**INSTITUTIONAL ANIMAL ETHICS COMMITTEE [IAEC]**

#### IAEC PROTOCOL COVER SHEET

**Date:**

From:

|  |  |  |
| --- | --- | --- |
| Name of the Principal Investigator | : |  |
| Designation | : |  |
| Emp. No | : |  |
| Department | : |  |
| Address for Communication | : |  |
|  |  |  |
|  |  |  |
| Pin code | : |  |
| Extension No. | : |  |

To

The Secretary-IAEC, Sri Ramachandra Institute of Higher Education and Research

**Subject: IAEC – Proposal – Submission – Regarding**

|  |  |  |
| --- | --- | --- |
| **Title of Project** | : |  |

Sir,

I am herewith submitting 1 original copy + 1 photocopy with one soft copy via [sruiaec@gmail.com](mailto:sruiaec@gmail.com) of the above proposal for approval at the \_\_\_\_ Session of the Institutional Animal Ethics Committee.

Thanking you

Yours truly,

xxxxxxxxxxx

|  |
| --- |
| Name and Signature of Principal Investigator |

**To be filled by the IAEC-Secretary**

Protocol Review #:………………………………………… Proposal Received on: …………………………………………

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Proposal Category | 🗖 New Proposal | 🗖 Revised Proposal | 🗖 Proposal  for Renewal/Extension | 🗖 Ph.D Provisional  Registration at SRIHER |
| Last Session appeared and Date | NA |  |  | NA |
| Enclosure (If any) |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 🗖 Self Funding | 🗖 Applied for funding | 🗖 Funding Sanctioned | 🗖 Consultancy |

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

**APPLICATION FOR PERMISSION FOR ANIMAL EXPERIMENTS**

**PART A 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 |  |
| 2. | Registration number and date of  Registration. |  |
| 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 CPCSEA  Reg. Number) |  |
| 6. | Date and Duration of experiment. |  |
| 7. | Type of research involved (Basic  Research / Educational/ Regulatory/  Contract Research) |  |

|  |  |
| --- | --- |
| Date | Signature |
| Place | Name & Designation of Investigator |

**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/Research Scholar/Research Guide/Advisor**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S. No.** | **Details** | **Principal Investigator / Research Scholar / Ph D student** | **Research Supervisor$** | **Co.guide /Advisor$** |
|  | Name |  |  |  |
|  | Designation |  |  |  |
|  | Dept/Div/Lab |  |  |  |
|  | Mobile No |  |  |  |
|  | Experience |  |  |  |
|  | PhD registration No**$**. |  | | |

**$ Applicable for SRIHER PhD Student**

1. **List of names of all individuals authorized to conduct procedures under this proposal.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S. No** | **Details** | **1** | **2** | **3** |
|  | Name |  |  |  |
|  | Designation |  |  |  |
|  | Dept/Div/Lab |  |  |  |
|  | Extension No. |  |  |  |
|  | Experience |  |  |  |

1. **Funding source with complete address (**Please attach the proof**):**

1. **Duration of the project:** *(IAEC approval is granted for one year)*

a. Date of initiation (Proposed) :

b. Date of completion (Proposed) :

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

(Please refer to the template attached herewith)

1. **Animals required**

|  |  |  |
| --- | --- | --- |
| a | Species / Common name |  |
| b | Age / Weight / Size |  |
| c | Gender (Male/Female) |  |
| d | Number to be used  (year-wise break-ups and total figures need to be given) |  |
| e | Number of days each animal will be housed |  |

1. **Rationale for animal usage** 
   1. Why is animal usage necessary for these studies?
   2. Whether similar study has been conducted on *in vitro* models? If yes, describe the leading points to justify the requirement of animal experiment.
   3. Why are the particular species selected?
   4. Why is the estimated number of animals essential?
   5. Are similar experiments conducted in the past in your establishment?
   6. If yes, justify why new experiment is required?
   7. Have similar experiments been conducted by any other organization in

same or other *in vivo* models? If yes, enclose the reference.

1. **Description the procedures to be used**
2. Describe all invasive and potentially stressful non-invasive procedures that

animals will be subjected to in the course of the experiments)

1. Furnish details of injections schedule Substances:

Doses :

Sites :

Volumes :

1. Blood withdrawal Details:

Volumes :

Sites :

1. Radiation (dosage and schedules):
2. Nature of compound/Broad classification of drug/NCE
3. **Does the protocol prohibit use of anesthetic or analgesic for the conduct of procedures? If yes, justify.**
4. **Will survival surgery be done?**

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

1. List and description of all such surgical procedures (including methods of asepsis)
2. Names, qualifications and experience levels of operators
3. Description of post-operative care
4. Justification in major survival surgery is to be performed more than once on single individual animals.
5. **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.

1. **Describe animal transportation methods if extra-institutional transport is**

**envisaged.**

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 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.

1. I will obtain approval from the IAEC/ CPCSEA before initiating any changes in this study.
2. 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).
3. I certify that I will submit appropriate certification of review and concurrence for studies mentioned in point 14.
4. I shall maintain all the records as per format (Form D) and submit to Institutional Animal Ethics Committee (IAEC).
5. 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.
6. I certify that I will ensure the rehabilitation policies are adopted (wherever required).

Signature

Name of Investigator

Date:

**DECLARATION FROM THE GUIDE/HEAD OF THE INSTITUTE**

I certify that the project entitled **“\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_”** submitted by Mr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for IAEC proposal at Sri Ramachandra Institute of Higher Education and Research is for the purpose of Teaching Practical Class/Department Basic research/ Seeking Grants to funding Agency/ Funded project/ Doctoral program / **Consultancy Services**. I understand that, he/she shall use the protocol described in this application as a basis for the above said purpose and it is my responsibility to ensure that the description of animal use in the research proposal, is identical in belief to that contained in the IAEC review application.

Herewith, I also assure that the scientist from CEFTE involved in the design and conduct of this research work will be duly acknowledged in project report/thesis and publication if any.

**Signature of the Guide/Head of Department/Institute:**

**Date with Seal:**

**ANNEXURE**

* + 1. Project/Dissertation/Thesis Title :
    2. Name of the Investigator :
    3. Address, Mob No and Email ID :
    4. Objective of the Study :
    5. Test Item Details :
    6. Test System Details :

Species

Strain

Sex

Body Weight

Age at starting of dosing

Source

* + 1. Acclimatization :
    2. Randomization :
    3. Identification of Animals :
    4. Grouping Design :

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Groups** | **Treatment** | **Number of Animals** | **From** | **To** |
| 1 | Control (Vehicle) |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |

* + 1. **Animal Husbandry**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Environmental conditions | : | Temperature, humidity and air exchange to be maintained in the range of 19-23°C, 30- 70% and 12-15 air changes per hour respectively. The animals to be maintained with photoperiod of 12 h artificial light and 12 h dark. |
|  | Housing | : | Animals to be housed in polypropylene cages covered with stainless steel grid top. Dedusted and autoclaved paddy husk was used as bedding material. Bedding material to be changed on alternate days. Animal to be housed as group (less than or equal to 1kg/cage).. |
|  | Diet | : | Animals to be provided *ad libitum* with standard rodent pelleted feed. Feed to be procured from approved vendors. |
|  | Water | : | Potable UV treated water to be provided *ad libitum* in autoclaved bottles. Water bottles to be changed on daily basis. |

* + 1. **Methods/Procedure**
* Justification for Selection of dose level
* Justification for the route of administration
* Preparation of Animals, if any
* Preparation of doses/dosing
* Test Item Administration procedure – frequency and period
  + 1. **Observation/Evaluation**
* General Observation/Clinical Observation – Frequency and period
* Signs of Toxicity :
* Morbidity /Mortality:
* Body Weight monitoring, Feed and Water Consumption
* Clinical pathology
* Hamatology, Serum Biochemistry etc
* Blood collection – Procedure, Site, volume and frequency etc
* Anatomic Pathology –
* Necropsy procedure
* Gross pathology & Histopahtology
* List of Organs /Tissue samples to be collected
  + 1. **References**