**Annexure: (UOR/04-001)**

Ethics review application form for animal research

 **APPLICATION FORM – ANIMAL RESEARCH**

**ETHICS REVIEW COMMITTEE**

**Faculty of Medicine, University of Ruhuna**

**Application No: [ ][ ][ ]/[ ][ ] Date received \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_**

**Version: [ ]**

**Name of Applicant: (Prof/Dr/Mr/Ms) ……………………………………………………..**

*Office use only*

This form should be filled and signed by the principal investigator who requests ethical approval for a research project involving ANIMALS. All entries should be typed. **Hand written forms will not be accepted.** **No cages should be left blank.**

Please read the **instructions given carefully when completing the application** and ensure all relevant documents as per the document checklist are submitted.

***This form can be filled in and the spaces provided are expandable as you type***

**PART 1 (Administrative details)**

**1.** **Title of Research Project:**

**2. Details of principal investigator**

|  |  |
| --- | --- |
| Title(Prof./Dr./Mr/Ms):       | Name:       |
| Current designation AND name and address of institution where the applicant is attached:       |
| Highest educational qualification of applicant:       |
| Mailing address:       |
| Phone:       | e-mail:       |

**3. Is this study a requirement for a postgraduate degree?** Yes [ ]  No [ ]

3.1 Have you already registered for this degree? Yes [ ]  No [ ]

|  |
| --- |
| Type of degree (MSc/PhD/MD/MS/other):       |
| Awarding University:       |
| Date of registration :       | Date of protocol approval by board of study :  | Letter annexed[ ]  |

***Please append letter of approval from Board of Study (if available)***

3.2 Do you have any other active studies at present? Yes [ ]  No [ ]

3.3 If yes, how many studies are there?

**4. Are there supervisors for this project?** Yes [ ]  No [ ]

|  |  |
| --- | --- |
| Title:       | Name:       |
| Department (or organization if not affiliated with FM/UR):       |
| Highest educational qualification :       |
| Mailing address:       |
| Phone:       | e-mail:       |

|  |  |
| --- | --- |
| Title:       | Name:       |
| Department (or organization if not affiliated with FM/UR):       |
| Highest educational qualification :       |
| Mailing address:       |
| Phone:       | e-mail:       |

***Please append additional pages with supervisors’ names if necessary.***

**5. Are there co-investigators for this project?** Yes [ ]  No [ ]

|  |  |
| --- | --- |
| Title:       | Name:       |
| Department (or organization if not affiliated with FM/UR):       |
| Highest educational qualification :       |
| Mailing address:       |
| Phone:       | e-mail:       |

|  |  |
| --- | --- |
| Title:       | Name:       |
| Department (or organization if not affiliated with FM/UR):       |
| Highest educational qualification :       |
| Mailing address:       |
| Phone:       | e-mail:       |

***Please append additional pages with Co-investigators names if necessary.***

**6. Location(s) where the research will be conducted:**

6.1 Is this a multi-site study? Yes [ ]  No [ ]

6.2 Specify all study sites including laboratories, animal houses and other:

|  |  |
| --- | --- |
| Type of site (laboratory/animal house) | Details  |
|       |       |
|       |       |

6.3 Will samples/tissue/data collected during the study be removed from the above study site/transported to a different site for investigation etc. Yes [ ]  No [ ]

If so provide details of these sites

6.4 Will samples/tissues collected during the study be taken out of the country for investigation storage Yes [ ]  No [ ]

If so provide details of these sites

**7. Investigator(s) training to handle animals in research**

7.1 Have all the investigator’s handling animals in this study been trained? Yes [ ]  No [ ]

7.2 Specify all training received:

|  |  |
| --- | --- |
| Name of investigator  | Training site, duration of course and type of training received  |
|       |       |
|       |       |

**8. Other research ethics board approval(s)**

8.1 Has any other ERC approved this project? Yes [ ]  No [ ]

If Yes, please provide details and a copy of the approval letter.

**9. Funding of this project**

|  |  |
| --- | --- |
| Funding Status | Source and amount  |
| Funded [ ]  | Agency:       Total Budget : SLR      |
| Applied for funding [ ]  | Agency:       Total Budget : SLR      |
| Unfunded [ ]  If unfunded, please explain why no funding is needed:      |

**PART 11 (Research Proposal)**

1. **Project start and end dates**

Estimated start date:

Estimated completion date:

1. **Objective of the project and justification**

Describe the objectives and rationale for the proposed project. The rationale for doing the study must be clear. Please include references in this section.

11.1 General objective

11.2 Specific objectives:

11.3 Justification (A clear justification should be given for investigating in ANIMALS). Explain why the research cannot be carried out with non-animal alternatives.

