

**MEDICAL RESEARCH INSTITUTE**

**Application for Ethics Approval**

**Part – III**

***(For Studies involving Animals)***

**For Office Use Only**

NA - Not applicable

Please tick the appropriate box

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| **1** | **General Information** | | | | | | | | | | | | | | |
| **1.1** | Title of the project |  | | | | | | | | | | | | | |
| **2** | **Scientific importance and validity** | | | | | | | | | | | | | | |
| **2.1** | What is the scientific importance of your study in relation to improving health care of animals/ humans and/or knowledge on the subject? | | | | | | | | | | | | | | |
| **2.2** | Is your study an original one or a replication of a previous study? | | | | Original | | | |  | | Replication | | | |  |
| If it is a replication study please justify. | | | | | | | | | | | | | | |
| **2.3** | Has this research proposal been subjected to scientific/ ethics review by any other committee? | | | | | | | | | Yes | |  | No |  | |
| If YES; what is the name of the committee? | | | | | | | | | | | | | | |
| **2.4** | Do the investigators have qualifications, competence and experience to conduct this study and to differentiate normal and abnormal behavior of animals? | | | | | | | | | Yes | |  | No |  | |
| If NO; please indicate how investigators are going to acquire knowledge and skills? | | | | | | | | | | | | | | |
| **2.5** | Is the use of animals necessary to obtain required information and are there any other alternative methods available? | | | | | | | | | Yes | |  | No |  | |
| **2.6** | Can the research be carried out with non-animal alternatives? | | | | | | | | | Yes | |  | No |  | |
| **2.7** | What is the species of animals used and the reason for selecting the said animal model? | | | | | | | | | | | | | | |
| **2.8** | What is the total number of animals used in the study and how did you calculate the sample size? | | | | | | | | | | | | | | |
| **2.9** | Have you obtained permission from relevant authorities to use the said animal species for your research? | | | | | | | | | Yes | |  | No |  | |
| If YES; inform the authority in order to obtain suitable species of animals and required number of animals for your experiment.  If NO, when and from where will you obtain permission? | | | | | | | | | | | | | | |
| **2.10** | What is the source of animals and the arrangements that you have made to ensure constant supply of animals? | | | | | | | | | | | | | | |
| **2.11** | Is it necessary to transport animals from another place to the site where the research is carried out? | | | | | | | | | Yes | |  | No |  | |
| If YES; what are the arrangements that you have made to transport animals with optimum care? | | | | | | | | | | | | | | |
| **2.12** | What are the housing conditions available at the site? | | | | | | | | | | | | | | |
| Single/group housing | |  | | | | | | | | | | | | |
| Type & size of cages | |  | | | | | | | | | | | | |
| Light – dark regime | |  | | | | | | | | | | | | |
| No. of animals per cage | |  | | | | | | | | | | | | |
| Bedding materials | |  | | | | | | | | | | | | |
| Ventilation | |  | | | | | | | | | | | | |
| Humidity | |  | | | | | | | | | | | | |
| Temperature | |  | | | | | | | | | | | | |
| **2.13** | Are the facilities available at the animal house/facility adequate to conduct this study? | | | | | | | | | Yes | |  | No |  | |
| **2.14** | Are the facilities adequate to provide optimum welfare to animals? | | | | | | | | | Yes | |  | No |  | |
| **2.15** | Who is responsible for maintaining the welfare diary during the study? | | | | | | | | | | | | | | |
| **2.16** | What is the type and source of food given to animals? | | | | | | | | | | | | | | |
| **2.17** | What are the arrangements made for feeding and for providing water? | | | | | | | | | | | | | | |
| **2.18** | Are the facilities adequate to provide good post-experimental care and rehabilitation or euthanasia of animals as appropriate upon cessation of research? | | | | | | | | | Yes | |  | No |  | |
| **3** | **Humane end points** | | | | | | | | | | | | | | |
| **3.1** | Are there any humane end points that would be expected during the study? | | | | | | | | | Yes | |  | No |  | |
| If YES; give details. | | | | | | | | | | | | | | |
| **3.2** | If you observe an animal suffering severely, will you take necessary steps to euthanise the animal to prevent further suffering? | | | | | | | | | Yes | |  | No |  | |
