ETHICS REVIEW COMMITTEE
Faculty of Health-Care Sciences
Eastern University, Sri Lanka

Application No: _____ **Date Received:** _____

ERC Meeting date: _____ **Date informed:** _____

Decision: _____

Names of the Reviewers: 1_____

2_____

(For office use only)

APPLICATION FORM FOR HUMAN RESEARCH

This form should be preferably filled online or hand written and signed by the principal investigator who request ethical approval for a research project involving Human Subjects.

The spaces in this form are expendable as you type online.

When fill the application, please read the instructions carefully and ensure all necessary documents as per the document checklist are submitted.

PART I (ADMINISTRATIVE DETAILS)

1. **Title of Research Project :**

2. **Details of Principal Investigator :**

Title (Prof/Dr/Mr/Ms) & Name	
Current designation:	
Affiliation:	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

3. **Is this study a requirement for a postgraduate degree?** Yes ☐ No ☐

If yes,

Type of degree (PhD/MD/M.Phil./MSc/other.)	
Awarding of University	
Date of Registration :	

4. **Are there supervisors for this project?** Yes ☐ No ☐

If yes, give the details of the supervisors

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

** Please append additional pages with Supervisors names if necessary*

5. Are there Co-investigators for this project? Yes ☐ No ☐

If yes, give the details of the Co-Investigators

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no.:	
e-mail:	

Title (Prof/Dr/Mr/Ms) & Name	
Department (or organization if not affiliated with FHCS/EUSL)	
Highest educational qualification:	
Postal address:	
Phone no. :	
e-mail:	

**Please append additional pages with Co-Investigators names if necessary*

******Please note that short curriculum vitae of all investigators should be attached with the application***

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

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), it is the responsibility of the researcher to obtain approval prior to starting the research.

Type of study sites (Hospital/Clinic/School/Community, etc.)	**Details**

7. Has ethical approval for this study been requested from ERC / FHCS or another similar committee?

Yes ☐ No ☐

If yes, give the details (names of committees and outcome of review)

Please note that for the studies sponsored by foreign funding agencies or sponsors ethics review and approval is required from the country of the funding agency or the sponsor.

8. Scientific review

Has this research proposal been subjected to scientific review by any other committee?
(Eg: Board of study, Research committee, Higher degree committee etc.)

Yes ☐ No ☐

If yes, give the details (names of the committees and outcome of the review)

9. Funding of this Project :

Funding Status	**Name and address of funding Source(s) and Amount**
Funded	Agency : Total Budget : LKR
Applied for funding	Agency : Total Budget : LKR

10. Proposed dates of research commencement and completion that involves human participants or data for this project *†

Date of Commencement: | | Date of Completion: | |

** From initial recruitment of participants until completion of all data collection*
† Retrospective approval will not be given for projects already started or completed

11. For Clinical trials only

11.1. What phase of clinical trial is being conducted?

- Phase I ☐
- Phase II ☐
- Phase III ☐
- Phase IV (post marketing) ☐
- OTHER ☐

If OTHER specify

11.2. Have you got GCP training (Good Clinical Practice)?

Yes ☐ No ☐

**If yes, please attach a copy of GCP training certificate.*

11.3. Is the clinical trial, registered in Sri Lanka Clinical Trial Registry (SLCTR)?

Yes ☐ No ☐ Pending ☐

If YES, give details (name of register and registration number)

**Please attach the approval letter of clinical trial registry*

If NO, give reasons

11.4. Has this study been approved by the SCOCT (Subcommittee on clinical trials) of the Ministry of Health

Yes ☐ No ☐ Pending ☐

If YES, give details of approval number

**Please attach the supportive document*

If NO, give reasons

11.5. Data Safety Monitoring Board (only if available)

Name and Designation of Members	Role

**Please attach the curriculum vitae of all members of the DSMB.*

11.6. Details of indemnity and insurance coverage for participants, investigators and ethics committee

PART II (RESEARCH PROPOSAL)

For official use

Application No:

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

12.1	Collaborative Partnership	Applicable		Section & Page in Protocol	Reviewer's Comments
		Yes	No		
1.	The collaborations you have established with institutions where the study is to be conducted	☐	☐		
2.	The collaborations you have established with community where the study is to be conducted	☐	☐		
3.	The benefits to institutions, communities, and participants in your research	☐	☐		

12.2	Social Value	Applicable		Section & Page in Protocol	Reviewer's Comments
		Yes	No		
1.	The beneficiaries of your research and the benefit to them	☐	☐		
2.	The plan for dissemination of study findings	☐	☐		

12.3	Scientific Validity	Applicable		Section & Page in Protocol	Reviewer's Comments
		Yes	No		
1.	The scientific importance of your study in relation to improving health care and/or knowledge on the subject.	☐	☐		
2.	The justification for a replication study, if your study is a replication study.	☐	☐		
3.	How the sample size was calculated	☐	☐		

