Ethics Review Committee

Faculty of Applied Sciences

University of Sri Jayewardenepura

Application Form

Application No: ...../..... **Date Received: .... /...../....**

Version.....

Name of Applicant: (Prof./Dr./Mr./Ms.) .....

Office use only

CHECKLIST (Please mark all documents submitted)

One copy of each of the following – Need to complete

1. Covering letter signed by the applicant ☐
2. Letter of recommendation from supervisor (if applicable) ☐
3. Application form ☐
4. Research proposal ☐
5. Study instruments ☐
6. Information sheet and consent forms (if applicable) ☐
7. Payment receipt ☐

Email a complete set of all documents submitted (including one copy of your application, proposal, study instruments, bank receipt and all other forms) as a single PDF file to at the time of submission.

The ERC office will not process your application until all required documents are received.

PART A: Administrative Details

1. Title of Research Project:

2. Details of Principal Investigator

Title (Prof./Dr./Mr/Ms):	Name:
Current designation and name and address of the institution where the applicant is attached:	
Highest educational qualification of applicant:	
Mailing address:	
Phone:	e-mail:

3. Details of Co-Investigator/s

Title (Prof./Dr./Mr/Ms):	Name:
Current designation and name and address of the institution where the applicant is attached:	
Highest educational qualification of applicant:	
Mailing address:	
Phone:	e-mail:

4. Information on the study programme

4.1. Type of study programme

Undergraduate ☐ Postgraduate ☐ Other ☐ Please specify: .....

If this is a postgraduate programme, provide the following information

4.2. Have you already registered for this degree? Yes ☐ No ☐

4.3. Details of the degree programme

Type of degree (MSc/PhD/MD/MS/other):		
Awarding University:		
Date of registration:	Date of protocol approval by the board of study:	Letter annexed ☐

Please append a letter of approval from the Board of Study

5. Details of Supervisors

Title:	Name:
Department (or organization if not affiliated with FAS/SJP):	
Highest educational qualification:	
Mailing address:	
Phone:	e-mail:

Title:	Name:
Department (or organization if not affiliated with FAS/SJP):	
Highest educational qualification:	
Mailing address:	
Phone:	e-mail:

Title:	Name:
Department (or organization if not affiliated with FMS/SJP):	
Highest educational qualification:	
Mailing address:	
Phone:	e-mail:

Please append additional pages with supervisors' names if necessary

6. Information on research sites/ location:

6.1 Is this a multi-site study? Yes ☐ No ☐

6.2 Specify all study sites

If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a hospital/school). In that case, it is the responsibility of the researcher/s to obtain approval prior to starting the project.

Type of site (University, Community, School)	Details

7. Information on approval from other research ethics boards

7.1 Has any other ERC approved of this project? Yes ☐ No ☐

If yes, please attach a copy of the approval letter.

8. Funding information

Funding Status		**Source and the amount**	**Details**
1. Funded			
2. Applied for Funding			
3. Unfunded			

PART B: Research Details

9. Title of the project:

10. Start and end dates of the project

Estimated date of commencement:

Estimated date of completion:

11. A summary of the research proposal (maximum 250 words)

12. Scientific significance of your study to improve knowledge of the subject

13. Justification for a replication study (only if your study is a replication study)

14. Investigators' experience with this type of research

(If there is no prior experience, please describe the training or preparation plan for the principal investigator and research team to ensure they are properly equipped for the study)

15. Are the facilities at the site adequate to support the study? Yes ☐ No ☐

16. Plan for dissemination of study findings

17. Respect for the dignity of the research participants

Informed consent Criteria		**Applicable**		**Provide details**
		Yes	**No**	
1	Procedure for obtaining informed consent	☐	☐	
1	Type of consent obtained*			
	Verbal	☐	☐	
	Written	☐	☐	
2	Procedure for ensuring the understanding of the information provided to participants	☐	☐	
3	Procedure for withdrawing consent	☐	☐	
4	Information on incentives/ rewards/ compensation to participants.	☐	☐	
5	Re-consent procedure if the research protocol changes during the research.	☐	☐	
6	Consent procedure if recruiting vulnerable groups /children under 18 years of age	☐	☐	
7	Consent procedure if children between the ages of 12-18 are recruited (For children between 12-18 years, in addition to parental consent, children's consent must be obtained) **	☐	☐	

