Faculty of Livestock, Fisheries & Nutrition

Wayamba University of Sri Lanka

Ethics Review Committee

Establishment & Operating Procedures

by

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Section 1: Establishment of an Ethics Review Committee (ERC) for the Faculty of Livestock Fisheries & Nutrition (FLFN)

1. Introduction

The Faculty of Livestock Fisheries & Nutrition (FLFN) which is comprised of Departments of Applied Nutrition, Food Science & Technology, Aquaculture and Fisheries, Livestock & Avian Sciences conduct research involving human participants, animals, and tissue and data. These guidelines have been prepared for the establishment of an Ethical Review Committee in the Faculty of Livestock Fisheries & Nutrition to enable the assessing of ethical conformity of research proposals. The operating procedures presented here are in compliance with the standard operating procedures presented at the forum of Ethics Review Committees, Sri Lanka for ethic committees that reviews research proposals involving humans and animals.

Section 2: Role of Ethics Review Committee of Faculty of Livestock Fisheries & Nutrition

The purpose of the ERC of FLFN is to review research involving human participants, tissue and data thus to contribute to safeguarding the dignity, rights, safety, health and well-being of all actual or potential participants in the research. In reviewing of research involving animals, the main focus is the protecting of the well being of animals as well as treating them as humane as possible. ERC should ensure the complete, independent, and timely evaluation of ethics of the proposed study before it carried out to make sure the following important aspects associated with research participants.

- The respect for the dignity of persons who involving in the research is to be protected.
- The objectives of research should be afforded while ensuring the protection of the health, well-being, and care of research participants.

- Need to demand protocol modifications and obtaining informed consent where it is needed.
- Benefits and burdens of research to be distributed fairly among all groups and classes in society, taking into account age, gender, economic status, culture, and ethnic considerations.
- Need to carry out the review of proposed research before the commencement of the research and a regular evaluation of the ethics of ongoing studies that received a positive decision should be done.
- Ethics Committee is responsible for acting in the full interest of potential research participants and concerned communities, taking into account the interests and needs of the researchers, and having due regard for the requirements of relevant regulatory agencies and applicable laws.

2.1 Terms of Reference

ERC of FLFN will be responsible for ensuring the ethical requirements of research conducted under the Faculty of Livestock Fisheries and Nutrition involving humans and animals.

2.2 Composition of ERC of FLFN

The responsibility of ERC is to provide independent, competent, and timely review of the ethics of proposed studies submitted. Thus, in the process of reviewing as well as in decision-making, ERC members need to have independence from political, institutional, professional, and market influences. They need similarly to demonstrate competence and efficiency in their work to submit their recommendations in timely manner. In addition, ERC of FLFN should be multidisciplinary and multi-sector in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and the concerns of the community.

2.3 Appointment

The ERC should be appointed by the faculty board of FLFN. All members in the ERC should have freedom to work independently and decide on the merits of proposals received.

2.4 Membership

2.4.1Membership requirements

Appointments of ERC members will be made by the Faculty board of FLFN by consensus or by majority vote.

Conflicts of interest should be avoided when making appointments, but where unavoidable there should be transparency with regard to such interests.

A rotation system for membership should be maintained that allows for continuity, the development and maintenance of expertise within the ERC, and the regular input of fresh ideas and approaches.

2.4.2 Composition of ERC membership

Number of members in the committee depend on the fields they will be required to review the proposals. As a general guide a minimum of 7 and a maximum of 13 are suggested. The suggested membership of the ERC of FLFN will be constituted as follows:

(a) Four (04) faculty members whose expertise covers research methods, research ethics and with a good research tract record

(b) A medical graduate/ veterinarian (01)

(c) Four (04) non medical scientists with research experience and research record (Sociologist/Agronomist/Zoologist/Food Scientist/Nutritionist depending on the requirements of research proposal)

(d) Faculty member who has fluency of Tamil language (01)

(e) Two (02) lay persons not associated with institution. (Preferred one male & one female)

A chairperson and the secretary should be appointed by the Faculty Board. The duties and responsibilities of each post should be clearly stated. In addition to ERC members adequate support staff for carrying out its responsibilities should be provided.

2.4.3 Quorum requirements

The quorum for meetings should be 7 including at least one lay member.

The presence of an expertise in the field of research application is mandatory and ad hoc appointments of expert consultants to the committee should be made when an opinion in any area that is not represented by the membership is required.

