Ethics Review Committee
Faculty of Allied Health Sciences
University of Ruhuna, Galle, Sri Lanka.

Application Form

Instructions for Applicants

Postgraduate / Undergraduate candidates

All candidates are expected to complete an Ethics Review Application Form prior to the commencement of the research or collecting any data after the enrolment as a Research Candidate.

Faculty Staff members / Others

The Application form must be completed in full consultation with any supervisors/co-investigators/ research students/ prior to the commencement of the research or collecting any data.

This application form consists of two sections with two subsections:

Section I: General information – Details of the candidate

Section II: The research project

Section II A – Ethical issues on the research proposal

Section II B – Risks and benefits

Candidate must complete all three sections and attach the necessary documents at relevance.

For office use only			
Application No:		Date Received:	

ERC Submission for	Date	Decision
1.		
2.		
3.		

Name of Reviewers	Date Forwarded
1.	
2.	
3.	

SECTION I: GENERAL INFORMATION

1. Title of the Research Project

Location of Research	
Date of Commencement of Research	
Expected Date of Completion of Research	

2. Information of the Investigator

2.1. Principal Investigator / researcher (Should be the applicant of ethics approval)

Title (Rev./Prof./Dr./Mr./Ms.)	Name:
Institution/Department:	
Designation (Prof. Senior Lecturer, Research officer, Student etc.)	
Mailing address	
Phone	
E-mail	

2.2. Co-investigator/ Co-researchers

Are co-investigators/ co-researcher's involved? Yes / No

If yes,

Co-investigator I	
Title (Rev./Prof./Dr./Mr./Ms.)	Name:
Institution/Department:	
Designation (Prof. Senior Lecturer, Research officer, Student etc.)	
Mailing address	
Phone	
E-mail	

Co-investigator II	
Title (Rev./Prof./Dr./Mr./Ms.)	Name:
Institution/Department:	
Designation (Prof. Senior Lecturer, Research officer, Student etc.)	
Mailing address	
Phone	
E-mail	

Please attach additional columns with the details of the co-investigators if necessary.

3. Nature of the research project

3.1. Is the project for an academic degree? Yes / No

3.2. Is for an academic degree specify: ……..

3.3. Have you already registered for this degree? Yes / No

3.4. If yes

Type of degree	
Awarding university	
Date of registration	

3.5. Nature of the study

a.	Laboratory based study with Human samples	
b.	Laboratory based study with Animals	
c.	Clinical trial	
d.	Observational study	
e.	Literature review	
f.		
g.		
h.		

4. Are there supervisors for this project? Yes / No

4.1. Details of supervisors:

Principal supervisor

Title (Rev./Prof./Dr./Mr./Ms.)	Name:		
Institution/Department:			
Highest educational qualification			
Mailing address			
Phone		E-mail	

Co-supervisor

Title (Rev./Prof./Dr./Mr./Ms.)	Name:		
Institution/Department:			
Highest educational qualification			
Mailing address			
Phone		E-mail	

Please append additional pages with supervisor's names if necessary

5. Location(s) where the research will be conducted:

5.1. Is this a multi-site study? Yes / No

5.2. Specify all study sites

If the research is to be conducted at a site requiring administrative approval/consent (eg.: in a hospital/school), it is the responsibility of the researcher to obtain approval prior to starting the project. (Attach letters)

Type of site (hospital/clinic/school/community etc.)	Details

6. Other research ethics committee approval(s)

6.1. Has any other ERC approved this project? Yes / No

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

7. Funding of this project.

Funding status		Source and Amount	
Funded		Agency:	Total budget: SLR
Applied for funding		Agency:	Total budget: SLR
Unfunded		If unfunded, please explain why no funding is needed.	

8. For clinical trials only.

8.1. What is the phase of the clinical trial that is being conducted?

Phase I	
Phase II	
Phase III	
Phase IV (post marketing)	
Other	
If other specify:	

8.2. Is it a multicentre trial? Yes / No

If yes, list the other trial sites.

……..

