

ANNEX D: APPLICATION FOR ETHICS REVIEW OF RESEARCH PROJECTS INVOLVING ANIMALS - PART I

for official use

Application No:								Date Received:			/			/		
Reviewed By:								ERC Meeting Date:			/			/		
Decision:								Date Informed:			/			/		

1. Title of Project

2. Investigators:

Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study and who will appear as co-authors in any publication arising out of the study.

2.1. Principal Investigator/Supervisor:

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Signature

2.2. Co-Investigator 1:

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Signature

2.3. Co-Investigator 2:

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:
Address:
Contact Nos:
Email Address:
Signature

2.4. Co-Investigator 3:

Title: Mr. Ms. Dr. Prof.
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact Nos:
Email Address:
Signature

2.5. Co-Investigator 4:

Title: Mr. Ms. Dr. Prof.
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact Nos:
Email Address:
Signature

3. Proposed starting and ending dates: * ‡

Start Date: End Date:

** From initial recruitment of animals until completion of data collection.*

‡ Retrospective approval will not be given for projects already started or completed.

4. Has ethics review for this study been requested earlier from this committee or another similar committee?

Yes No

If yes,

*Where?

*When?

*Result:

APPLICATION FOR ETHICS REVIEW OF RESEARCH PROJECTS INVOLVING ANIMALS - PART II

for official use

Application No:

1. Title of Project

2. Funding

Name and Address of Funding Source(s)

Amount

<input type="text"/>	<input type="text"/>
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3. A brief summary of the research proposal in simple language (maximum 500 words)

4. Scientific importance and validity of the study

4.1. What is the scientific importance of your study in relation to improving health care of animals/humans and/or knowledge on the subject?

4.2. Is your study an original one or a replication of a previous study?

Original Replication

If it is a replication study please justify.

4.3. Has this research proposal been subjected to scientific review by any other committee?

Yes No

If YES, what is the name of the committee?

4.4. Do the investigators have basic knowledge and competence to conduct this study and to differentiate normal and abnormal behaviour of animals?

Yes No

If NO, please indicate how investigators are going to acquire knowledge and skills?

4.5. How will the results of the study be disseminated?

4.6. Is the use of animals necessary to obtain required information?

Yes No

4.7. Why the research cannot be carried out with non-animal alternatives?

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

4.9. Have you obtained permission from relevant authorities to use the said animal species for your research?

Yes No

If YES, please state the authority. If NO, when and from where will you obtain permission?

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

4.11. 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?

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

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

Yes No

4.14. Are the facilities adequate to provide optimum welfare to animals?

Yes No

4.15. Who is responsible for maintaining the welfare diary during the study?

4.16. What are the housing conditions available at the site?

Single/group housing	<input type="checkbox"/>	Temperature	<input type="checkbox"/>	Humidity	<input type="checkbox"/>
Type & size of cages	<input type="checkbox"/>	No. of animals per cage	<input type="checkbox"/>	Bedding materials	<input type="checkbox"/>
Light – dark regime	<input type="checkbox"/>	Ventilation	<input type="checkbox"/>		

4.10. Are the facilities adequate to provide good post-experimental care and rehabilitation or euthanasia of animals as appropriate upon cessation of research?

Yes No

4.11. What is the type and source of food given to animals?

4.12. What are the arrangements made for feeding and for providing water?

Humane end points

4.13. Are there any humane end points that would be expected during the study?

Yes No

If YES, give details.

4.20. If you observe an animal suffering severely, will you take necessary steps to euthanise the animal to prevent further suffering?

Yes No

4.14. What is the method used to euthanise the animal? If a drug is used give details.

4.15. Who is responsible for euthanising the animal?

Experimental end points

4.16. What is the method/mode of disposal of used animals after research?

4.17. Are you euthanising the animals at the end of the study?

Yes No

4.18. What is the method used to euthanise the animal? If a drug is used give details.

4.19. 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 Not applicable

If YES, justify.