Whenever there is an association with the research application, to avoid the conflict of interest member should declare their connection with the application and should withdraw from the deliberations.

2.4.4 Terms of Appointment

Terms of appointment should be as follows.

Appointment should be made for one year allowing two consecutive extensions.

In the event of breeching responsibilities of ERC the faculty board can disqualify the appointment after going through an investigation done by a faculty board appointed subcommittee including Dean for this purpose.

Any ERC member can resign after giving two months notice and the replacement of ERC members should be done following similar procedure for initial appointment

2.4.5 Conditions of Appointment

The conditions of appointment should be as follows.

ERC member should be willing to publicize his/her full name, profession, and affiliations with other institutions and organizations.

ERC member should sign a confidentiality agreement regarding meeting deliberations, applications, information on research participants, and related matters; in addition, all ERC administrative staff should sign a similar confidentiality agreement.

2.4.6 Education and training for ERC Members

ERC members need initial and continued education and training regarding the ethics and science of biomedical research and research involving animals.

Members should be provided introductory training in work of an ERC as well as ongoing opportunities for improving their capacity for ethical review.

2.4.6 Responsibility of ERC of FLFN and indemnity

A clear understanding is necessary of who bears ultimate responsibility in the event of complaints by clients of ERC or research participants

ERC should work independently and should take responsibility of their decisions which made based on the examination of the proposal and the application of approved methodology.

Provided there have been no shortcomings in the ethical review process, in cases of litigation, FLFN and WUSL need to bear the ultimate responsibility. Therefore, suitable

indemnity should be provided for ERC members. Members should be given this indemnity in their letters of appointment.

It is the responsible of ERC members to advise investigators to obtain appropriate insurance policies to meet the challenges of possible claims for medical expenses or compensation by research participants.

Section 3: Ethics Review Process

3.1 General considerations

Ethics Review Committee;

should ensure the broadest possible coverage of protection for potential research participants and contribute to the highest attainable quality in the science and ethics of biomedical and animal research.

need to ensure that investigators declare conflict of interest both financial and non financial.

Should monitor and review where possible the conduct of research approved by the ERC.

3.2 Submitting application for ethics review

ERC is responsible for establishing well-defined requirements for submitting an application for review of a biomedical and animal research projects. These requirements should be readily available to prospective applicants. Researchers should respond adequately to all questions in the application form.

Applicants should be informed of the following

-whether applications are accepted from persons outside the institution;

-whether applications for research using animals are accepted;

-fees, if any, that are payable and the mode of payment;

-method of submitting applications, i.e. hard copies, electronic copies, or both;

-some indication of dates of ERC meetings and lead time required for processing of applications, review and communicating decisions; and procedure for inquiries and follow-up.

3.3 Application

An application for the review of the ethics of proposed biomedical research should be submitted by a qualified researcher responsible for the ethical and scientific conduct of the research.

Application requirements

The requirement for the submission of a research project for the ethical review should be clearly described in an application procedure.

These requirements are as follows.

The name (s) and address (es) of the ERC secretariat or member (s) to whom the application material is to be submitted;

The application form (s)

The format for submission;

The documentation ;

The language (s) in which (core) documents are to be submitted;

The number of copies to be submitted;

The dead line for the submission of the application in relation to review dates;

The means by which applications will be acknowledged, including the communication of the incompleteness of an application;

The excepted time for notification of the decision following review;

The time frame to be followed in cases where the ERC requests supplementary information or changes to documents from the applicant;

The fee structure, if any, for reviewing an application;

The application procedure for amendments to the protocol, the recruitment material, the potential research participant information, or the informed consent form,

3.3.1 Documentation

All documentation required for a thorough and complete review of the ethics of proposed research should be submitted by the applicant. This may include, but is not limited to,

Signed and dated application form;

The protocol of the proposed research (clearly identified and dated), together with supporting documents and annexure;

A summary (as far as possible in non-technical language), synopsis, or diagrammatic presentation ('flowchart') of the protocol;

A description (usually included in the protocol) of the ethical considerations involved in the research;

Case report forms, diary cards, and other questionnaires intended for research participants;

When the research involves a study product (such as a new food or pharmaceutical or device under investigation), an adequate summary of all safety, pharmacological,

pharmaceutical, and toxicological data available on the study product together with a summary of clinical experience with the study product to date (e.g., recent investigator's brochure, published data, a summary of the product's characteristics);