1. **Methodology**

12.1 Description of the procedures : Describe in DETAIL all procedures and techniques to be used, **emphasizing those performed on animals**. Use flowcharts to illustrate procedures as appropriate. Append additional page(s) if necessary.

**Description of the procedure involving animals (for which ethical clearance if being sought). DO NOT LEAVE BLANK, sections13 - 20 must be filled for ALL projects**

**13. Description of animal**

13.1 What is the species of animals used and the reason for selecting the said animal model?

13.2 What is the source of animals and the arrangements that you have made to ensure constant supply of animals?

13.3 What is the total number of animals used in the study and how did you calculate the sample size?

13.4 How long will animals be used in the study?

13.5 How often will animals be monitored?

13.6 Who will handle the animals?

|  |  |  |
| --- | --- | --- |
| Name  | Position in study team (PI, research assistant/ supervisor, etc, | Training received to handle animals |
|       |       | Yes [ ]  No [ ]  |
|       |       | Yes [ ]  No [ ]  |

**14. Procedures and Drugs**

Is there any administration of drugs/herbs/chemicals to the animals : Yes [ ]  No [ ]

If yes, specify for each agent (append additional pages if necessary):

Amount of agent and dosage:

Route of administration:

Potential health risks to humans or animals:

Special animal care requirement(s):

Precautions to be taken by personnel (including animal care staff):

14.1 What is the procedure for dealing with adverse events?

14.2 Is there any procedure for reporting adverse events?

**15. Animal welfare**

Are the facilities available at the animal house/facility adequate to conduct this study?

Yes [ ]  No [ ]

15.1 Are the facilities adequate to provide optimum welfare to animals? Yes [ ]  No [ ]

15.2 What are the arrangements made for feeding and for providing water?

**16. Endpoints**

Please specify ENDPOINTS: Endpoints are clear criteria to define the point at which humane intervention must be implemented to prevent or relieve unnecessary pain and/or distress. Should the experimental animal acquire experimentally-induced disease, illness or life threatening condition?

 16.1 Are any drugs used for anaesthesia /analgesia of animals: Yes [ ]  No [ ]

If Yes, specify the drug, dosage and route of administration

16.2 Please specify the method of euthanasia:

16.3 Give details of final disposal of animals:

**17. Experience of Investigators with this type of research**

17.1 Please provide a brief description of previous experience with this type of research by (i) the principal investigator, (ii) the research team and (iii) the people who will have direct contact with the animals. If there has not been previous experience, please describe how the principal investigator/research team will be trained.

**PART III – (description of the risks and benefits)**

**18. Assessment of Risks/Benefits**

18.1. Are there any risks (physical, psychological) to animals in the study? Yes [ ]  No [ ]

If YES, identify them and state how you plan to prevent or minimize these risks?

18.2. Are there any benefits to the animals used in the study? Yes [ ]  No [ ]

If YES, identify them

18.3. Are there any risks to research team by conducting this study? Yes [ ]  No [ ]

If yes identify them and state how you would overcome these risks

**19. Data Security, Retention and Access**

19.1 Describe the provisions that will be made to protect confidentiality of data:

19.2 If data will be shared with other researchers or users, please describe how and where the data will be stored and any restrictions that will be made regarding access.

**20. Conflicts of Interest**

20.1 Will the researcher(s), members of the research team, and/or their partners or immediate family members: receive any personal benefits (e.g., financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection with this study? Yes [ ]  No [ ]

20.2 If **Yes**, please describe the benefits below. (Do not include conference and travel expense coverage, or other benefits which are considered standard for the conduct of research.)

**21. Declaration of applicant**

As the Principal Investigator on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving animal participants. I understand that if there is any significant deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study. I declare that I am not seeking approval for a study that has already commenced or has already been completed. I understand that at least two months are required for ethics review and granting of ethics clearance. I will submit progress reports/reports of adverse events and side effects as requested by the ERC FM/UR.

………………………………………………..

Signature of Principal Investigator Date: \_\_\_ /\_\_\_\_/\_\_\_\_\_\_

Full name of Principal Investigator:

**22. Consent from all Investigators**

We, the undersignedhereby confirm thatwe have consented to be co investigators of the project titled:

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Qualifications | Institutional affiliations | Signature |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

**23. Acknowledgement (***Office use only)*

**Name of Applicant: (Prof/Dr/Mr/Ms)** …………………………………………………………….

**Application No ………………………………. Date received \_\_\_\_/\_\_\_\_/\_\_\_\_\_\_\_**

**Version :…………………………………**

Thank you for submitting the above research proposal. The proposal has been assigned the protocol number stated above. It will be considered by the Ethics Review Committee at its meeting in ………………………and will be assigned to three principal reviewers. The ERC may contact you in due course if any clarifications; additional documentation; or revisions are required.

……………………………………………

Administrative Officer/Convenor/Secretary

ERC,FM, UOR