**Guidelines for filling FORM - B**

**FORM B (per rule 8(a)\***

###### APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMETS

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.

* Central Laboratory Animal Resources, JNU, New Delhi - 110067

2 Registration number and date of registration.

* 19/GO/ReBi/S/99/CPCSEA dated: 10.03.1999

3. Name, address and registration number of breeder from whom animals acquired (or to be acquired) for experiments mentioned in parts B & C.

* Central Laboratory Animal Resources, JNU, New Delhi - 110067
1. Place where the animals are presently kept (or proposed to be kept).
* Central Laboratory Animal Resources, JNU, New Delhi – 110067, if other place so clearly mention for how many days with proper justification.
1. Place where the experiment is to be performed (please provide CPCSEA Reg. Number).
* Central Laboratory Animal Resources, JNU, New Delhi – 110067 Or clearly mention for how many days animal will be housed at place other than Central Laboratory Animal Resources and proper justification for the same.
* (CPCSEA Reg. No. 19/GO/ReBi/S/99/CPCSEA dated: 10.03.1999)
1. Date on which the experiment is to commence and duration of experiment.
* Mention experiments will start only after IAEC approval and mention the duration of experiments.
1. Type of research involved (Basic Research/ Educational / Regulatory/ Contract Research).
* Please mention which type of research as above.

(The appropriate form for the research proposal – Part B in the case of experiments using animals other than non human primates, Part C for use of non-human primates-to be duly filled in, signed and appended to this form)

Date Signature

Place Name and designation of Investigator

###### PART B

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

1. **Project / Dissertation / Thesis Title:**

* Please mention title clearly
1. **Principal Investigator/ Research Scholar/ Research Guide/ Advisor:**
	* 1. Name : (mention the name)
		2. Designation : (mention designation)
		3. Dept/Div/Lab : (mention department with lab number)
		4. Telephone No. : (mention telephone number & mobile number)
		5. Experience : (mention the total experience)
2. **List of names of all individuals authorized to conduct procedures under this proposal.**

 Co- guides and others

* + 1. Name : (mention all the names)
		2. Address: (mention address & mobile number)
		3. Experience : (mention total experience)
1. **Funding source with complete address (Please attach the proof)**
* Mention the Funding source with complete address and attached copy also.
1. **Duration of the project**

a. Number of months : Mention number of months for the duration of project.

b Date of initiation (Proposed) : Mention as after IAEC approval

c. Date of completion (Proposed) : Mention the date as per your duration after IAEC approval (example 24 months after IAEC approval.)

1. Detailed study plan may be given (Not more than one page)
* Please provide a brief description of the project, in lay man’s language, incorporating the following information:

(a). Background, including work done in the area and review literature, clearly indicting the lacunae in literature.

(b). Main objectives of research to be carried out and its relevance to science, and human health.

(c). Provide References/ Bibliography of work done in the area of your proposed research.

1. **Animals required**
	* 1. Species/Common name : mention the species clearly
		2. Age/weight/size : mention the age, weight/ size of animal
		3. Gender : mention the gender of the animal
		4. Number to be used(Year-wise breakups and total figures needed to be given)
* Mention year wise break up clearly
	+ 1. Number of days each animal will be housed.
* Mention number of days/months/years the animal will be housed.
	+ 1. Proposed source of animals.
* Mention the Central Laboratory Animal Resources, JNU, New Delhi – 67 or mention clearly from any other registered source if any (eg. NIN)
1. Rationale for animal usage
	* 1. Why is animals usage necessary for these studies?
* Mention clearly why the experiment is required for to be performed on animal model?
	+ 1. Why are the particular species selected required?
* Mention clearly the reason why particular species is required?
	+ 1. Why is the estimated number of animals essential?
* Mention why the proposed number of animals essential for the study?
	+ 1. Are similar experiments conducted in the past? If so, the number of animals used and result obtained in brief.
* Mention clearly about the same in brief.
	+ 1. If yes, why new experiment is required?
* Mention clearly about the same
	+ 1. Have similar experiments been made by any other organization agency? If so, their result in your knowledge.
* Mention clearly the name & address of the agency.
1. **Description 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 Mention clearly schedule, doses & sites of administration of substances to be given during experiments.

Substances :

Doses :

Sites :

Volumes :

Blood withdrawal :

Volumes :

Sites :

Radiation (dosage and schedules) :

Refer below for the site and volume of blood withdrawal: -

|  |  |  |
| --- | --- | --- |
| **Animals** | **Volume** | **sites** |
| Mice | small volumes (< 0.1 ml) | Tail vein  |
| Mice | More than 0.1 ml | Retro Orbital sinus  |
| Mice | Maximum volume  | Cardiac puncture (after sacrifice)  |
| Rat  | small volumes (< 1.0 ml) | Tail vein  |
| Rat | More than 1.0 ml | Retro Orbital sinus  |
| Rat  | Maximum volume  | Cardiac puncture (after sacrifice)  |
| Rabbit | 10-15 ml | Ear vein |
| Rabbit | Maximum volume | Cardiac puncture (after sacrifice) |

1. **Please provide brief description 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.**
* Mention clearly about the same.
1. **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.**
* Mention clearly about the same.
1. **Will survival surgery be done?**

**If yes, the following to be described**.

* + 1. List and description of all such surgical (including methods of asepsis) and use of pre-anesthetics.
		2. Mention clearly the recordings for the vital statistics of animal during surgery. c. Names, qualifications and experience levels of operators
1. Description of post-operative care.
2. Justification if major survival surgery is to be performed more than once on a single individual animals.
* Mention clearly about the same
* Permissible anesthetics are (i). Isoflurane (ii) Ketamine & Xylazine (iii) Sodium thiopentone
1. **Methods of disposal post-experimentation**
	* 1. Euthanasia (Specific method): Permissible are (i) Over dose of Sodium                                                   Thiopentone ( 3 times the anesthetic doze)                                                   (ii) CO2  chamber (iii)                                                   (iii) Cervical dislocation write whichever is                                                    applicable.
		2. Method of carcass disposal: Through Bio-waste service provider to                                                  Central Laboratory Animal Resources

                            JNU

* + 1. Rehabilitation: Mention clearly if required
1. **Animal transportation methods if extra-institutional is envisaged.**
* Air Conditioned vehicle with provisions for proper caging, bedding, feed and water shall be used for the transportation of the laboratory animals, if required.
1. **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 bio-safety level required, appropriate therapeutic measures and the mode of disposal of contaminated food, animal wastes and carcasses must be identified).**
2. Radionuclides
3. Microorganisms/ Biological infectious Agents
4. Hazardous chemicals or drugs
5. Recombinant DNA
6. Any other (give name)

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

* If your projects doesn’t involves use of above mention not applicable.

**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 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.

* 1. 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).
	2. Institutional Biosafety Committee’s (IBC) certification of review and concurrence will be taken (Required for studies utilizing DNA agents of human pathogens).
	3. I shall maintain all the records as per format (Form D).
	4. I certify that, I will not initiate the study unless approval from CPCSEA received in wiring. Further, I certify that I will follow the recommendations of CPCSEA.
	5. I certify that I will ensure the rehabilitation policies are adopted.

 **Signature**

**Date: Name of Investigator**