Investigator (s)'s curriculum vitae (updated, signed, and dated);

Material to be used (including advertisements) for the recruitment of potential research participants;

3.4 Obtaining consent

Written and other forms of information for potential research participants (clearly identified and dated) in the language(s) understood by the potential research participants and, when required, in other languages;

Informed consent form (clearly indentified and dated) in the language understood by the potential research participants and, when required, in other languages;

a statement describing any compensation for the study participation (including expenses and access to medical care) to be given to research participants;

a description of the arrangements for indemnity, if applicable;

a description of the arrangements for insurance coverage for research participants, if applicable;

a statement of agreement to comply with ethics principals set out in relevant guidelines;

All significant pervious decisions (e.g., those leading to a negative decision of modified protocol) by other ERCs or regulatory authorities for the proposed study (whether in the same location or elsewhere) and an indication of modification(s) to the protocol should be made on the account. The reasons for previous negative decisions should be provided.

Section 4: Reviewing Process

Ethics review committee should provide independent, competent and timely review of the ethics of research proposals submitted. All applications should be reviewed in a systematic manner developed by the ERC.

4.1 Meeting requirements

ERC members should meet regularly on scheduled dates that are announced in advance, except for applications that rise only minor ethical issues.

ERC members should be given at least 3 weeks in advance of the meeting to review the relevant documents.

Meeting should be minuted and minutes should be approved in the following meeting.

The applicant, sponsor, or representative of sponsor and/or investigator may be invited to present the proposal or elaborate on specific issues.

Independent consultants may be invited to the meeting or to provide written comments, subject to applicable confidently agreement.

4.2 Elements of the review

The primary task of an ERC lies in the review of research proposals and their supporting documents, with special attention given to the informed consent process, documentation, and the suitability and feasibility of the protocol. ERCs need to take into account prior scientific reviews, if any, and the requirements of applicable laws and regulations. The following should be considered, as applicable.

4.3 Scientific design and conduct of the study

The appropriateness of the study design in relation to the objectives of the study, the statistical methodology (including sample size calculation) and the potential for reaching sound conclusions with the smallest number of research participants;

The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;

The justification for the use of control arms;

Criteria for prematurely withdrawing research participants;

Criteria for suspending or terminating the research as a whole;

The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a data safety monitoring board (DSMB);

The adequacy of the site, including the supporting staff, available facilities, and emergency procedures;

The manner in which the results of the research will be reported and published;

4.4 Recruitment of research participants

The characteristics of the population from which the research participants will be drawn (including gender, age literacy, culture, economic status, and ethnicity)

The means by which initial contact and requirement is to be conducted

The means by which full information is to be collected from research participants or their representatives;

Inclusion criteria for the research participants;

Exclusion criteria for the research participants;

4.5 Care and Protection of Research Participants

The suitability of the investigator(s)'s qualification and experience for the proposed study;

Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action;

The medical care to be provided to research participants during and after the course of the research;

The adequacy of medical supervision and the psycho-social support for the research participants;

Steps to be taken if the research participants voluntarily withdraw during the course of the research;

The criteria for extended access to, the emergency use of, and/or the compassionate use of study products;

The arrangements, if appropriate, for informing the research participant's general practitioner (family doctor), including procedures for seeking the participant's consent to do so;

A description of any plans to make the study product available to the research participants following the research;

The rewards and compensations for the research participants (including money, services, and/or gifts);

the provisions for the compensation/treatment in the case of the injury/ disability/ death of a research participant attributable to participation in the research;

the insurance and indemnity arrangements;

4.6 Protection of Research Participant Confidentiality

A description of the persons who will have access to personal data of the research participants, including medical records and biological samples;

The measures taken to ensure the confidentiality and security of personal information concerning research participants;

4.7 Community considerations

The impact and relevance of the research on the local community and on the concerned communities from which the research participants are drawn;

The steps taken to consult with the concerned communities during the course of designing the research;

The influence of the community on the consent of individuals;

Proposed community consultation during the course of the research;

The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research and ability to respond to public health needs;

A description of the availability and affordability of any successful study product to the concerned communities following the research;

The manner in which the results of the research will be made available to the research participants and concerned communities.

Most projects will require formal review by the full ERC. But there some investigations that do not pose any ethical problems (ethically minor investigations), where there is no risk of distress or injury, physical or psychological, to the subjects e.g. some epidemiology, some surveys on eating or smoking habits, assessment of patient information and education. Projects such as these should be the subject of an application but may not require review by the full committee.