5.6. Is veterinary support for the animals adequate?

Yes No Not applicable

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 Not applicable

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?

6.2. Do you ensure that you take adequate measures to reduce suffering of animals during the research?

Informed consent

6.3. Write briefly your procedure for obtaining informed consent from the owners of animals use for the research.

6.4. Who will obtain consent?

6.5. Is it written or verbal consent?

Written Verbal Not Applicable

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 consented under your care?

Yes No

If YES how you would 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 Not Applicable

Confidentiality

6.13. How will data/samples be obtained?

6.14. How long will data/samples be kept?

6.15. Are you collecting the minimum information/samples required to fulfill the study objectives?

Yes No

6.16. Who will have access to the personal data of the owners and animals?

6.17. How will you safeguard the privacy of the owners?

6.18. What is the data/sample storage and disposal procedure in relation to ensuring confidentiality and security of personal information?

6.19. If you are planning to store data/samples for future study, will you obtain appropriate consent?

Yes No

Rights of the owners of animals

6.20. How will you ensure the owners unconditional right to withdraw their animals from the research at any time?

6.21. Outline the procedures you will provide for the owners to ask questions and register complaints on behalf of their animals.

6.22. Who will be the contact person for the owners?

6.23. Is there provision for owners to receive information that is relevant to participation of their animals?

Yes No Not Applicable

If YES/NO Explain.

6.24. Is there provision for the owners to be informed of results of clinical research? Explain.

6.25. Is there provision to make the study product if any available to the owners following the research?

Yes No Not Applicable

If YES/NO Explain.

7. Fair selection of animals

7.1. What is your study population?

7.2. Justify your choice of study population.

7.3. 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 Not Applicable

If YES/NO Explain.

7.4. How is the initial contact of owners and recruitment of animals to be conducted?

7.5. Is the research conducted on a vulnerable group of animals?

Yes No

If YES please fill up section 9.

7.6. Is the research an externally sponsored research?

Yes No

If YES please fill up section 10.

7.7. Is your research involves community animals?

Yes No

If YES please fill up section 11.

7.8. Is your research a clinical trial?

Yes No

If YES please fill up section 12.

8. Responsibilities of the researcher

8.1. What are the responsibilities of the researcher for provision of veterinary services to animals use in the study?

8.2. What are the provisions for continuation of care after the research is over?

8.3. Have you followed any applicable legal regulations or other guidelines?

Yes No Not Applicable

If YES, provide details.

If NO Explain.

8.4. 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).

8.5. 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).

8.6. I do not wish the following reviewers/ ERC members to review my application.

8.7. I am willing to provide 6 monthly reports of my research to the Ethics Committee.

Yes No Not Applicable

9. Vulnerable groups (stray animals, animals from animal homes, animals under the threat of extinction, wild animals, animals having specific diseases etc.)

9.1. What is the justification for the using the vulnerable group instead of the general animal population of the same species?

9.2. What is the procedure for obtaining consent of the owners of the vulnerable group of animals?

9.3. What is the procedure for withdrawal from research due to refusal of owners of the

vulnerable group of animals?

9.4. Are you providing adequate veterinary support? Explain.

9.5. Will the benefits of research be made reasonably available to this group of animal population? Explain.

10. Externally sponsored research

10.1. 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.

10.2. Why is the research carried out in Sri Lanka and not in the sponsoring country?

10.3. What is the relevance of this study to Sri Lanka?

10.4. What are the post research benefits to Sri Lanka such as capacity building etc?

10.5. Are you adhering to any specific laws/ regulations/ guidelines of Sri Lanka and the sponsoring country/countries applicable to the study?

Yes No Not applicable

If YES, give details.

If No Explain.

10.6. Have you taken into account cultural and social customs, practices, and taboos in Sri Lanka when designing your study?

Yes No Not Applicable

If YES/NO Explain.