**If written please include a 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*

*** Attach a consent form for children between the ages of 12-18*

18. Confidentiality

Criteria		Applicable		Provide details
		Yes	**No**	
1	Methods for collecting data/samples*	☐	☐	
2	Duration for retaining data/samples	☐	☐	
	Information and justification for the sample size	☐	☐	
3	Justification for collecting personally identifiable data	☐	☐	
4	Persons authorized to handle the personal data of research participants	☐	☐	
5	Measures to safeguard the confidentiality of participants	☐	☐	
6	Data and sample storage procedure	☐	☐	
7	Data and sample disposal procedure	☐	☐	

**Please provide adequate proof to show that clinical samples (where applicable) are collected by appropriate health care professionals.*

**Please include questionnaires or other forms used (in Sinhala/Tamil/English).*

19. Fair participant selection

Criteria		Applicable		Provide details
		Yes	**No**	
1	Description of the study population	☐	☐	
2	Justification for the selection of the study population.	☐	☐	
3	Procedure for initial contact and recruitment of participants	☐	☐	
4	Justification for participant selection to ensure minimized risks, maximized benefits, and fair distribution of research burden	☐	☐	

20. Vulnerable groups (those socially disadvantaged on account of illiteracy, economic status, social status, etc., and those with limited autonomy such as prisoners, service personnel, etc.)

Criteria		**Applicable**		**Provide details**
		Yes	**No**	
1	Involvement of vulnerable groups	☐	☐	
2	Justification for using the vulnerable group instead of the general population.	☐	☐	
	procedure for withdrawal from research due to refusal (dissent) of the research participant	☐	☐	
3	Procedure for making the research results available to this population	☐	☐	

21. Community-based research

Criteria		**Applicable**		**Provide details**
		Yes	**No**	
1	Impact and relevance to the community in which research is to be conducted	☐	☐	
2	Steps taken to consult with the relevant community in designing the research	☐	☐	
3	Procedure/s used to obtain community approval	☐	☐	
4	Contribution to capacity building of the community	☐	☐	
5	Procedure for making the results of the research available to the community	☐	☐	

Questions 22 to 27 mainly apply to projects that require observation, capturing, and handling of animals in the field.

22. Details of the study site/s

22.1. Location/s of the study:

22.2. Does this area fall within any protected area? Yes ☐ No ☐

22.3. If **'Yes'**, specify.

23. Details of the animal subjects

23.1. Species being studied:

Scientific name:

Common name:

23.2. Status of the species (e.g. nationally threatened, rare, endemic):

23.3. Information and justification for the sample size

24. Details of the sex and age groups included in the study.

25. Handling and capturing

25.1. Would you need to capture and handle the animal(s)? Yes ☐ No ☐

If **'Yes'**, answer to following questions

25.2. Purpose of capturing and handling the animals/s

25.3. Briefly outline the capture method

25.4. Provide proof that the capturing and handling procedures follow standard methods used for studying these animals

25.5. State any previous experience in using the method/s.

25.6. Any plan for removing captured animals from the environment in which they are captured. Yes ☐ No ☐

25.7. If yes, explain the arrangements made to ensure the safe and optimal transportation of the animals

25.8. Provide details about the animals' housing conditions during captivity a the length of their captivity

25.9. Outline the welfare arrangements for captive animals

25.10. Specify the disposal/release methods of animals after the experiment.

25.11. Briefly explain the measures to treat animals in case of injuries during capturing or handling.

26. Tranquilization

26.1. Are you going to tranquilization of animals Yes ☐ No ☐

26.2. If **'Yes'**, answer the following questions

26.3. Describe the method(s) proposed for tranquilization

26.4. Provide proof that the tranquilization procedure follows standard methods used for studying these animals

27. Observation of animals

27.1. Does your study require night sampling? Yes No

27.2. Describe the measures you have taken to minimize disturbance to the animals in the field

28. Collaborative partnership/s

Criteria		**Applicable**		**Provide details**
		Yes	**No**	
1	Collaborations you have established with institutions where the study is to be conducted	☐	☐	
2	Collaborations you have established with the community where the study is to be conducted	☐	☐	
3	Benefits to institutions, communities, and participants of your research	☐	☐	