| **3.3** | What is the method used to euthanise the animal? If a drug is used give details. | | | | | | | | | | | | | | |
| **3.4** | Who is responsible for euthanising the animal? | | | | | | | | | | | | | | |
| **4** | **Experimental end points** | | | | | | | | | | | | | | |
| **4.1** | What is the method/mode of disposal of used animals after research? | | | | | | | | | | | | | | |
| **4.2** | Are you euthanising the animals at the end of the study? | | | | | | | | | Yes | |  | No |  | |
| **4.3** | What is the method used to euthanise the animal? If a drug is used give details. | | | | | | | | | | | | | | |
| **4.4** | Who is responsible for euthanising the animal? | | | | | | | | | | | | | | |
| **5** | **Assessment of Risks/Benefits** | | | | | | | | | | | | | | |
| **5.1** | Are there any risks (physical, psychological) to animals during the study? | | | | | | | | | Yes | |  | No |  | |
| If YES; identify them and state how you plan to prevent or minimize these risks? | | | | | | | | | | | | | | |
| **5.2** | Are there any benefits to the animals used in the study? | | | | | | | | | Yes | |  | No |  | |
| If YES; identify them. | | | | | | | | | | | | | | |
| **5.3** | 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. | | | | | | | | | | | | | | |
| **5.4** | Justify the potential benefits to animals/humans against risks. | | | | | | | | | | | | | | |
| **5.5** | Is standard therapy, e.g. for therapeutic studies on sick animals, going to be withheld from the animals recruited for the study? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES; justify. | | | | | | | | | | | | | | |
| **5.6** | Is veterinary support for the animals adequate? | | | | Yes | |  | | | No | |  | NA |  | |
| If NO; explain. | | | | | | | | | | | | | | |
| **5.7** | What is the procedure for dealing with adverse events? | | | | | | | | | | | | | | |
| **5.8** | Is there any procedure for reporting adverse events? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES; give details.  If No; explain. | | | | | | | | | | | | | | |
| **6** | **Respect for the dignity of the animals and owners of animals** | | | | | | | | | | | | | | |
| **6.1** | Do you ensure that the animals are handled with care and compassion? | | | | | | | | | Yes | |  | No |  | |
| **6.2** | Do you ensure that you take adequate measures to reduce suffering of animals during the research? | | | | | | | | | Yes | |  | No |  | |
|  | ***Informed consent*** | | | | | | | | | | | | | | |
| **6.3** | Write briefly your procedure for obtaining informed consent from the owners of animals used for the research. | | | | | | | | | | | | | | |
| **6.4** | Who will obtain consent? | | | | | | | | | | | | | | |
| **6.5** | Is it written or verbal consent? | | | Written | |  | | Verbal | | | |  | NA |  | |
| If written please include consent form with translations. If verbal, please state in simple  words (in Sinhala / Tamil / English) in a separate sheet what information you would convey to the participants and state below how consent would be documented | | | | | | | | | | | | | | |
| **6.6** | How will you ensure that the owner is adequately informed? Please include information sheets with translations. | | | | | | | | | | | | | | |
| **6.7** | How will you ensure your information is understood by the owners and queries answered? | | | | | | | | | | | | | | |
| **6.8** | Would the owners have difficulty in understanding the information due to illiteracy? | | | | | | | | | Yes | |  | No |  | |
| If YES; detail the arrangements that you would make to obtain consent from such owners. | | | | | | | | | | | | | | |
| **6.9** | Are you offering any financial or other incentives/ rewards/ compensation for giving consent for the use of their animals? | | | | | | | | | Yes | |  | No |  | |
| If YES; please list them and state why they do not constitute undue inducement for granting consent? (All incentives to be provided to owners must be approved by the ERC). | | | | | | | | | | | | | | |
| **6.10** | How will you ensure that consent is given voluntarily and not due to deception, intimidation or inducement? | | | | | | | | | | | | | | |
| **6.11** | Are the animals of the owners who gave consent under your care? | | | | | | | | | Yes | |  | No |  | |