12.4	Confidentiality	Applicable		Section & Page in Protocol	Reviewer's Comments
		Yes	No		
1.	How the data and sample will be obtained	☐	☐		

2.	How long data and sample will be kept	☐	☐		
3.	Justification for a collection of personal identification data	☐	☐		
4.	Who will have access to the personal data of the research participants	☐	☐		
5.	How the confidentiality of participants will be ensured	☐	☐		
6.	The procedure for data and sample storage	☐	☐		
7.	The procedure for data and sample disposal	☐	☐		

12.5	**Right of the Participants**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	Procedure for subjects to withdraw from the research at any time	☐	☐		
2.	Procedure for subjects to ask questions and register complaints	☐	☐		
3.	The contact person for research subjects	☐	☐		
4.	Provision for participants to be informed of results	☐	☐		
5.	Provision to make the study product available to the study participants after research	☐	☐		

12.6	**Fair participant selection**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The justification for the selection of the study population	☐	☐		
2.	The inclusion and exclusion criteria	☐	☐		

12.7	**Responsibilities of the Researcher**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The provision of medical services to research participants	☐	☐		
2.	The provision for continuation of care after the research is completed	☐	☐		
3.	Declaration of conflicts of interests and how the investigators plan to manage the conflicts	☐	☐		

4.	The ethical/legal/social and financial issues relevant to the study	☐	☐		

12.8	**Vulnerable Populations**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	Justification for conducting the study in this population	☐	☐		

12.9	**Research funded by Foreign Agencies / Companies**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		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.	The steps taken to take to take into account cultural and social customs, practices, and taboos in Sri Lanka	☐	☐		
5.	The sharing of rights to intellectual property	☐	☐		
6.	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	☐	☐		
7.	How the results of research will be conveyed to relevant authorities in Sri Lanka	☐	☐		
8.	The agreement between the sponsor/funding agency and the investigator	☐	☐	Please Attach	
9	The materials transfer agreement, if biological material is to be transferred abroad	☐	☐	Please Attach	

12.10	**Community Based Research**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	The impact and relevance of the research on the community in which it is to be carried out	☐	☐		
2.	The steps taken to consult with the concerned community during the design of the research	☐	☐		
3.	The procedure used to obtain community consent	☐	☐		

4.	The contribution to capacity building of the community	☐	☐		
5.	The procedure for making available results of research to the community	☐	☐		

12.11	**Clinical Trials**	**Applicable**		**Section & Page in Protocol**	**Reviewer's Comments**
		Yes	**No**		
1.	Justification for withdrawing any therapy from participants to prepare them for the trial	☐	☐		
2.	Justification for withholding standard therapy from trial participants (eg. Control group)	☐	☐		
3.	Justification for providing care which is not the standard of care	☐	☐		
4.	Procedure for dealing with adverse events	☐	☐		
5.	Procedure for reporting adverse events	☐	☐		
6.	Provisions for safety monitoring	☐	☐		
7.	Provisions / criteria for termination of the trial	☐	☐		
8.	Provisions for making the trial drug available to participants after the trial if found to be effective	☐	☐		

12.12	**Information Sheet (IFS) / Informed Consent Form(ICF) Check List** *(The following list of sections should be included in the IFS / ICF)*	**Applicable**		**Section IFS/ICF**	**Reviewer's Comments**
		Yes	**No**		
1.	Purpose of the study	☐	☐		
2.	Voluntary participation	☐	☐		
3.	Duration, procedures of the study and participant's responsibilities	☐	☐		
4.	Potential benefits	☐	☐		
5.	Risks, hazards and discomforts	☐	☐		
6.	Reimbursements	☐	☐		
7.	Confidentiality	☐	☐		
8.	Termination of study participation	☐	☐		

12.13	Consent	Applicable		Section & Page in Protocol	Reviewer's Comments
		Yes	No		
1.	The Procedure for initial contact of participants *	☐	☐		
2.	The Procedure for obtaining informed consent (Verbal)	☐	☐		
	The Procedure for obtaining informed consent (Written)	☐	☐		
3.	The information (written/oral) provided to participants	☐	☐		
4.	The procedure for ensuring that subject have understood the information provided	☐	☐		
5.	The Procedure for obtaining proxy consent	☐	☐		
6.	The Procedure for withdrawing consent.	☐	☐		
7.	Incentives/reward/compensation provided to participants.	☐	☐		
8.	The Procedure for re – consenting if the research protocol changes during the course of research.	☐	☐		
9.	The Procedure for consenting, if vulnerable groups/children under 18 years of age are being recruited	☐	☐		
10.	The Procedure for consenting, if children aged 12 -18 years of age being recruited. (For children aged 12 – 18 years, in addition to the parental consent, children's assent must be sought)**	☐	☐		

*** Attach a copy of all posters, advertisements, flyers, and letters to be used for recruitment**
**** Attach an assent form for children aged 12 – 18 Years**

12.14	Data Collection	Applicable		Section & Page in Protocol	Reviewer's Comments
		Yes	No		
1.	The procedure to be carried out on these subjects (**details of all study instruments** to be used in collection of samples/blood/application of tests/administration of drugs etc,)	☐	☐		

13. Experience of investigators with this kind of research

Please provide a brief description of previous experience with this type of research by either principal investigator or the research team or 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.

