Annex-2

Ethics Review Committee, Faculty of Livestock Fisheries & Nutrition,

Wayamba University of Sri Lanka

Application for Ethics Review involving Animals-Part I

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Application No:		Date received:	/ /
Name of reviewer:		Date of meeting:	/ /
Reviewer's Decision		Date informed:	/ /

1. Title of research Project

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Investigators (Attach brief CV of all investigators separately)

Principal Investigator:			
Title & Name	Designation	Place of work & address	Contact Nos& email address
Co- Investigators:			

3. Proposed commencement and completion dates:

Date of commencement:		Date of completion:	

4. Submission for ethics review

Has ethics review for this study been requested earlier from this committee or any other similar committee?	Yes:	No:
If yes where		
When		
Decision		

5. Conflict of Interest

5.1Do you believe this project has a conflict of interest?	Yes:	No:
If yes please explain.		
5.2 Does any member of research team have any affiliation with the provider(s) of funding, or a financial interest in the outcome of the research?	Yes:	No:
If yes please explain.		

Ethics Review Committee, Faculty of Livestock Fisheries & Nutrition,

Wayamba University of Sri Lanka

Application for Ethics Review involving Animals-Part II

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Application No:										

1. Title of Project

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2. Name and address of funding source(s)

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3. Scientific importance and validity of the research project

3.1Briefly explain the scientific importance of your study. (Not more than 150 words)		
3.2 Is your study an original one or are replication of a previous study?	Original:	Replication
Please justify if it is a replication study.		
3.3Has this research proposal been subjected to scientific review by any other committee?	Yes:	No:

If Yes, what is the name of the committee?		
3.4Are the investigator's/investigators' qualifications and experience appropriate to conduct the study?	Yes:	No:
3.5 Are the facilities adequate to conduct the study?	Yes:	No:
3.6 How will the results of the study be disseminated?		
3.7 Is the use of animals necessary to obtain required information?	Yes:	No:

4. Assessment of Risks/Benefits

4.1 Is the use of animals necessary to obtain the required information?	Yes:	No:
4.2Why the research cannot be carried out with non animal alternatives?		
4.3 What is the species of animals used and the reason for selecting the said animal model?		
4.4Have 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?		
4.5What is the source of animals and the arrangements that you have made to ensure constant supply of animals?		
4.6Is 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?		
4.7What is the total number of animals used in the study and how did you calculate the sample size?		
4.8Are the facilities available at the animal house/facility adequate to conduct this study?	Yes:	No:
4.9Are the facilities adequate to provide optimum welfare to animals?	Yes:	No:

4.10Who is responsible for maintaining the welfare diary during the study?		
4.11What are the housing conditions available at the site?		
Single/group housing		
Type & size of cages		
Light-dark regime		
Temperature		
No. of animals per cage		
Ventilation		
Humidity		
Bedding materials		
4.12 Are the facilities adequate to provide good post-experimental care and rehabilitation or euthanasia of animals as appropriate upon cessation of research?	Yes:	No:
4.13 What is the type and source of food given to animals?		
4.14 What are the arrangements made for feeding and for providing water?		
Humane end points		
4.15 Are there any humane end points that would be expected during the study?	Yes:	No:
If Yes, give details.		
4.16 If you observe an animal suffering severely, will you take necessary steps to euthanize the animal to prevent further suffering?	Yes:	No:
4.17 What is the method used to euthanize the animal? If a drug is used give details.		

4.18 Who is responsible for euthanizing the animal?			
Experimental end points			
4.19 What is the method/mode of disposal of used animals after research?			
4.20 Are you euthanizing the animals at the end of the study?		Yes:	No:
4.21 What is the method used to euthanize the animal? If a drug is used give details.			
4.22 Who is responsible for euthanizing the animal?			
4.23 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?			
4.24 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.			
4.25 Justify the potential benefits to animals/humans against risks.			
4.26 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.			
4.27 Is veterinary support for the animals adequate?	Yes:	No:	Not applicable:

If No, explain.			
4.28 What is the procedure for dealing with adverse events?			
4.29 Is there any procedure for reporting adverse events?	Yes:	No:	Not applicable:
If Yes, give details.			
If No, explain.			

5. Respect for the dignity of the animals and owners of animals

5.1Do you ensure that the animals are handled with care and compassion?			
5.2 Do you ensure that you take adequate measures to reduce suffering of animals during the research?			
Informed consent			
5.3 Write briefly your procedure for obtaining informed consent from the owners of animals use for the research?			
5.4 Who will obtain consent?			
5.5 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 separate sheet what information you would convey to the participants and state below how consent would be documented			
5.6 How will you ensure that the owner is adequately informed? Please include information sheets with translations.			
5.7 How will you ensure your information is understood by the owners and queries answered?			
5.8Would 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.			
5.9Are 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).			
5.10 How will you ensure that consent is given voluntarily and not due to deception, intimidation or inducement?			
5.11Will the animals of the owners consented be 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.			
5.12Will you obtain fresh informed consent if the procedures are changed during the research	Yes:	No:	Not applicable:
Confidentiality			
5.13 How will data/ samples be obtained?			
5.14 How long will data/ samples be kept?			
5.15Are you collecting the minimum information/ samples required to fulfill the study objectives?		Yes:	No:
5.16 Who will have access to the personal data of the owners and animals?			
5.17 How will you safeguard the privacy of the owners?			
5.18 What is the date/ sample storage and disposal procedure in relation to ensuring confidentiality and security of personal information?			
5.19If you are planning to store data/ samples for future study, will you obtain appropriate consent?		Yes:	No:
Rights of the owners of animals			
5.20 How will you ensure the owners unconditional right to withdraw their animals from the research at any time?			
5.21Outline the procedures you will provide for the owners to ask questions and register complaints on behalf of their animals.			
5.22 Who will be the contact person for the owners?			
5.23 Is there provision for owners to receive information that is relevant to participation of their animals?	Yes:	No:	Not applicable:

