Annex -1

Ethics Review Committee, Faculty of Livestock Fisheries & Nutrition, Wayamba University of Sri Lanka

Application for Ethics Review involving Humans - Part I

For official use

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

1. Title of research project

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2. 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

5.1 Do 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 Humans - 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

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

3.4 Are 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?		

4. Assessment of Risks/Benefits

4.1 Is the involvement of human subjects necessary to obtain the required information?	Yes:		No:
4.2 What are the risks (physical, psychological, social, legal, and economic) involve to the participants? (No risk is not an answer for this question)			
State how you plan to prevent or minimize these risks?			
4.3 Are there any benefits to the individual participants?	Yes:		No:
If Yes identify them.			
4.3.1 What are the benefits to the community and healthcare system			
4.4 Justify the potential benefits against the risks. (Attach separate sheets if necessary)			
4.5 In case of patients, is standard therapy going to be withheld from the participants?	Yes:	No:	Inapplicable:
If Yes, justify			
4.6 Is the standard care available locally?	Yes:	No:	Inapplicable:
If No, explain. (Attach separate sheets if necessary)			

4.7 Is the medical and psychological support for the participants adequate?	Yes:	No:	Inapplicable:
If No, explain			
4.8 What is the procedure for dealing with adverse events? (Attach separate sheets if necessary)			
4.9 What is the procedure for reporting adverse events to investigator?			
4.10 Is there provision for compensation for participants who sustain injuries?	Yes:	No:	Inapplicable:
If Yes/No explain			
4.11 What are the provisions for safety monitoring and termination of research?			

5. Respect for the dignity of the research participants

Informed consent
5.1Write briefly your procedure for obtaining informed consent (written/oral).
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.

5.2 How will you ensure that the participant is adequately informed? Please include information sheets with translations.			
5.3 How will you ensure your information is understood (comprehension) and queries answered?			
5.4 Would the participants have difficulty understanding the information due to, for example, age (children under 16 or senility), illiteracy, and impaired cognition due to illness/trauma?	Yes:	No:	Inapplicable:
If Yes justify the use of this group and detail the arrangement for obtaining **proxy consent**? (Attach separate sheets if necessary)			
5.5 How will you ensure that consent is given voluntarily and not due to deception, intimidation or inducement?			
5.6 Will you obtain fresh informed consent if the procedures are changed during the research?	Yes:	No:	Inapplicable:
6. **Confidentiality**			
6.1 How will data/samples be obtained?			
6.2 How long will data/samples be kept?			
6.3 Are you collecting the minimum information/ samples required to fulfill the study objectives?	Yes:	No:	
6.4 Who will have access to the personal data of the research participants?			
6.5 How will you safeguard the privacy of the research participant?			

6.6 What is the data/sample storage and disposal procedure in relation to ensuring confidentiality and security of personal information?		
6.7 If you are planning to store data/samples for future study, will you obtain appropriate consent?	Yes:	No:

Rights of the participants

6.8 How will you ensure the participants unconditional right to withdraw from the research at any time?			
6.9 Outline the procedures you will provide for the research participants to ask questions and register complaints.			
6.10 Who is the contact person for the research participants?			
6.11 Is there provision for participants to receive information that is relevant to their participation?	Yes:	No:	Inapplicable:
If Yes/No Explain.			

6.12 Is there provision for the participants to be informed of results of clinical research?	Yes:	No:	Inapplicable:
6.13 Is there provision to make the study product, if any, available to the study participants following the research?	Yes:	No:	Inapplicable:
If Yes/No Explain			

7. Fair participant selection

7.1What is your study population?
7.2 Justify your choice of the study population

7.3 Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?	Yes:	No:	Inapplicable:
If Yes/No Explain			
7.4 How is the initial contact and recruitment to be conducted?			
7.5 Is your research a community research?	Yes:	No:	
If Yes please fill up section 9			
7.6 Is your research a clinical trial?	Yes:	No:	
If Yes please fill up section 10			

8. Responsibilities of the researcher

8.1 Have you followed any applicable legal regulations or other guidelines?	Yes:	No:	Inapplicable:
If No Explain			
8.2 Have you obtained permission from the relevant authorities?	Yes:	No:	Inapplicable:
If Yes name the authorities. If No who are you planning to get permission from?			
8.3 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).			

8.4 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).
8.5 I do not wish the following reviewers / ERC members to review my application.

8. Community based research

9.1 State the impact and relevance of the research on the community in which it is to be carried out
9.2 State the steps taken to consult with the concerned community during the design of the research
9.3 What procedures will be used to obtain community consent?
9.4 What procedures will be used to obtain individual consent?
9.5 How will you safeguard the privacy of the participants?
9.6 If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study? If not, explain why.
9.7 Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the population?

9.8 How does the research contribute to capacity building of the community?
9.9 How will the results of the research be made available to the concerned community?

10. Clinical trials

10.1 What phase clinical trial is being conducted?				
Phase 1:	Phase 11:	Phase 111:	Phase 1V:	Other:
If Other specify:				
10.2 Is it a multicentre trial?				
10.3 Have adequate animal toxicity and teratogenicity trials been carried out?				
10.4 What is the justification for using a control arm?				
10.5 Does the control group receive the standard therapy?				
10.6 Are all participants treated equally?				
If not explain.				
10.7 What is the procedure for dealing with adverse events?				
10.8 What is the procedure for reporting adverse events?				
10.9 Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?				

10.10 What are the criteria for termination of the trial?
10.11 Is there provision for insurance of the trial participants? Explain.

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 (maximum 500 words).

(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 Humans - 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. Information sheet for research participants (Should be provided in appropriate language all three languages – Sinhala, Tamil, and English). (12 copies) ☐

5. Consent forms (Should be provided in all three languages – Sinhala, Tamil, and English). (12 copies) ☐

6. Data collection booklets/forms/questionnaires. Advertisement (Should be provided in all three languages – Sinhala, Tamil, and English if self-administered by research participants) (12 copies) ☐

7. Short CVs of Investigators ☐

7. 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