| If YES; how would you ensure they would not feel obliged to give consent in order to receive better veterinary care for their animals. | | | | | | | | | | | | | | |
| **6.12** | Will you obtain fresh informed consent if the procedures are changed during the research? | | | | | | | | | Yes | |  | No |  | |
| **7** | **Confidentiality** | | | | | | | | | | | | | | |
| **7.1** | How will the data/samples be obtained? | | | | | | | | | | | | | | |
| **7.2** | How long will the data/samples be kept? | | | | | | | | | | | | | | |
| **7.3** | Are you collecting the minimum information/samples required to fulfill the study objectives? | | | | | | | | | Yes | |  | No |  | |
| **7.4** | Who will have access to the personal data of the owners and animals? | | | | | | | | | | | | | | |
| **7.5** | How will you safeguard the privacy of the owners? | | | | | | | | | | | | | | |
| **7.6** | What is the data/sample storage and disposal procedure in relation to ensuring confidentiality and security of personal information? | | | | | | | | | | | | | | |
| **7.7** | If you are planning to store data/samples for future study, will you obtain appropriate consent? | | | | | | | | | Yes | |  | No |  | |
| **8** | **Rights of the owners of animals** | | | | | | | | | | | | | | |
| **8.1** | How will you ensure the owners unconditional right to withdraw their animals from the research at any time? | | | | | | | | | | | | | | |
| **8.2** | Outline the procedures you will provide for the owners to ask questions and register complaints on behalf of their animals. | | | | | | | | | | | | | | |
| **8.3** | Who will be the contact person for the owners? | | | | | | | | | | | | | | |
| **8.4** | Is there provision for the owners to be informed of results of clinical research?  Explain. | | | | | | | | | | | | | | |
| **8.5** | Is there provision to make the study product if any, available to the owners following the research? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES/NO; Explain. | | | | | | | | | | | | | | |
| **9** | **Fair selection of animals** | | | | | | | | | | | | | | |
| **9.1** | Is the selection of animals (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitable distributed? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES/NO; Explain. | | | | | | | | | | | | | | |
| **9.2** | How is the initial contact of owners and recruitment of animals to be conducted? | | | | | | | | | | | | | | |
| **9.3** | Is the research conducted on a vulnerable group of animals? | | | | | | | | | Yes | |  | No |  | |
| If YES; please fill up section - 11 | | | | | | | | | | | | | | |
| **9.4** | Is the research an externally sponsored research? | | | | | | | | | Yes | |  | No |  | |
| If YES; please fill up section - 12 | | | | | | | | | | | | | | |
| **9.5** | Does your research involve community animals? | | | | | | | | | Yes | |  | No |  | |
| If YES; please fill up section - 13 | | | | | | | | | | | | | | |
| **9.6** | Is your research a clinical trial? | | | | | | | | | Yes | |  | No |  | |
| If YES; please fill up section - 14 | | | | | | | | | | | | | | |
| **10** | **Responsibilities of the researcher** | | | | | | | | | | | | | | |
| **10.1** | What are the responsibilities of the researcher for provision of veterinary services to animals used in the study? | | | | | | | | | | | | | | |
| **10.2** | What are the provisions for continuation of care after the research is over? | | | | | | | | | | | | | | |
| **10.3** | Have you followed any applicable legal regulations or other guidelines? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES; provide details.  If NO; explain. | | | | | | | | | | | | | | |
| **10.4** | Please declare any conflicts of interest including payments received by you or co-researchers and other rewards (Please list them and state how you would prevent them from influencing the conduct of the study). | | | | | | | | | | | | | | |
| **10.5** | Do you see any other ethical / legal / social / financial issues in your study? (Please list them and state how you would prevent them from influencing conduct of the study). | | | | | | | | | | | | | | |
| **11** | **Vulnerable groups (stray animals, animals from animal homes, animals under the threat of extinction, wild animals, animals having specific diseases etc.)** | | | | | | | | | | | | | | |
| **11.1** | What is the justification for the using the vulnerable group instead of the general animal population of the same species? | | | | | | | | | | | | | | |
