GUIDELINES FOR FILLING FORM B

Central Animal Facility
Indian Institute of Science
Bangalore 560 012
Karnataka

Reviewing of Form B

A brief description is given under each section/subheading which describes for the benefit of members. Every section should be answered with appropriate answer. No column should be However, these descriptions are not exhaustive and complete, and if any clarification is required, contact CAF office.

FORM B

APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS

Application to be submitted to sent either to the CPCSEA (address in form A above) or Institutional Animal Ethics Committee (IAEC)

Part A

1*	Name and address of establishment ***In this section, details about the organization/institute should be provided*** ***Ex :*** ***Central Animal Facility*** ***Indian Institute of Science*** ***Bangalore – 560 012***
2*	Registration number and date of registration ***In this section, registration number of the animal facility/Organization and date of registration should be provided*** ***Ex :*** ***48/GO/ReBi/SL/1999/CPCSEA 11-03-1999***
3	Name, address and registration number of breeder from which animals acquired (or to be acquired) for experiments mentioned in parts B & C ***Details of the breeder with registration number from where the animals will be procured should be provided in this section*** ***Ex :*** ***Central Animal Facility*** ***Indian Institute of Science*** ***Bangalore – 560 012*** ***48/GO/ReBi/SL/1999/CPCSEA***
4	Place where the animals are presently kept (or proposed to be kept)

	In this section, address of the animal facility should be given ***Ex :*** ***Central Animal Facility*** ***Indian Institute of Science*** ***Bangalore – 560 012***
5	Place where the experiment is to be performed (Please provide CPCSEA Reg. Number) ***In this section, address of the animal facility where the experiment is carried out should be given. If it is different from the above, mention the address.*** ***Ex :*** ***Central Animal Facility*** ***Indian Institute of Science*** ***Bangalore – 560 012*** ***48/GO/ReBi/SL/1999/CPCSEA***
6	Date on which the experiment is to commence and duration of experiment ***Details about the probable date of starting the experiment and duration of the experiment should be provided. Nominees should check the date properly and should never permit the experiment which has been completed earlier***. ***Ex : April 1, 2015 and 3 years***
7	Type of research involved (Basic Research/Educational/Regulatory) ***Mention the type of experiment from the above*** ***Ex : Basic***

Signature

Xxxxxx

Name and designation of the Investigator

Date: ***xx.xx.xxxx***

Place: ***Bangalore***

*Applicable only for application to be submitted to CPCSEA

PART B

Protocol form for research proposals to be submitted to the committee/Institutional Animal Ethics Committee, for new experiments or extensions of ongoing experiments using animals other than non-human primates.

1. Project / Dissertation / Thesis Title:

A brief title of the proposed project should be given here

2. Principal Investigator / Research Scholar / Research Guide /Advisor :

a. Name
b. Designation
c. Dept / Div/ Lab
d. Telephone No.
e. Experience

In this section, complete details about the investigator should be provided including his designation, dept., telephone number and experience in the field of animal experimentation

3. List of names of all individuals authorized to conduct procedures under this proposal Co -guides

a. Name
b. Address
c. Experience

In this section details of the personnel involved in conducting the experiments should be given including address and their experience in the field of animal experimentation

4. Funding source with complete address (Please attach the proof)

In this section, a brief note on the source and address of funding agency should be mentioned whether it is in-house/Govt./private funding.

5. Duration of the project

a. Number of months
b. Date of initiation (Proposed)
c. Date of completion (Proposed)

Approximate duration of the animal study should be mentioned here with the tentative date of starting the experiment and also tentative date of completion. Do

not mention the duration of the funded project here.

6. Detailed study plan may be given (Not more than one page)

In this section, investigator should briefly mention the objective of the study and the study plan to achieve the objective. This should be in lay man language and should be easy to read and understand by nominee and socially aware member. Hence, too many scientific terms/words should be avoided. This study plan should not exceed more than one page.

7. Animals required

a. Species/Common name — ***Details of the animal species and its common name, required for the study should be provided***

b. Age / weight / size — ***Details about the age/weight/size of the animals required for the study should be mentioned***

c. Gender — ***Sex of animal should be specified***

d. Number to be used (Year-wise breakups and total figures needed to be given) — ***Detailed breakup of animal should be given in this section. The investigator should mention the number of groups in the study and also number of animals in each group. This will help the members to assess the need for required number of animals. Give breakup as mentioned below.***

Year	***Group***	***No. of animals***
	Total	

e. Number of days each animal will be housed. — ***Mention how long (number of days) these animals are housed for experimental purpose.***

f. Proposed source of animals — ***Mention the source from where the***

animals are procured. Whether bred in the colony or procured from registered vendor.
Ex. Central Animal Facility
Indian Institute of Science
Bangalore

8. Rationale for animal usage

a. Why is animal usage necessary for these studies?