4.8 Confidentiality

Confidentiality of ethical review committee proceedings (as distinct from decisions) should be preserved because issues considered are often complicated and delicate; an uninformed or unbalanced publicity could cause damage. Moreover, some investigators who have had an original idea may fear that this may be passed on to others who are competing them.

4.9 Co-option

Area of particular difficulty or sensitivity , e.g. research involving the fetus, neonates, cancer, pregnancy and ethnic minorities, it is useful to co-opt additional lay or professional advisers for an individual application or meeting.

4.10 Declaration of interest

Just as applicants should declare any interest, members of the ERC should declare their interests, for example, where an application relates to testing a product of company to which the member is an adviser. The chairmen will decide whether the interest disqualifies the members from the discussion. Where the chairman has an interest, a Vice- chairman should take his place.

4.11 Accidents

In the event of a serious accident to research subjects, the ERC should satisfy itself that a proper inquiry is conducted and consider whether the research study should continue.

4.12 Access to Ethics Review Committee

There should be access to the ERC for research subjects who may be dissatisfied. It will be the responsibility of investigators to inform research subject of this.

4.13 Fees

The service is free for the members of WUSL. The service will be offered to other institutions with a service charge.

Members of the ERC shall not be paid and shall not receive any honorarium from anybody with an interest in the outcome of the applications.

4.15 Expedited Review

ERC should establish procedures for the expedited review of research proposals. These procedures should specify the following:

the nature of the applications, amendments, and other considerations that will be eligible for expedited review;

the quorum requirement(s) for expedited review;

the status of decisions (e.g., subject to confirmation by full EC or not).

Section 5: Decision-making

In making decisions on applications for the ethical review of biomedical research, an EC should take the following into consideration:

- a member should withdraw from the meeting for the decision procedure concerning an application where there arises a conflict of interest; the conflict of interest should be indicated to the chairperson prior to the review of the application and recorded in the minutes;
- a decision may only be taken when sufficient time has been allowed for review and discussion of an application in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of EC staff;

- decisions should only be made at meetings where a quorum (as stipulated in the EC's written operating procedures) is present;
- the documents required for a full review of the application should be complete and the relevant elements mentioned above (see 6.2) should be considered before a decision is made;
- only members who participate in the review should participate in the decision;
- there should be a predefined method for arriving at a decision (e.g., by consensus, by vote); it is recommended that decisions be arrived at through consensus, where possible; when a consensus appears unlikely, it is recommended that the EC vote;
- advice that is non-binding may be appended to the decision;
- in cases of conditional decisions, clear suggestions for re-vision and the procedure for having the application re-reviewed should be specified;
- a negative decision on an application should be supported by clearly stated reasons.

Section 6: Communicating a decision

A decision should be communicated in writing to the applicant according to EC procedures, preferably within two weeks' time of the meeting at which the decision was made. The communication of the decision should include, but is not limited to, the following:

the exact title of the research proposal reviewed;

the clear identification of the protocol of the proposed research or amendment, date and version number (if applicable) on which the decision is based;

the names and (where possible) specific identification numbers (version numbers/dates) of the documents reviewed, including the potential research participant information sheet/material and informed consent form;

the name and title of the applicant;

the name of the site(s);

the date and place of the decision;

the name of the ERC taking the decision;

a clear statement of the decision reached;

any advice by the ERC;

in the case of a conditional decision, any requirements by the ERC, including suggestions for revision and the procedure for having the application re-reviewed;

in the case of a positive decision, a statement of the responsibilities of the applicant; for example, confirmation of the acceptance of any requirements imposed by the ERC; submission of progress report(s); the need to notify the ERC in cases of protocol amendments (other than amendments involving only logistical or administrative aspects of the study); the need to notify the ERC in the case of amendments to the recruitment material, the potential research participant information, or the informed consent form; the need to report serious and unexpected adverse events related to the conduct of the study; the need to report unforeseen circumstances, the termination of the study, or significant decisions by other ERCs; the information the ERC expects to receive in order to perform ongoing review; the final summary or final report; the schedule/plan of ongoing review by the ERC;

in the case of a negative decision, clearly stated reason(s) for the negative decision;

signature (dated) of the chairperson (or other authorized person) of the ERC.