Please attach ethics approval from the sponsoring country or country of the overseas principal investigator (if any)

8.3. Is the clinical trial registered with a clinical trials registry? Yes / No / Pending

If yes, give details

Name of register	
Registration number	

If no, give reasons

8.4. Has this study been approved by the SCOCT (Subcommittee on Clinical Trials) at the Ministry of Health? Yes / No / Pending

If yes, give details of Approval number

If no, give reasons

8.5. Data safety monitoring board (only if available)

8.6. Details of indemnity and insurance coverage for participations, investigators and ethics committee.

SECTION II A: ETHICAL ISSUES ON THE RESEARCH PROPOSAL

9. Please include the following information as given in your project proposal indicating the page number(s) relevant to each section.

9.1. Collaborative partnership

	Applicable Yes / No	Section in Protocol & page
The collaborations you have established with institutions where the study is to be conducted		
The collaborations you have established with the community where the study is to be conducted		
The benefits to institutions, communities, and participants in your research		

9.2. Social Value

	Applicable Yes / No	Section in Protocol & page
The beneficiaries of your research and the benefit to them		
The plan for dissemination of study findings		

9.3. Scientific Validity

	Applicable Yes / No	Section in Protocol & page
The scientific importance of your study in relation to improving health care and/or knowledge on the subject.		
The justification for a replication study, if your study is a replication study.		
How the sample size was calculated		

9.4. Confidentiality

	Applicable Yes / No	Section in Protocol & page
How the data and samples will be obtained		
How long data and samples will be kept		
Justification for collection of personal identification data		
Who will have access to the personal data of the research participants		
How the confidentiality of participants will be ensured		
The procedure for data and sample storage		
The procedure for data and sample disposal		

9.5. Rights of the participants

	Applicable Yes / No	Section in Protocol & page
Procedure for subjects to withdraw from the research at any time		
Procedure for subjects to ask questions and register complaints		
The contact person for research subjects		
Provisions for participants to be informed of results		
Provision to make the study product available to the study participants after research		

9.6. Fair participant selection

	Applicable Yes / No	Section in Protocol & page
The justification for the selection of the study population		
The inclusion and exclusion criteria		

9.7. Responsibilities of the researcher

	Applicable Yes / No	Section in Protocol & page
The provision of medical services to research participants with special reference to research/trial related injuries		
The provisions for continuation of care after the research is completed		
Declaration of conflicts of interests and how the investigators plan to manage the conflicts		
The ethical/legal/social and financial issues relevant to the study		

9.8. Vulnerable population

	Applicable Yes / No	Section in Protocol & page
Justification for conducting the study in this population		

9.9. Research funded by foreign agencies/companies

	Applicable Yes / No	Section in Protocol & page
Justification for conducting the study in Sri Lanka		
Relevance of the study to Sri Lanka		
Post research benefits to Sri Lanka		
The steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka		
The sharing of rights to intellectual property		
The fate of data and biological samples including whether they will be transferred abroad and what will happen to them after the conclusion of the study		Please attach
The materials transfer agreement, if biological material is to be transferred abroad		Please attach

9.10. Community based research

	Applicable Yes / No	Section in Protocol & page
The impact and relevance of the research on the community in which it is to be carried out		
The steps taken to consult with the concerned community during the design of the research		
The procedure used to obtain community consent		
The contribution to capacity building of the community		
The procedure for making available results of research to the community		

9.11. Clinical trials

	Applicable Yes / No	Section in Protocol & page
Justification for withdrawing any therapy from participants to prepare them for the trial		
Justification for withholding standard therapy from trial participants (e.g. control group)		
Justification for providing care which is not the standard of care		
Procedure for dealing with adverse events		
Procedure for reporting adverse events		
Measures in place for management of trial related injuries		
Provisions for safety monitoring		
Provisions/criteria for termination of the trial		
Provisions for making the trial drug available to participants after the trial if found to be effective		

9.12. Information Sheet (IFS) / Informed Consent Form (ICF) Check list

List the sections in IFS/ICF where you have dealt with the following	Section IFS/ICF
Purpose of the study	
Voluntary participation	
Duration, procedures of the study and participant's responsibilities	
Potential benefits	
Risks, hazards and discomforts	
Reimbursements	
Confidentiality	
Termination of study participation	