| **11.2** | What is the procedure for obtaining consent of the owners of the vulnerable group of animals? | | | | | | | | | | | | | | |
| **11.3** | What is the procedure for withdrawal from research due to refusal of owners of the vulnerable group of animals? | | | | | | | | | | | | | | |
| **11.4** | Are you providing adequate veterinary support? Explain. | | | | | | | | | | | | | | |
| **11.5** | Will the benefits of research be made available to this group of animal population? Explain. | | | | | | | | | | | | | | |
| **12** | **Externally sponsored research (Foreign Funded)** | | | | | | | | | | | | | | |
| **12.1** | Has the research project been approved by an ERC in the sponsoring country? | | | | | | | | | Yes | |  | No |  | |
| If YES; please attach documentary evidence.  If NO; give reasons. | | | | | | | | | | | | | | |
| **12.2** | Why is the research carried out in Sri Lanka and not in the sponsoring country? | | | | | | | | | | | | | | |
| **12.3** | Are you sending data or samples from study animals abroad? If so, have you obtained permission to do so from relevant authorities? Please provide documentary evidence. | | | | | | | | | | | | | | |
| If YES; describe the fate of the data or biological samples at the conclusion of the study. | | | | | | | | | | | | | | |
| **12.4** | What is the relevance of this study to Sri Lanka? | | | | | | | | | | | | | | |
| **12.5** | What are the post research benefits to Sri Lanka? | | | | | | | | | | | | | | |
| **12.6** | Are you adhering to any specific laws/ regulations/ guidelines of Sri Lanka and the sponsoring country/countries applicable to the study? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES; give details.  If No; explain. | | | | | | | | | | | | | | |
| **12.7** | Have you taken into account cultural and social customs, practices, and taboos in Sri Lanka when designing your study? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES/NO; Explain | | | | | | | | | | | | | | |
| **12.8** | Are the animals used in the study receiving the best current treatment as part of the protocol? | | | | Yes | |  | | | No | |  | NA |  | |
| If NOT; explain why? | | | | | | | | | | | | | | |
| **12.9** | What is the ancillary care provided (treatment that is not part of the protocol)? | | | | | | | | | | | | | | |
| **12.10** | What are the provisions for continuity of care? | | | | | | | | | | | | | | |
| **12.11** | How will the rights to intellectual property be shared? | | | | | | | | | | | | | | |
| **12.12** | How will the results of research be conveyed to relevant authorities in Sri Lanka? | | | | | | | | | | | | | | |
| **13** | **Community animals based research** | | | | | | | | | | | | | | |
| **13.1** | State the impact and relevance of the research on the community animals in which it is to be carried out. | | | | | | | | | | | | | | |
| **13.2** | State the steps taken to recruit community animals for the research. | | | | | | | | | | | | | | |
| **13.3** | If the intervention is shown to be beneficial will the sponsor continue to provide it to animals after conclusion of the study? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES/NO; explain. | | | | | | | | | | | | | | |
| **13.4** | Will the intervention or product developed or knowledge generated be made available and affordable for the benefit of the animals of the same species? | | | | Yes | |  | | | No | |  | NA |  | |
| If YES/NO; explain how? | | | | | | | | | | | | | | |
| **13.5** | Will there be any contribution of the research towards improvement of health/welfare of concerned community group of animals? Explain. | | | | | | | | | | | | | | |
| **13.6** | How will the results of the research be made available to the relevant authorities for necessary improvement of health/welfare of concerned community group of animals? | | | | | | | | | | | | | | |

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| **14** | **Declaration** | | | |
| **I understand that the application for ethics clearance will not be accepted unless all documents are submitted. 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 ethics clearance.** | | | | |
|  | | Name | Signature | Date |
| Principal Investigator | |  |  |  |
| Co-investigator 1 | |  |  |  |
| Co-investigator 2 | |  |  |  |
| Co-investigator 3 | |  |  |  |