Section 7: Follow-up

ERC should establish a follow-up procedure for following the progress of all studies for which a positive decision has been reached, from the time the decision was taken until the termination of the research. The ongoing lines of communication between the ERC and the applicant should be clearly specified. The follow-up procedure should take the following into consideration:

the quorum requirements, the review procedure, and the communication procedure for follow-up reviews, which may vary from the requirements and procedures for the initial decision on an application;

the follow-up review intervals should be determined by the nature and the events of research rojects, though each protocol should undergo a follow-up review at least once a year;

the following instances or events require the follow-up review of a study:

a. any protocol amendment likely to affect the rights, safety, and/or well-being of the research participants or the conduct of the study;
b. serious and unexpected adverse events related to the conduct of the study or study product, and the response taken by investigators, sponsors, and regulatory agencies;
c. any event or new information that may affect the benefit/risk ratio of the study;

a decision of a follow-up review should be issued and communicated to the applicant, indicating a modification, suspension, or termination of the ERC's original decision or confirmation that the decision is still valid;

in the case of the premature suspension/termination of a study, the applicant should notify the EC of the reasons for suspension/termination; a summary of results obtained in a study prematurely suspended/terminated should be communicated to the EC;

ERCs should receive notification from the applicant at the time of the completion of a study;

ERCs should receive a copy of the final summary or final report of a study.

Section 8: Documentation and archiving

All documentation and communication of an ERC should be dated, filed, and archived according to written procedures. A statement is required defining the access and retrieval procedure (including authorized persons) for the various documents, files, and archives. It is recommended that documents be archived for a minimum period of 3 years following the completion of a study. Documents that should be filed and archived include, but are not limited to,

the constitution, written standard operating procedures of the ERC, and regular (annual) reports;

the curriculum vitae of all ERC members;

a record of all income and expenses of the ERC, including allowances and reimbursements made to the secretariat and ERC members;

the published guidelines for submission established by the ERC;

the agenda of the ERC meetings;

the minutes of the ERC meetings;

one copy of all materials submitted by an applicant;

the correspondence by ERC members with applicants or concerned parties regarding application, decision, and follow-up;

a copy of the decision and any advice or requirements sent to an applicant;

all written documentation received during the follow-up;

the notification of the completion, premature suspension, or premature termination of a study;

the final summary or final report of the study.

Supporting documents

Ethics Review Committee Guidelines . Forum of Ethics Review Committees, Sri Lanka (2007)

Guidelines for Ethics Review of Research proposals involving animals in Sri Lanka. Forum of Ethics Review Committees of Sri Lanka (2009)

Establishment & Operational guidelines submitted to the Senate of Wayamba University of Sri Lanka by Dr Renuka Silva (2002)

World Medical Association, *Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects*. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964. Amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; the 35th World Medical 23.Assembly, Venice, Italy, October 1983; the 41st World Medical Assembly, Hong Kong, September 1989; and the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

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

For official use

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	Yes:	No:

scientific review by any other committee?		
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
    a. Study design
    b. Study setting
    c. Study population
    d. Sample size
    e. Sampling method
    f. Study instruments
    g. Data collection
    h. 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

For official use only

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.

…….... ….……

Signature of Principal Investigator Date

Annex-2

Ethics Review Committee, Faculty of Livestock Fisheries & Nutrition,

Wayamba University of Sri Lanka

Application for Ethics Review involving Animals-Part I

For official use only

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

1. Title of research Project

……

……

……

……

……

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

For official use only

Application No:										

1. Title of Project

……

……

……

……

……

2. Name and address of funding source(s)

……

……

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
    a. Study design
    b. Study setting
    c. Study population
    d. Sample size
    e. Sampling method
    f. Study instruments
    g. Data collection
    h. 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

For official use only

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.

……..... ….……

Signature of Principal Investigator Date

Annex -3

Ethics Review Committee, Faculty of Livestock Fisheries & Nutrition,

Wayamba University of Sri Lanka

Ethics Review Application Evaluation Form

Application No:	Date reviewed (d/m/y)
Name of Reviewer:	

		Yes	No	NA	Comments
1	Will the study lead to improvements in human/animal health, wellbeing and/or advancement of science ?				
2	Background & justification sufficient?				
3	Objectives of the study clear?				
4	Is there provision for dissemination of results of the research?				
5	Needs for human/animals justified?				
6	Should the study be referred to a technical expert, policy maker or statistical expert?				
7	Study design appropriate?				
8	Sample size and statistical techniques have adequate power to produce reliable and valid results?				
9	Are the investigators qualifications, competence and experience appropriate?				
10	Are the facilities at the site adequate to support the study?				
11	Inclusion criteria appropriate?				
12	Exclusion criteria appropriate?				
13	Voluntary participation is assured?				
14	Privacy and confidentiality is protected?				