PART III (DESCRIPTION OF THE RISKS AND BENEFITS)

14. Possible Risks

14.1.Please indicate all potential risks to participants that may arise from this research.

1. Physical risks (E.g. any bodily contact or administration of any substance) Yes ☐ No ☐
2. Psychological/emotion risks (E.g. feeling uncomfortable, embarrassed, upset) Yes ☐ No ☐
3. Social risks (E.g. loss of status, privacy and/or reputation) Yes ☐ No ☐
4. Legal risks (E.g. apprehension or arrest, subpoena) yes ☐ No ☐

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

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

15. Possible Benefits

15.1. Describe any potential direct benefits to participants from their involvement in the project

15.2. Describe any potential direct benefits to the community (e.g. capacity building)

15.3. Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

16. Compensation

16.1. Will participants receive compensation for participation?

1. Financial Yes ☐ No ☐
2. In-kind Yes ☐ No ☐
3. Other Yes ☐ No ☐

16.2. If **yes**, please provide details and justification for the amount or the value of the compensation offered.

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

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

17. 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.)

18. Do you think that the project has a Conflict of Interest?

18.1. Commercially

18.2. Financially

18.3. Intellectually

18.4. Other (Explain)

19. 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:

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

21. 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 approved I must submit an amendment to the ERC for approval prior to its implementation.
- I have submit all significant previous decisions by this or any 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 FHCS/EUSL.**
- I will submit the final reports at the completion of the study.

……. **Date:** ……../……./……..

Signature of Principal Investigator

Full Name of Principal Investigator:……

22. **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**

PART IV CHECK LIST (Please mark all documents submitted)

CHECK LIST			To be marked by the applicant	To be marked by ERC office
One copy each of the following				
1	Covering letter signed by the applicant		☐	☐
2	Letter from supervisor (If relevant)		☐	☐
3	Bank receipt		☐	☐
4	Copy of approval letter from Board of Study (for postgraduate student only)		☐	☐
5	Curriculum Vitae of all the investigators		☐	☐
6	Letter signed by all the investigators confirming their participation.		☐	☐
Three copies each of the following				
7	Completed application form		☐	☐
• *The following documents (where relevant) must be submitted.* • *They must be stapled or bound together to form 3 completes sets of documents.* • *All documents must the carry the Title and Version Number as a header (E.g. Version I)*				
8.	Proposal		☐	☐
9.	Study Instruments	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐

10.	Information Sheet	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
11.	Consent Forms	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
12.	Assent Forms	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
13.	Advertisement for Recruitment	English	☐	☐
		Tamil	☐	☐
		Sinhala	☐	☐
14.	12 Copies of summary sheet of the proposal			
15.	Email a complete set of all documents submitted (include of copy of your application, protocol, instruments and forms in all languages) as pdf files to erc.fhcs@esn.ac.lk at the time of submission.		☐	☐

**Your application will not be processed until all required documents are received by the ERC office*.

……. Date:…….
……./……./……..
Signature of Principal Investigator
(E-Signatures are not accepted)

REVIEWERS' REPORT

Recommendation: Approve ☐

Reject ☐

Conditional approval (*please state the condition*) ☐

Reviewers' overall comments:

Reviewer:……..Signature:……..Date:……

(For office use only)

PART V: DOCUMENT RECEIPT CHECKLIST

For office use

Application No: ☐

This receipt will be handed over to the applicant by the ERC / FHCS member accepting the application.

The ERC confirms that the following documents were handed in by the applicant:

1. Duly filled Application form ☐
2. Covering letter signed by the applicant ☐
3. Letter from supervisor (If relevant) ☐
4. Bank receipt ☐
5. Copy of approval letter from Board of Study (for postgraduate student only) ☐
6. Approval letter to conduct the study from different institution (if relevant) ☐
7. Curriculum Vitae of all the investigators ☐
8. Letter signed by all the investigators confirming their participation. ☐
9. Project Proposal ☐
10. Study Instruments ☐
11. Information Sheet ☐
12. Consent Forms ☐
13. Assent Forms ☐
14. Advertisement for Recruitment ☐
15. Indemnity / Insurance coverage (for clinical trial) ☐
16. Summary of the proposal (Flow chart / for clinical trial) ☐
17. GCP training certificate ☐
18. Brief CVs of all investigators ☐
19. CVs of all DSMB members ☐

The application number appearing on top of this page has been assigned to this application. Please quote the number in all correspondence with the committee.

…… ……

Authorized Signatory for ERC Date