29. Responsibilities of the researcher

Criteria		**Applicable**		**Provide details**
		Yes	**No**	
1	Provisions for follow-up care after research	☐	☐	
2	Declaration of conflicts of interest and strategies to address and manage them	☐	☐	

3	Ethical, legal, social, and financial issues relevant to the study	☐	☐	

30. Research funded by foreign agencies/companies

Criteria		**Applicable**		**Provide details**
		Yes	**No**	
1	Justification for conducting the study in Sri Lanka	☐	☐	
2	Relevance of the study to Sri Lanka	☐	☐	
3	Post-research benefits to Sri Lanka	☐	☐	
4	Measures taken into account cultural and social customs, practices, and taboos in Sri Lanka	☐	☐	
5	Distribution of intellectual property rights	☐	☐	
6	Disposition of data and biological samples, including whether they will be sent overseas and their handling after the study concludes.	☐	☐	
7	Methods for communicating the research findings to relevant authorities in Sri Lanka	☐	☐	
8	Agreement between the sponsor or funding agency and the investigator	☐	☐	Please Attach
9	Materials transfer agreement, if biological materials are to be transferred overseas	☐	☐	Please Attach

PART C: Description of risks and benefits

31. Assessment of Risks and Benefits

31.1. Is the participation of human/animal subjects necessary to obtain the Required information? Yes ☐ No ☐

31.2. Please indicate all potential risks to participants of their involvement in the project

i. Physical risks Yes ☐ No ☐

ii. Psychological risks Yes ☐ No ☐

iii. Social risks Yes ☐ No ☐

iv. Legal risks: Yes ☐ No ☐

31.3. If **'Yes'** to any of the above, please elaborate.

31.4. Specify the measures implemented during the project to eliminate or reduce these risks.

31.5. Describe any potential benefits to participants/ communities of their involvement in the project

31.6. Comment on the potential benefits to the scientific or scholarly community as well as to society that would justify individuals' participation in this study.

31.7. Justify the potential benefits against the risks.

32. Compensation

32.1. Will participants be compensated for their involvement in this study?

Financial	Yes ☐	No ☐
In-kind	Yes ☐	No ☐
Other	Yes ☐	No ☐

32.2. If **'Yes'**, please provide details of the compensation and the reasoning behind the amount or value offered.

32.3. If '**No**', please explain why compensation is not possible or inappropriate.

32.4. If participants decide to withdraw, how will their compensation be impacted?

33. Potential for a conflict of interest in the project.

33.1. Commercially

33.2. Financially

33.3. Intellectually

33.4. Other (Explain)

34. Does any member of the research team have an affiliation with the funder/sponsor(s) or a financial interest in the research results? Yes ☐ No ☐

If **'Yes'**, please explain:

35. If a duality of interest is identified, describe the nature of the interest and determine whether it presents a potential conflict of interest.

PART D: Declaration and consent

36. Declaration of applicant

- As the Principal Investigator for this project, my signature confirms that I will ensure all procedures carried out under the project comply with all relevant national and international policies and regulations.
- I understand that any deviation from the originally approved project must be submitted as an amendment to the ERC for approval before implementation.
- I have provided all relevant previous decisions made by this or any other ERC and/or regulatory authorities of the proposed study.
- I declare that I am not seeking approval for a study that has already begun or has already been completed.
- I understand that a minimum of two months is required for the ethics review and the granting of ethics clearance.

- I will submit progress reports, reports on adverse events, and side effects, as requested by the ERC/FAS.

- I will submit the final report upon completion of the study.

.....

Signature of Principal Investigator Date :___ /____/_____

Full name of Principal Investigator:

37. Consent from all Investigators

We, the undersigned, hereby confirm that we have agreed to be co-investigators for the project titled

Name	Qualifications	Institutional Affiliations	Signature