

Ethics Review Committee

Faculty of Applied Sciences

University of Sri Jayewardenepura

Application Form

Application No:/ D	ate 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	e) 🗆
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 Proje	ct:
2. Details of Principal Inv	estigator
Title (Prof./Dr./Mr/Ms):	Name:
Current designation and attached:	name and address of the institution where the applicant is
Highest educational qua	lification of applicant:
Mailing address:	
Phone:	e-mail:
Title (Prof./Dr./Mr/Ms): Current designation and attached:	Name: name and address of the institution where the applicant is
Highest educational qua	lification of applicant:
Mailing address:	
Phone:	e-mail:

4.3. Details of the degree programme

Type of degree (M	1Sc/P	hD/MD/MS/other):	
Awarding Univers	sity:		
Date of registration	on:	Date of protocol approval by the board of study:	Letter annexed
Please append a lette	r of ap	proval from the Board of Study	
5. Details of Supe	ervisc	ors	
Title:	Nan	ne:	
Department (or o	rgani	zation if not affiliated with FAS/SJP):	
Highest educatio	nal q	ualification:	
Mailing address:			
Phone:		e-mail:	
Title:	Nam	ne:	
Department (or o	rgani	zation if not affiliated with FAS/SJP):	
Highest educatio	nal q	ualification:	
Mailing address:			
Phone:		e-mail:	
Title:	Nam	ne:	
Department (or o	rgani	zation if not affiliated with FMS/SJP):	
Highest educatio	nal q	ualification:	
Mailing address:			
Phone:		e-mail:	

Please append additional pages with supervisors' names if necessary

6.	Informat	tion on research sites/	location:		
6	3.1 Is this	a multi-site study?	Yes □ No		
6	6.2 Speci	fy all study sites			
		chool). In that case, it is the			proval/consent (e.g., in a in a in a pproval prior to starting
Тур	pe of site	9	Details		
(U	niversity	, Community, School)			
7.	Informat	tion on approval from c	other researc	h ethics boards	
7	'.1 Has a	ny other ERC approved	d of this proje	ect? Yes □ No □	
	If yes, pl	ease attach a copy of t	he approval	letter.	
8.	Funding	information			
	Fundin	g Status		Source and the	Details
				amount	
	1.	Funded			
	2.	Applied for Funding			
	3.	Unfunded			

PART B: Research Details

9. Title of	the project:
10. Start ar	nd end dates of the project
	Estimated date of commencement:
	Estimated date of completion:
11. A sumr	mary of the research proposal (maximum 250 words)
12. Scienti	fic significance of your study to improve knowledge of the subject
13. Justific	ation for a replication study (only if your study is a replication study)
14. Investi	gators' experience with this type of research
	ere is no prior experience, please describe the training or preparation plan for the principal stigator 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 $\;\square\;$ No $\square\;$
16. Plan fo	r dissemination of study findings

17. Respect for the dignity of the research participants

Informed consent Criteria			cable	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

Cr	iteria	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			
	Data and sample storage procedure Data and sample disposal procedure			

19. Fair participant selection

Cri	iteria	Appl	icable	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			

^{*}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).

Cr	iteria	Appl	icable	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			
om	munity-based research			
	munity-based research iteria	Appl	icable	Provide details
	*	Appl Yes	icable No	Provide details
Cr	*		1	Provide details
Cr 1	iteria Impact and relevance to the community in		1	Provide details
	Impact and relevance to the community in which research is to be conducted Steps taken to consult with the relevant		1	Provide details
C r	Impact and relevance to the community in which research is to be conducted Steps taken to consult with the relevant community in designing the research Procedure/s used to obtain community		1	Provide details

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.)

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

22. De	tails of	the study site/s				
22.	1.	Location/s of the study:				
22.2	2.	Does this area fall within any protected area? Yes \Box No \Box				
22.3	3.	If 'Yes' , specify.				
23. De	tails of	the animal subjects				
23.	1.	Species being studied:				
		Scientific name:				
		Common name:				
23.2	2.	Status of the species (e.g. nationally threatened, rare, endemic):				
23.3.		Information and justification for the sample size				
24. De	tails of	the sex and age groups included in the study.				
25. Ha	ındling a	and capturing				
25.	1.	Would you need to capture and handle the animal(s)? Yes $\ \square$ No $\ \square$				
		If 'Yes' , answer to following questions				
25.2	2.	Purpose of capturing and handling the animals/s				
25.3	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 \Box No \Box		
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. Tranquil	ization		
26.1.	Are you going to tranquilization of animals Yes \Box No \Box		
26.2. If 'Yes' , answer the following questions			

26	26.3. Describe the method(s) proposed for tranquilization							
26	26.4. Provide proof that the tranquilization procedure follows standard methods							
	used for studying these animals							
27. O	bse	ervation of animals						
27	.1.	Does your study require night sampling? Y	′es ľ	No				
27	.2.	Describe the measures you have taken to m	ninimiz	e disturl	pance to the			
		animals in the field						
28. C	olla	borative partnership/s						
	Cri	teria	Appli	cable	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. R	esp	onsibilities of the researcher						
	Cri	iteria	Appli	cable	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						
		Strategies to dadress 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			Please
	agency and the investigator			Attach
9	Materials transfer agreement, if biological			Please
	materials are to be transferred overseas			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 Physical risks i. Yes □ No □ ii. Psychological risks Yes \square No □ iii. Social risks Yes □ No □ iv. Legal risks: Yes \square 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 pote	inst the risks.	
32. Compe	ensation		
32.1.	Will participant	s be compensate	ed for their involvement in this study?
	Financial	Yes \square	No □
	In-kind	Yes \square	No □
	Other	Yes \square	No □
32.2. behi	If 'Yes' , please ind the amount or v		f the compensation and the reasoning
32.3.	If ' No ', please e	explain why comp	pensation is not possible or inappropriate.
32.4.	If participants o	decide to withdrav	w, how will their compensation be impacted?
33. Potenti	al for a conflict of i	nterest in the pro	ject.
33.1.	Commercially		
33.2.	Financially		

33.3.

Intellectually

33.4.	Other (Explain)				
34. Does any	34. Does any member of the research team have an affiliation with the funder/sponsor(s) or				
a financia	l interest in the research results? Yes $\ \square$ No \square				
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.						
	•••••	••••••					
Signatu	ure of Principal Inv	estigator	Date	:/			
Full na	me of Principal Inv	vestigator:					
37. Cor	nsent from all Inve	estigators					
We, the undersigned, hereby confirm that we have agreed to be co-investigators for the project titled							
Name	<u> </u>	Qualifications	Institutional	Signature			
			Affiliations				
			•				