animal required, instead choose higher range and quote variability factors...
- Check if the calculations of the total number of animals are accurate and verified.

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.

Sl. No. 8b

Please refer to already published or unpublished data - in vitro studies/pilot studies before selecting in-vivo animal model

- c. Why are the particular species selected?
- d. Why is the estimated number of animals essential?

Sl no. 8d

Wherever possible use appropriate statistical tools like power analysis to justify statistically significant numbers per experimental group (mentioned in Sl. No. 7d) or quote scientific references of similar studies or past research work experience in the lab to justify the required animal numbers (detailed calculations can be enclosed in annexure if required).

- e. Are similar experiments conducted in the past in your establishment?

Sl. No. 8e

If the project is a continuation work in the lab OR applied for renewal, mention the previous year's research results.

- 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 :

Sl. No. 9b

- Test compounds like Drugs, tamoxifen, hormones, control substances etc.

- Route of administration via injections or oral or via food or drinking water

Volumes :

c. Blood withdrawal Details:

Sl. No. 9c

Volumes :

Please indicate blood collection method.

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.

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

12. Describe post-experimentation procedures.

Sl. No. 12b

Please indicate that the animals will be euthanized with proper reasoning.

a. Scope for Reuse:

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

c. Describe method of Euthanasia.

Sl. No. 12c

Describe method of euthanasia in detail (Do NOT mention as per standard protocol).

d. Method of carcass disposal after euthanasia.:

Sl. No. 12d

Describe method of carcass disposal after euthanasia with work order number reference for biomedical waste collection agency.

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

Sl. No. 13

If the animals are being transported for experimental purposes to collaborators, then mention that animals will be transported in temperature controlled conditions in filter top transport crates by air or road

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

Sl. No. 14b

- Enclose IBSC approval certificate if applicable.
- Project title mentioned in Form B and IBSC certificate has to be same, if that is not possible for some reason, then IBSC approved protocol must be mentioned in the issued certificate.

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: