**Ethics Review Evaluation Form – Animal**

**Ethics Review Committee – Medical Research Institute**

***for office use***

**Application No:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **NA** | **Comments** |
| **1. Scientific importance and validity of the study** |
| 1.1. Will the study lead to improvements in health care of animals/humans and/or knowledge on the subject |  |  |  |  |
| 1.2. If the study is a replication of a previous study, is it justified? |  |  |  |  |
| 1.3. Has the research protocol been approved by a competent body? |  |  |  |  |
| 1.4. Are the investigators qualifications, competence and experience appropriate to conduct this study? |  |  |  |  |
| 1.5. Is there provision for dissemination of results of the research? |  |  |  |  |
| 1.6. Should the study be referred to a technical expert, policy maker or statistical expert? If YES, please inform the Secretary/ERC as soon as possible, suggesting a suitable person. |  |  |  |  |
| 1.7. Are the objectives stated clearly? |  |  |  |  |
| 1.8. Is the study design appropriate in relation to the objectives? |  |  |  |  |
| 1.9. Is the study designed using accepted principles, methods and practices? |  |  |  |  |
| 1.10. Is there a plausible data analysis plan? |  |  |  |  |
| 1.11. Do the sample size and statistical techniques have adequate power to produce reliable and valid  results using the smallest number of animals? |  |  |  |  |
| 1.12. If use of animals necessary to obtain required information, is it justified? |  |  |  |  |
| 1.13. If the research cannot be carried out with non-  animal alternatives, is it justified? |  |  |  |  |
| 1.14. Is the reason for selecting the specified animal  model justified? |  |  |  |  |
| 1.15. Have the researchers obtained permission from relevant authorities to use the said animal species  for their research? |  |  |  |  |
| 1.16. Have the researchers arranged facilities for  animals if transportation of animals are necessary  from another place to the site where the research  is carried out? |  |  |  |  |
| 1.17. Are the facilities available at the animal  house/facility adequate to conduct this study? |  |  |  |  |
| 1.18. Are the facilities adequate to provide optimum  welfare to animals? |  |  |  |  |
| 1.19. Is the person responsible for maintaining the  welfare diary during the study indicated? |  |  |  |  |
| 1.20. Are the facilities adequate to provide good  postexperimental care and rehabilitation or  euthanasia of animals as appropriate upon  cessation of research? |  |  |  |  |
| 1.21. Is the type and source of food given to animals mentioned? |  |  |  |  |
| 1.22. Are the arrangements made for feeding and for providing water? |  |  |  |  |
| ***Humane end points*** |
| 1.23. Are the humane end points that would be expected during the study mentioned? |  |  |  |  |
| 1.24. Are the steps taken to minimize  suffering/euthanizing the animals mentioned? |  |  |  |  |
| ***Experimental end points*** |
| 1.25. Is the method/mode of disposal of used animals  after research mentioned? |  |  |  |  |
| **2. Assessment of Risks/Benefits** |
| 2.1. Are the risks (physical, psychological) to animals during the study mentioned? |  |  |  |  |
| 2.2. Are there any benefits to the animals used in the study? |  |  |  |  |
| 2.3. Are the researchers qualifications, competence, and experience suitable to ensure safe conduct of the study? |  |  |  |  |
| 2.4. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits of the research for animals/humans adequately? |  |  |  |  |
| **3. Respect for the dignity of the animals and owners of animals** |
| 3.1. Have the researchers taken adequate measures for the welfare of animals and to reduce suffering of animals during the research? |  |  |  |  |
| ***Informed consent*** |
| 3.2. Is the process for obtaining informed consent of owners appropriate and adequately explained? |  |  |  |  |
| 3.3. Do you approve the financial or other incentives/ rewards/ compensation offered for giving consent for the use of their animals? |  |  |  |  |
| 3.4. Is the consent given voluntarily and not due to deception, intimidation or inducement? |  |  |  |  |
| 3.5. Will the fresh informed consent be obtained if the procedures are changed during the research? |  |  |  |  |
| ***Confidentiality*** |
| 3.6. Will the researcher collect only the minimum information/samples required to fulfill the study objectives? |  |  |  |  |
| 3.7. Is the privacy of the owners safeguarded? |  |  |  |  |
| 3.8. Are data/sample storage and disposal procedure in relation to ensuring confidentiality and security of personal information adequate? |  |  |  |  |
| ***Rights of the owners of animals*** |