Briefly mention why the animals are necessary in the proposed study. Whether the study can be carried out without animals? If not, mention the need for animals in this study.

b. Why are the particular species selected required?

Justify why the particular species is selected for experiment. If higher animals like dogs and monkeys are required, then mention whether similar kind of study have been carried out on lower animals like rats/rabbits. For using higher animals, proper justification is essential.

c. Why is the estimated number of animals essential?

Justify the number of animals requested for the proposed study. Whether the estimated number is sufficient enough to get statistically valid results? If more number of animals is requested, then proper justification should be provided.

d. Are similar experiments conducted in the past? If so, the number of animals used and results obtained in brief.

If similar kind of study conducted earlier, it should be mentioned here and also the number of animals used and a brief report on the results obtained.

e. If yes, why new experiment is required?

If it is done already, justify why the similar kind of experiment is planned again.

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

If similar kind of study done elsewhere, it should be mentioned here with brief result of the study.

9. Description of the procedures to be used.

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

Furnish details of injections schedule

Substances	***Details about the test material should be given here***
Doses	***Doses of the test material to be administered should be mentioned here***
Sites	***Route of administration of the test compound should be mentioned here***
Volumes	***Quantity of test compound to be injected should be mentioned here***
Blood withdrawal Volume	***The proposed quantity of blood withdrawn from the animal should be mentioned here.***
Sites	***The route of blood collection should be mentioned here such as retro orbital vein, tail vein, ear vein etc.***
Radiation (dosage and schedule)	***If any radiation is used, then dosage and schedule should be mentioned here***

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

If any study is carried out using similar test compound on other animal models, then it should be mentioned here. If already information is available from other animal model, then investigator should justify the need for present study

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

If any of the experiment prohibits the use of anesthetic or analgesic drug which may interfere with the outcome of the study, such experiments should be mentioned here. If any painful experiment is proposed to be carried out without the use of anesthesia or analgesia, then proper justification should be provided here.

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)

If any surgery is done on animals, detailed procedure should be given

b. Names, qualifications and experience levels of operators

The person who is doing surgery and his educational qualification and experience should be mentioned here.

c. Description of post-operative care

Detailed procedure about how the animals are taken care after the surgery should be mentioned in detail.

d. Justification if major survival surgery is to be performed more than once on a single individual animal.

If investigator wants to perform repeated surgery on a single animal, this should be properly justified here. Multiple major survival surgical procedures on a single animal are discouraged but may be permitted if scientifically justified by the user and approved by the IAEC. Multiple major survival surgical procedures can be justified if they are related components of a research project, if they will conserve scarce animal resources, or if they are needed for clinical reasons. Cost savings alone should not an adequate reason for performing multiple major survival surgical procedures.

13. Methods of disposal post-experimentation

a. Euthanasia (Specific method):

The specific method of euthanasia should be mentioned (Carbon dioxide, over dosage of anesthesia, cervical dislocation, decapitation etc.). Verify whether the method or the drug used is approved by the CPCSEA or not.

b. Method of carcass disposal :

Briefly describe how the animals are disposed whether they are incinerated or disposed through authorized waste disposal firms. Burning or burial of the dead animals is not permitted.
Ex : Incineration of the carcass at CAF incinerator facility

c. Rehabilitation:

The large animals must be rehabilitated after the experimentation if they are not used for any terminal experiments. If animals rehabilitated after the experimentation, mention where it is rehabilitated. This section is not applicable for small laboratory animals such as rats, mice, G.pigs, hamsters and rabbits.

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

If animals are to be transported from other places or breeder facilities, then how these animals are transported (rail/road/air) and type of vehicle and also type of boxes/cages used should be mentioned in detail

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) Radionuclides :
If any radioactive compounds are used, it should be mentioned here. The compound, dose and route should be mentioned in detail.

(b) Microorganisms / Biological infectious Agents:
If any microorganisms or infectious agents are used, then details should be given here.

(b) Hazardous chemicals or drugs :
If any chemicals are used, then details should be given here. The nature of the chemical and the precaution to be taken while handling such compounds should be explained in detail.

(c) Recombinant DNA :
If any recombinant DNAs are used, then details should be given here

(d) Any other (give name)

If, your project involved use of any of the above, attach copy of the minutes of IBSC granting approval. It is mandatory to attach the approval letter of Institutional Biosafety committee if the proposal involves any of the above mentioned items are used

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 is received in wiring. Further, I certify that I will follow the recommendations of CPCSEA.

9. I certify that I will ensure the rehabilitation policies are adopted.

Signature

Date: Name of Investigator

NB : Investigator should read this declaration and sign. It is his responsibility to follow the guidelines of CPCSEA while conducting the experiment and also to maintain the records (Form D).

Guidelines for designing the projects

1. While designing a project, the investigator should first consider whether the aims of the project could be realized by using *in vitro* techniques or less sentient animal species, such as insects or nematodes. The replacement of one animal species with another, particularly if the species used is non-vertebrate, could also be considered to be an alternative method. Therefore, the model selected should be the lowest phylogenetic species, and also the least sentient species, which will allow the scientific objectives to be realized. If the use of living vertebrates is considered to be essential, the aim should be to use the minimum possible number of animals which provides statistically significant results and to use strategies which will ensure that the animals used are subjected to the minimum discomfort.

2. Reduction alternatives are methods for obtaining comparable levels of information from the use of fewer animals in scientific procedures, or for obtaining more information from a given number of animals, so that, in the long run, fewer animals are needed to complete a given research project or test. The greater the number of animals used in an experiment, the greater will be the overall costs, in terms of animal suffering. Thus, the numbers of animals used should be the minimum which is consistent with the aims of the experiment.
3. Research strategy is also important and should be given due consideration. For example *in vitro* systems, may be readily used for the random screening of potential new pharmaceutical agents.
4. Small pilot studies which can be reviewed before committing animals and resources to major experiments.
5. In view of the importance of good experimental design and approximate statistical analysis in supporting high quality research, and the potential savings in terms of the numbers of animals used, due consideration should be given to optimum experimental design and statistical input.
6. Refinement alternatives encompass those methods which alleviate or minimize potential pain and distress, and which enhance animal well-being. “Distress” is an aversive state in which an animal is unable to adapt completely to stressors and the resulting stress, and therefore shows maladaptive behaviors. The stressors may induce physiological, psychological or environmental stress. “Pain” results from potential or actual tissue damage that caused by injury, surgery or disease, and can lead to distress. Pain and distress can result from both experimental and non-experimental causes. Potential sources of experimental pain and

distress includes improper or prolonged restraint, experimental infections, chemical induced toxic effects, surgical, and experimental procedures, post-operative pain and improper euthanasia techniques. Non-experimental sources includes naturally occurring infectious and non-infectious diseases, sub optimal environmental conditions, improper handling, stressful housing situations, injuries sustained during fighting, and injuries associated with the housing or caging. Much potential pain and distress can be avoided or at least alleviated with the proper use of anesthetics, analgesics and tranquilizers, which is a critical component of any comprehensive programme of adequate veterinary care. All experimental protocols should be sufficiently detailed with regard to the type and severity of likely adverse effects, the times of peak occurrence, humane end points, and the remedial actions to be taken.

7. Replacement alternative methods and approaches includes the following:
    - The improved storage, exchange and use of information about animal experiments already carried out, so that unnecessary repetition of animal procedures can be avoided.
    - The use of physical and chemical techniques and of predictions based on physical and chemical properties of molecules
    - The use of mathematical and computer models, including:
        - Modeling of quantitative structure-activity relationships, i.e. taking advantages of correlations between molecular structure and biological activity in the prediction of the potential desired and undesired effects of series of related chemicals.
        - Molecular modeling and the use of computer graphics, for example in actively designing drugs and other chemicals for specific purposes.
        - Modeling of biochemical, physiological, pharmacological, toxicological and behavioral systems and processes.
        - The use of “lower” organisms with limited sentience, including invertebrates, plants and microorganisms; for example, the use of bacteria in genotoxicity testing.
        - The use of the early developmental stages of vertebrates before they reach the point at which their use in experiments and other scientific procedures is regulated.
        - The use of *in vitro* methods, including sub cellular fractions, short term maintenance of tissue slices, cell suspensions, and perfused organs, and tissue culture proper (cell and organotypic culture), including human tissue culture.

- Human studies, including the use of human volunteers, post-marketing surveillance and epidemiology; for example, skin patch testing in humans before marketing, and monitoring consumer response after marketing as alternative to the animal testing of cosmetic products.

In many areas of the biomedical sciences, *in vitro* methods are increasingly used as the methods of choice in place of animal studies.