RESEARCH ETHICS REVIEW COMMITTEE

Faculty of Allied Health Sciences
University of Sri Jayewardenepura

Application No :[ ] **Date received ____/____/_____**
Version : [ ]

Course : Nursing /MLS/B.Pharm/Optometry/other : ……..

Office use only

APPLICATION FORM – UNDERGRADUATE HUMAN STUDIES ONLY

This form should be filled 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 as per the document checklist are submitted. Students must obtain approval from their respective departments/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. Sumit the soft copy to the department (include one copy of your application, protocol, instruments and forms in **all languages)** as a **single** *pdf* file to at the time of submission ☐

Four(4) copies of the following documents

Document		**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 all required documents are received by the REC office.

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

PART 1 (Administrative details)

1. Course : Nursing ☐ B.Pharm ☐ MLS ☐ Optometry ☐ other :

2. Title of Research Project:

3. Details of principal investigator(s)

Surname with initials	FMSR/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

Title:	Name:
Department (or organization if not affiliated with FMS/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. 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/community,etc.)	Details

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

If so provide details of these sites

7. Other research ethics board approval(s)

7.1 Has any other REC approved this project? Yes ☐ No ☐

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

8. Funding of this project

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

PART 11 (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 for 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 humansubjects (for which ethical clearance if being sought) DO NOT LEAVE BLANK sections 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.**

13.3 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

13.4 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 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

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 provide 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 their 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 ☐ No ☐

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 REC for approval prior to its implementation. I have submitted all significant previous decisions by this or any other REC 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 FMS/SJP.

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 : - - - - - - - - - - - - - - - - -