| 3.9. Is the owner’s unconditional right to withdraw their animals from the research at any time safeguarded? |  |  |  |  |
| 3.10. Is there provision to make the study product if any available to the owners following the research? |  |  |  |  |
| **4. Fair selection of animals** |
| 4.1. Has the study population been determined primarily, based on the scientific goals of the study? |  |  |  |  |
| 4.2. Is the research conducted on a vulnerable group of animals? |  |  |  |  |
| 4.3. Is the research an externally sponsored research? |  |  |  |  |
| 4.4. Is the research involves community animals? |  |  |  |  |
| 4.5. Is the research a clinical trial? |  |  |  |  |
| **5. Responsibilities of the researcher** |
| 5.1. Is the veterinary care to be provided to animals during and after the research adequate? |  |  |  |  |
| 5.2. What are the provisions for continuation of care after the research is over? |  |  |  |  |
| 5.3. Has the researcher followed any applicable legal regulations or other guidelines? |  |  |  |  |
| 5.4. Has the researcher obtained permission from the relevant authorities? |  |  |  |  |
| 5.5. Are there any conflicts of interest including payments and other rewards |  |  |  |  |
| 5.6. Are there any ethical / legal/ social/ financial issues in the study? |  |  |  |  |
| **6. Vulnerable groups (stray animals, animals from animal homes, animals under the threat of extinction, wild animals, animals having specific diseases etc.)** |
| 6.1. Is the use of vulnerable group instead of the general animal population of the same species, justified? |  |  |  |  |
| 6.2. Is the procedure for obtaining consent of the owners of the vulnerable group of animals adequate? |  |  |  |  |
| **7. Externally sponsored research** |
| 7.1. Is there a local collaborator? |  |  |  |  |
| 7.2. Has the research project been approved by a ERC in the sponsoring country? |  |  |  |  |
| 7.3. Is the research relevant to Sri Lanka? |  |  |  |  |
| 7.4. Is the justification for post research benefits to Sri Lanka such as capacity building etc adequate? |  |  |  |  |
| 7.5. Are relevant local laws/ regulations/ guidelines of each country adhered to? |  |  |  |  |
| 7.6. If the data or biological samples to be transferred overseas are there adequate provision to safeguard the interests of the owner’s of animals and protects intellectual property rights? |  |  |  |  |
| 7.7. How will the results of research be conveyed to relevant authorities in Sri Lanka? |  |  |  |  |
| **8. Community animals based research** |
| 8.1. Is the impact and relevance of the research on the community animals in which it is to be carried out acceptable? |  |  |  |  |
| 8.2. Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the animals of the same species? |  |  |  |  |
| 8.3. Will there any contribution of the research towards improvement of health/welfare of concerned community group of animals? |  |  |  |  |
| 8.4. Are the results of the research being made available to the relevant authorities to do necessary improvements of health/welfare of concerned community group of animals? |  |  |  |  |
| **9. Clinical trials** |
| 9.1. If it is a multicentre trial, are all centres following the same protocol? |  |  |  |  |
| 9.2. Is the clinical trial registered with a clinical trial registry? |  |  |  |  |
| 9.3. Have adequate animal toxicity and teratogenecity trials been carried out? |  |  |  |  |
| 9.4. Is there a sufficient justification for using a control arm? |  |  |  |  |
| 9.5. Does the control group receive the standard therapy? |  |  |  |  |
| 9.6. Are all animals treated equally? |  |  |  |  |
| 9.7. Is the procedure for dealing with adverse events adequate? |  |  |  |  |
| 9.8. Is the procedure for reporting adverse events adequate? |  |  |  |  |
| 9.9. Are the criteria for termination of the trial detailed? |  |  |  |  |
| 9.10. Is there provision for insurance of the animals  used in the trial? |  |  |  |  |

**Final Assessment:**

**Pass Concerns**

Collaborative partnership

Scientific value

Scientific Validity

Fair Selection of animals

Favourable Risk / Benefit ratio

Informed Consent of owners

Respect for animals enrolled for the study

Additional Comments:

………………………………………………………………………………………………….……………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………………….……………………………………………………………………………………………………………………………………………………………………………………………………………

Recommendation: Approve

Reject

 Conditional Approval

(If Conditional Approval, Please state the conditions) …………………………………………………………………………………………………...……………………………………………………………………………………………………...…………………………………………………………………………………………………...……

Name of the Reviewer: ………………………………………………………………

Signature: ……………………………

Date: ………………………………