9.13. Consent

	Applicable Yes / No	Section in Protocol & page
The procedure for initial contact of participants*		
The procedure for obtaining informed consent Verbal Written		
The information (written/oral) provided to participants		
The procedure for ensuring that subjects have understood the information provided.		
The procedure for obtaining proxy consent.		
The procedure for withdrawing consent.		
Incentives/rewards/compensation provided to participants.		
The procedure for re-consenting if the research protocol changes during the course of research.		
The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited.		
The procedure for consenting if children aged 12 – 18 years of age are being recruited. (for children aged 12-18 years in addition to parental consent, children's assent must be sought)**		

*** Attach a copy of all posters, advertisements, flyers, letters, to be used for recruitment.**
**** Please attach an assent form for children aged 12-18 years**

10. Data collection

10.1. What is the procedure to be carried out on these subjects (give details of all study instruments to be used, collection of samples/blood/application of tests/administration of drugs etc, in detail).

Page number/s	
Section/s	

11. Experience of investigators with this type of research.
    11.1. Please provide a brief description of previous experience with this type of research by (i) the principal investigator, (ii) the research team and (iii) the people who will have direct contact with the participants. If there has not been previous experience, please describe how the principal investigator/research team will be trained/prepared.

SECTION II B: RISKS AND BENEFITS

12. Possible risks
    12.1. Please indicate all potential risks to participants that may arise from this research:

	Yes	No
Physical risks (e.g., any bodily contact or administration of any substance):		
Psychological/emotional risks (feeling uncomfortable, embarrassed, upset):		
Social risks (e.g., loss of status, privacy and/or reputation):		
Legal risks (e.g., apprehension or arrest, subpoena):		

    12.2. If yes to any of the above, please describe.

    12.3. State measures employed during the procedure/study to remove or minimize these risks

13. Possible benefits
    - Describe any potential direct benefits to participants from their involvement in the project
    - Describe any potential direct benefits to the community (e.g., capacity building)
    - Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

14. Compensation
    14.1. Will participants receive compensation for participation?

	Yes	No
Financial		
In-kind		
Other		

14.2. If Yes, please provide details and justification for the amount or the value of the compensation offered.

14.3. If No, please explain why compensation is not possible or inappropriate.

14.4. If participants choose to withdraw, how will compensation be affected?

15. Feedback/debriefing/referral/after care

Please describe what information/feedback/services will be provided to participants and/or communities after their participation in the project is complete (e.g., health education, referral to clinic/hospital, etc.)

16. Do you have any conflict of interests with regards to this project? Yes / No

If yes, please state below.

Commercially	
Financially	
Intellectually	
Other (Explain)	

17. Does any member of the research team have any affiliation with the provider(s) of funding/ support, or a financial interest in the outcome of the research? Yes / No

If yes, please explain:

18. If there is a duality of interest identified above describe the interest and state whether it constitutes a potential conflict of interest.

Declaration of applicant

- As the Principal Investigator on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant national and international policies and regulations that govern research involving human participants.
- I understand that if there is any deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation.
- I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study.
- 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 of ethics clearance.
- I will submit progress reports/reports of adverse events and side effects as requested by the ERC of the Faculty of Allied Health Sciences.

…….. Date: ___ /____/_____
Signature of Principal Investigator

Full name of Principal Investigator: …….

Consent from all Investigators

We, the undersigned hereby confirm that we have consented to be co investigators of the project titled: ……

Name	Qualifications	Institutional Affiliations	Signature

Acknowledgment (*Office use only)*

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

Application No ……. Date received ____/____/_____

Version :……
Thank you for submitting the above research proposal. The proposal has been assigned the protocol number stated above. It will be considered by the Ethics Review Committee at its meeting on …… and will be assigned to two principal reviewers. The ERC may contact you in due course if any clarifications; additional documentation; or revisions are required.

Secretary /ERC, FAHS