10.7. Are the animals used in the study receiving the best current treatment as part of the protocol?

Yes No Not Applicable

If NOT, explain why?

10.8. What is the ancillary care provided (treatment that is not part of the protocol)?

10.9. What are the provisions for continuity of care?

10.10. How will the rights to intellectual property be shared?

10.11. Are any of the data or biological samples to be transferred overseas?

Yes No

If YES, describe the fate of the data or biological samples at the conclusion of the study.

10.12. How will the results of research be conveyed to relevant authorities in Sri Lanka?

11. Community animals based research

11.1. State the impact and relevance of the research on the community animals in which it is to be carried out.

11.2. State the steps taken to recruit community animals for the research.

11.3. If the intervention is shown to be beneficial will the sponsor continue to provide it to animals after conclusion of the study?

If YES/NO explain.

11.4. 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?

Yes No Not Applicable

If YES/NO Explain how?

11.5. Will there any contribution of the research towards improvement of health/welfare of concerned community group of animals? Explain.

11.6. How will the results of the research be made available to the relevant authorities to do necessary improvements of health/welfare of concerned community group of animals?

12. Clinical trials

12.1. What phase clinical trial is being conducted?

12.2. Is it a multicentre trial?

Yes No

If YES Give details.

12.3. Is the clinical trial registered with a clinical trial registry?

Yes No

If YES name it.

12.4. Have adequate animal toxicity and teratogenicity trials been carried out?

Yes No

12.5. What is the justification for using a control arm?

12.6. Does the control group receive the standard therapy?

Yes No Not Applicable

12.7. Are all animals treated equally?

Yes No Not Applicable

If NOT Explain.

12.8. What is the procedure for dealing with adverse events?

12.9. What is the procedure for reporting adverse events?

Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?

Yes No

12.10. What are the criteria for termination of the trial?

12.11. Is there provision for insurance of the animals used in the trial? Explain.

Yes No

APPLICATION FOR ETHICS REVIEW OF RESEARCH PROJECTS INVOLVING ANIMALS – PART III

for official use

Application No:																				
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Application Checklist

I declare that I have attached the following documents (please tick the check box and confirm):

- 1. Application Form: Part I. [2 copies]
- 2. Application Form: Part II. [2 copies]
- 3. The complete research proposal including the justification, objectives, and methods in detail. [2 copies]
- 4. Information sheet for owners of animals, if applicable. (Should be provided in all three languages – Sinhala, Tamil and English. [2 copies]
- 5. Consent forms for owners of animals, if applicable. (Should be provided in all three languages – Sinhala, Tamil and English)[2 copies]
- 6. Copy of the working protocol. [2 copies]
- 7. Data collection booklets/forms/questionnaires. (Should be provided in all three languages – Sinhala, Tamil and English – if applicable) [2 copies]
- 8. Copies of relevant permission letters. [2 copies]
- 9. Copy of the working protocol. [2 copies]

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.

.....
Signature of the Principal Investigator

.....
Date

Appendix E: Ethics Review Evaluation Form

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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 post-experimental 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?				
<i>Humane end points</i>				
1.23. Are the humane end points that would be expected during the study mentioned?				
1.24. Are the steps taken to minimize suffering/euthanising the animals mentioned?				
<i>Experimental end points</i>				
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?				
<i>Informed consent</i>				
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?				
<i>Confidentiality</i>				
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 teratogenicity 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	<input type="checkbox"/>	
Scientific value	<input type="checkbox"/>	
Scientific Validity	<input type="checkbox"/>	
Fair Selection of animals	<input type="checkbox"/>	
Favourable Risk / Benefit ratio	<input type="checkbox"/>	
Informed Consent of owners	<input type="checkbox"/>	
Respect for animals enrolled for the study	<input type="checkbox"/>	

Additional Comments:

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Recommendation: Approve *Reject*

Conditional Approval (Please state the conditions)

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Name of the Reviewer:

Signature:

Date: