ETHICS REVIEW COMMITTEE
Faculty of Health-Care Sciences
Eastern Universitv. Sri Lanka

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

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

Decision: _____

Name of the Reviewer: _____

(For office use only)

APPLICATION FORM – UNDERGRADUTE HUMAN STUDIES ONLY

This form should be filed and signed by the students and supervisors investigator who requests ethical approval for a UNDERGRADAUTE research project involving **human subjects**. Please read the **guidelines for application** before completing the form and ensure all relevant documents checklist are submitted. Students must obtain approval from their respective department/units **before** applying for ethical clearance and the application must be forwarded with the signature of the head of the department.

All undergraduate studies are exempt from payment of administration fee.

CHECK LIST (Please mark all documents submitted)

One copy each of the following			
1. Covering letter signed by the Student applicants	☐		
2. Letter from supervisor(S)	☐		
3. Email a complete set of all documents submitted (include one copy of your application, protocol, instruments and forms in **all languages**) as a single pdf file to erc_fhcs@esn.ac.lk at the time of submission	☐		
Two(2) copies of the following documents			
Documents		**Date**	**Version**
4. Application form	☐		
5. Research proposal	☐		
6. Study instruments	☐ English ☐ Sinhala ☐ Tamil		
7. Informed consent form	☐ English ☐ Sinhala ☐ Tamil		
8. Assent form	☐ English ☐ Sinhala ☐ Tamil		
9. Advertisement for recruitment			

PLEASE NOTE :

The two copies of the documents submitted must be stapled or bound together to form 02 complete sets of documents.
All documents must carry the date and version number as a header/footer.
Your application will not be processed until required documents are received by the ERC office.

This form can be filled in and the spaces provided are expandable as you type.

PART 1 (Administrative details)

1. **Course: MBBS** ☐ **Nursing** ☐
2. **Title of Research Project:**
3. **Details of principal investigator(s):**

Surname with initials	Registration number	Contact number

Please append additional pages with investigators names if necessary

4. **Provide contact details for one of the principal investigators:**

Name:	
Mailing address:	
Phone:	e-mail:

5. **Details of Supervisors:**

Tittle:	Name:
Department (or organization if not affiliated with FHCS/EUSL):	
Highest educational qualification:	
Mailing address:	
Phone:	e-mail:

Tittle:	Name:
Department (or organization if not affiliated with FHCS/EUSL):	
Highest educational qualification:	
Mailing address:	
Phone:	e-mail:

Please append additional pages with supervisors' names if necessary

6. **Location(s) where the research will be conducted:**
   6.1 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 researchers to obtain approval prior to starting the project. Please note some hospitals have their own ethics committee from which you will need to obtain approval.

Type of Site (hospital/clinic/school/university/community,etc.)	**Details**

6.2 Will samples/tissue/date collected during the be removed from the above study site/transported to different site for investigation etc. Yes No ☐ ☐

7. Other research ethics board approval(s):

7.1 Has any other ERC approved this Project? Yes ☐ No ☐

If Yes, please provide details: and a copy of the approval letter.

8. Funding of the project:

Funding Status	Source and amount
Funded ☐	Agency : Total Budget : SLR
Applied for funding ☐	Agency : Total Budget : SLR
Unfunded ☐	

PART II (Research Proposal)

9. Project start and end dates:

Estimated start date that involves human participants or data:

Estimated completion date of involvement of human participants or data for this project:

10. Objective of the project and justification:

Describe the objectives and rationale for the proposed project. The rationale doing the study must be clear. Please include references in this section.

10.1 General objective:

10.2 Specific objectives:

10.3 Justification (A clear justification should be given for investigating human subjects)

11. Methodology:

11.1 Clearly state the study design (for all phases of the project)

11.2 Give a brief description of the methodology for all phases of the project (include flow charts whenever required to improve clarity)

12. Description of the procedure involving human subjects (for which ethical clearance if being sought) DO NOT LEAVE BLANK Section 12 – 20 must be filled for ALL projects unless exclusively records based

12.1 Who are the study subjects and what are the criteria used in the selection of subjects. (inclusion and exclusion criteria):

12.2 How will they be selected for the study (describe the sampling procedure)

12.3 Sample size: How many subjects will be recruited/sampled, include justification for The sample size calculation

13 Recruitment of participants:

13.1 How will informed consent be elicited ? Verbal ☐ or Written ☐

13.2 Describe the consent procedure (who will obtain consent and how) :

Describe the process that you will use to obtain informed consent. Please note, it is the quality of the consent not the format that is important: if there will be no written consent form, please explain why (e.g, if culturally inappropriate) If the research involves extraction or collection of personal information, please describe how consent from the individuals will be obtained. If relevant, describe any translation of recruitment materials, how this will occur and whether or not those people responsible for recruitment will speak the language of the participants.

- **Attach a copy of all posters, advertisements, flyers, letters, to be used for recruitment.**

13.1 Are there any individuals with special considerations such as vulnerable groups/children under 18 years of age being recruited, if so how will consent be sought from them?

13.2 Does the study subjects include children aged 12 – 18 years? Yes ☐ No ☐
If yes, for children aged 12 – 18 years in addition to parental consent, children's assent must be sought. How will this be arranged?

Please attach an assent form for children aged 12 – 18 years Attached ☐

14. Data Collection:

14.1 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):

PART III (Description of the risks and benefits)

15. Possible Risks:

15.1 Please indicate all potential risks to participants that may arise from this research:

I. Physical risks (e.g.,any bodily contact or administration of any substance): Yes ☐ No ☐

II. Psychological/emotional risks (feeling uncomfortable, embarrassed, upset) Yes ☐ No ☐

III. Social risks (e.g., loss of status, privacy and/or reputation): Yes ☐ No ☐

IV. Legal risks (e.g., apprehension or arrest, subpoena): Yes ☐ No ☐

15.2 Please briefly describe each of the risks noted above

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

16. Possible Benefits:

- Describe any potential direct benefits to participants from their involvement 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.

17. Compensation:

17.1 Will participants receive compensation for participation?

Financial Yes ☐ No ☐ In – kind Yes ☐ No ☐

Other Yes ☐ No ☐

17.2 If **Yes**, please proved details and justification for the amount or the value of the compensation offered.

17.3 If **No**, please explain why compensation is not possible or appropriate.

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

18. 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)

19. Data Security, Retention and Access:

19.1 Describe the provisions that will be made to protect confidentiality of data: Describe how data (including written records, video/audio recordings, artifacts and questionnaires) will be protected during the conduct of the research and dissemination of results.

19.2 Describe the procedures to be used to protect the confidentiality of participants and any limitations to protecting the confidentiality of participants whether due to the law, the methods used, or other reasons (e.g., a duty to report).

19.3 If data will be shared with other researchers or users, please describe how and where the data will be stored and any restrictions that will be made regarding access.

20. Conflicts of Interest:

20.1 Will the researcher(s), members of the research team, and/or partners or immediate family members: receive any personal benefits (e.g., financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection with this study? Yes ☐ ☐

20.2 If **Yes**, please describe the benefits below. (Do not include conference and travel expense coverage, or other benefits which are considered standard for the conduct of research)

Declaration of applicant

As a 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/animal participants. I understand that if there is any significant 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 of adverse events and side effects as requested by the ERC, FHCS/EUSL

Signature of students	Surname with Initials	Date:

Declaration of the Supervisor(s)

As the supervisor on this project, my signature testifies that I have reviewed and approve the scholarly merit of the research project and this ethics protocol submission. I will provide the necessary supervision to the student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with University, provincial and national policies and regulations that govern research involving human subjects. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the supervisor.

Signature of Supervisor	Surname with Initials	Date:

Declaration of the head of the Department

As the Head of the Department of …….. my signature testifies that I am aware of the proposed activity, and have approved the proposed methodology of the study. My department will oversee the conduct of research involving human subjects to ensure compliance with University, provincial and national policies and regulations.

Signature of the head of the Department and stamp:

Date: ……

REVIEWERS' REPORT

Recommendation: Approve ☐

Reject ☐

Conditional approval (*please state the condition*) ☐

Reviewers' overall comments:

Reviewer:……..Signature:……..Date:……

(For office use only)