15	Risk & benefit assessment is satisfactory?				
16	Procedures for obtaining informed consent appropriate?				
17	Content of information sheet and consent form is clear?				
18	Is the procedure for obtaining (proxy) consent adequate?				
19	Is the procedure for dealing with adverse events adequate?				
20	Are the criteria for termination of the trial detailed?				
21	Will the benefit of the research be made reasonably available to this group?				
22	Is there any inducement for participation?				
23	Translations of all forms are consistent?				
24	Will the fresh informed consent be obtained if procedures are changed?				
25	Will the researcher collect only minimum information/samples to fulfill objectives ?				
26	Is safe disposal of biological/chemical samples assured?				

Additional Comments:

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Recommendation:

Approve	Approve subject to Minor revisions	Re submit after major revisions	Reject	Exempt

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Signature: .....

Date ...../...../.....

Annex - 4

Ethics Review Committee, Faculty of Livestock Fisheries & Nutrition,

Wayamba University of Sri Lanka

Participant Information Sheet Template

Introduction

Write the name the group of individuals for whom this participant information sheet is written.

(Example: This participant information sheet is for participants who are invited to participate in research on (general area of research project)…….

Provide the following information under headings as shown below.

Title of the project
Organization
Names and contacts of Investigators
Background of study (300 words)
Purpose of study

State why theses participants have been chosen for this research and Indicate clearly that they can choose to participate or not.

(Example: If you are interested in taking part in this study, please read through the questions and answers carefully. If you wish to know more please contact one of the above investigators.)

You need to provide information for following questions. These information can be given as follows.

1. Issues that may arise in your mind before participating
2. Who can participate for the study?
3. How will you know that you have been recruited for the study?
4. What is the duration of the study?
5. Does this involve any risk for your/your animal health?
6. Does this study involve any biological sample?
7. What should you do if you/your animal take part in the study?
8. To what extent is the information you give is confidential?
9. Whom you should contact if you need any further clarification?

Annex - 5

Ethics Review Committee, Faculty of Livestock Fisheries & Nutrition,

Wayamba University of Sri Lanka

Consent form Template

Title of the project

Organization

1. I have read and clearly informed by (names of investigators), the attached information sheet with regard to the study on (name of project)
2. They have explained me the purpose, and importance of the study and I understand what is required from me. I have been answered satisfactorily for the questions I raised and I agree for the procedures described in the information sheet which relates to my participation.
3. I understand that the participation is entirely voluntary and the information they collect is with my consent.
4. I understand that I can withdraw from the study at any point without giving reasons and I know that it will not affect me what so ever.
5. I have received a copy of this consent form and of the accompanying information sheet.

Name :……

NIC No (optional) :……

Signature :……

Date :……

Investigator: Name & signature……

Date : ……

Annex - 6

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

Assent form Template

For studies involving children aged 16 to less than 18 years, the child's assent must be obtained in addition to the parent's or guardian's consent. The respondent must sign a form which states that the information sheet has been read and discussed with the investigator and that the subject agrees to participate in the presence of parent or guardian.

Title of the project

Organization

1. I have read the information sheet and understand what the study (name of the project) involves.
2. I understand that refusal to participate in the study will not affect my treatment or care in any way.
3. I understand that I may withdraw at anytime and it will not affect me adversely in any manner.
4. They have explained me the purpose, and importance of the study and I understand what is required from me. I have been answered satisfactorily for the questions I raised and I agree for the procedures described in the information sheet which relates to my participation.
5. I therefore agree to participate in this study. I have received a copy of this consent form and of the accompanying information sheet.

Signature of the participant:……..

Full name:……...

Date:…….

Postal address:……

Signature of the parent/guardian:……..

Full name:……...

Date:……

Postal address:…….

NIC No (optional):……

I have been present while the procedure has been explained to the child and I have witnessed his/her consent to take part in the study.

Signature of the witness:……

(The witness should be a person NOT connected with the study)

Full name:……...

Date:……

Postal address:……..