If Yes/ No explain.			
5.24Is there provision for the owners to be informed of results of clinical research? explain			
5.25Is their provision to make the study product if any available to the owners following the research?	Yes:	No:	Not applicable:
If Yes/ No explain.			

6. Fair selection of animals

6.1 What is your study population?			
6.2 Justify your choice of study population.			
6.3 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.			
6.4 How is the initial contact of owners and recruitments of animals to be conducted?			
6.5Is the research conducted on a vulnerable group of animals?		Yes:	No:
If Yes, please fill up section 9.			
6.6Is the research an externally sponsored research?		Yes:	No:
If Yes, please fill up section 10.			
6.7Does your research involve community animals?		Yes:	No:
If Yes, please fill up section 9			
6.8Is your research a clinical trial?		Yes:	No:
If Yes, please fill up section 10			

7. Responsibilities of the researcher

7.1 What are the responsibilities of the researcher for provision of veterinary services to animals use in the study?			
7.2 What are the provisions for continuation of care after the research is over?			
7.3 Have you followed any applicable legal regulations or other guidelines?	Yes:	No:	Not applicable:
If Yes, provide details.			
If No, explain.			
7.4 Please declare any conflicts of interest including payments received by you or co-researchers and other rewards (please list them and state you would prevent them from influencing the conduct of the study)			
7.5 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)			
7.6 I do not wish the following reviewers/ ERC members to review my application			

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

8.1What is the justification for the using the vulnerable group instead of the general animal population of the same species?
8.2What is the procedure for obtaining consent of the owners of the vulnerable group of animals?
8.3What is the procedure for withdrawal from research due to refusal of owners of the vulnerable group of animals?
8.4 Are you providing adequate veterinary support? Explain

8.5 Will the benefits of research be made reasonably available to this group of animal population? Explain			
Externally sponsored research			
8.6 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.			
8.7 Why is the research carried out in Sri Lanka and not in the sponsoring country?			
8.8 What is the relevance of the study to Sri Lanka?			
8.9 What are the post research benefits to Sri Lanka such as capacity building etc?			
8.10 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			
8.11 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			
8.12 Are the animals used in the study receiving the best current treatment as part of the protocol?	Yes:	No:	Not applicable:
8.13 What is the ancillary care provided (treatment that is not part of the protocol)?			
8.14 What are the provisions for country of care?			
8.15 How will the rights to intellectual property be shared?			
8.16 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			
8.17 How will the result of research be conveyed to relevant authorities in Sri Lanka?			

9. Community animals based research

9.1 State the impact and relevance of the research on the community animals in which it is to be carried out.			
9.2 State the steps taken to recruit community animals for the research.			
9.3 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			
9.4 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?			
9.5Will there any contribution of the research towards improvement of health/ Welfare of concerned community group of animals? explain			
9.6 How will the result of the research be made available to the relevant authorities to do necessary improvements of health/ welfare of concerned community group of animals?			

10. Clinical trials

10.1 What phase clinical trial is being conducted?			
10.2Is it a multicenter trial?		Yes:	No:
If Yes, give details.			
10.3Is the clinical trial registered with a clinical trial registry?		Yes:	No:
If Yes, name it.			
10.4Have adequate animal toxicity and teratogenicity trials been carried out?		Yes:	No:
10.5 What is the justification for using a control arm?			
10.6Does the control group receive the standard therapy?	Yes:	No:	Not applicable:

10.7Are all animals treated equally?	Yes:	No:	Not applicable:
If Not explain.			
10.8What is the procedure for dealing with adverse events?			
10.9What 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:
10.10 What are the criteria for termination of the trial?			
10.11Is there provision for insurance of the animals used in the trial? Explain		Yes:	No:

11. Research Protocol under the headings of:

1. Title
2. Background and Rationale
3. Objectives
4. Methodology
    - Study design
    - Study setting
    - Study population
    - Sample size
    - Sampling method
    - Study instruments
    - Data collection
    - Plan of analysis
5. Ethical considerations
6. Time frame

12. A summary of the research proposal in simple language(maximum500words).

(Sections 11 & 12 of application form -Please attach as separate sheets)

Ethics Review Committee, Faculty of Livestock Fisheries & Nutrition,

Wayamba University of Sri Lanka

Application for Ethics Review involving Animals-Part III

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Application No:										

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 (12 copies) ☐

3.The complete research proposal including the justification ,objectives, and methods, work plan, in detail(12 copies) ☐

4. Short CVs of Investigators ☐

5.Soft copies of all documents ☐

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.

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Signature of Principal Investigator Date