ETHICS REVIEW COMMITTEE
Faculty of Science
University of Kelaniya

For office use only

Application No : ___ /__ / _____ **Date received ____/____/_____**
Version :

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

Names of the reviewers:
1.
2.
3.

Decision of the ERC Faculty of Science, Univ. of Kelaniya:

Annex II – STUDIES INVOLVING HUMAN SUBJECTS

The application for ethical clearance should be completed and signed by the principal investigator of the study involving HUMAN SUBJECTS. Please read the **instructions carefully before completing the application** and ensure all relevant documents are included in the application to avoid any delays in processing the application.

CHECK LIST (Mark all included documents)

One copy each of the following

1.	Cover letter signed by the applicant	☐
2.	Proof of processing fee payment	☐
3.	A letter of verification/ certificate(s) of training by the investigator(s) Biosafety & Research ethics	☐

3 copies of the following documents

		Date	Version	
4.	Application form			☐
5.	Annex II (Human Studies)			☐
6.	Patient Information Sheet			
	English			☐
	Sinhala (If relevant)			☐
	Tamil (If relevant)			☐
7.	Informed Consent Form			
	English			☐
	Sinhala (If relevant)			☐
	Tamil (applicable)			☐
8.	Data sheet/ Questionnaire			☐

9.	Material Transfer agreement (if applicable)	☐
10.	**Email** documents submitted (copy of signed cover letter, application form, Annex II, letter of verification/ certificate(s) of research involving human subjects, Biosafety (if applicable) and Research ethics training**,** Patient information sheet, Informed Consent form, Data Sheet as *pdf* file to erc.fs.@kln.ac.lk at the time of submission	☐

NOTE:
All documents must carry the date and version number as a header. Your application will not be processed until all required documents are received by the ERC office.

PART I (General Information)

1. Title of Research Project:

2. Principal Investigator(s): (A **principal investigator** (PI) is the holder of an independent grant administered by a university and the lead researcher for the grant **project**, usually in the sciences, such as a laboratory **study** or a clinical trial.)

Name (Prof./Dr./Mr/Ms):	
Designation (Prof., Senior lecturer, Research officer etc.,)	
Name and address of institution where the applicant is attached:	
Highest educational qualification:	
Mailing address if different from above	
Phone	E mail

3. Location(s) where the research will be conducted:
Clearly mark N/A to indicate where not applicable.

3.1 All study sites including laboratories, clinics and other institutions

Location	Type of site (laboratory/ clinic etc)

4. Investigator(s) training to conduct the study including Biosafety (if relevant) and Research ethics

4.1 Have all the investigators in this study involved in the study undergone the necessary training? Yes ☐ No ☐

Specify all training received:

Name of investigator	Training Program/ Institution	Duration	Type of training received

5. Ethical review

5.1 Has ethical review for this study been requested earlier from this Ethics Review Committee?
* *Attach documentary evidence* Yes ☐ No ☐

If Yes,

Reference number	
Decision	
Date	

5.2 Has ethical review for this study been requested from any other Ethics Review Committee?
Yes ☐ No ☐

If Yes,

Reference number	
Decision	
Date	

5.3 Has this study been submitted to an ERC / similar body in the country/ countries of foreign collaborator/s? Yes ☐ No ☐

If Yes,

Reference number	
Decision	
Date	

6. Has this project been subjected to scientific review?

Yes ☐ No ☐

If Yes,

Name and address of the committee	
Decision	
Date	

7. Funding for the project

Funding Status	Source of funding	Budget (Rs.)
Funded ☐	Agency:	
Applied for funding ☐	Agency:	
Unfunded ☐		

If unfunded, justify why no funding is needed:

PART II (Research Protocol)

8. Project duration

Estimated start date:	
Estimated completion date:	

9. Summary of the research project

Provide brief background, objectives and the rationale of the project (maximum one page).

10. Background/ Introduction of the research project

Provide detailed background, objectives and the rationale of the project. Please include references in this section. (Use additional sheets)

11. Objective of the project and justification

Describe the objectives and rationale for the proposed project in brief. The rationale for doing the study must be clear. (Use additional sheets)

11.1 General objective

11.2 Specific aim(s):

11.3 Justification (A clear justification should be given for investigating in humans). Explain why the research cannot be carried out with non-human alternatives.

12. Methodology

Description of the procedures: Describe in detail all procedures and techniques to be used, **emphasizing those performed on humans**. Use flow charts to illustrate procedures as appropriate. Append additional page(s) if necessary. Include the following:

1. Study design
2. Study population
3. Sample size and calculation of sample size
4. Inclusion criteria
5. Exclusion criteria
6. Study instrument/s
7. Pilot study
8. Description of procedure(s)
9. Data collection (*Include Data Sheet/ Questionnaire Annex V*)
10. Data analysis
11. Dissemination of results

PART III (Clinical Trial/ Intervention)

For Clinical trial/ intervention studies only

13. Intervention study

13.1 What phase clinical trial/intervention study is being conducted?

Phase I ☐

Phase II ☐

Phase III ☐

Phase IV ☐

Others (Specify) ☐

13.2 Is the clinical trial registered with a clinical trial registry? Yes ☐ No ☐

Name of the clinical trial registry*:	

*Submit documentary evidence of approval from clinical trial registry when receive registration

14. Procedures and Drugs

14.1 Are there any administration of drugs/herbs/chemicals to the participants?

Yes ☐ No ☐

If Yes, specify for each agent (append additional pages if necessary):

Amount of agent and dosage	
Route of administration	
Potential health risks	
Special requirement(s)	
Precautions to be taken by personnel (including staff)	

14.2 Criteria for termination of participants from the trial:

14.3 Criteria for termination of the trial:

14.4 Justification for withholding/ withdrawing standard therapy:

14.5 Provision for making the trial drug available after completion of the trial:

PART IV (Biological Samples)

For studies involving biological samples only

15. Biological Samples

Complete this section regarding handling and disposal of biological samples if applicable

15.1 Justify the use of biological sample(s)

15.2 Provide procedure(s) for collection, storage and disposal of biological sample(s)

15.3 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 Yes, what is the fate of transferred data and biological/ genetic material?

15.4 Will samples/tissues collected during the study be taken out of the country for investigation or storage? Yes ☐ No ☐

If Yes, provide details:

a) Attach the material transfer agreement.
b) Describe the fate of the biological sample at the conclusion of the study.

15.5 Justify transfer of data and /or biological/ genetic materials to the country of foreign collaborator

PART V (Ethical Considerations)

16.Assessment of risks/ benefits

16.1 Are there any risks (physical, psychological) to participants in the study?

Yes ☐ No ☐

If Yes, identify them and state how you plan to prevent or minimize these risks.

16.2 Are there any benefits to the participants by participating in the study?

Yes ☐ No ☐

If Yes, what are the benefits?

16.3 Are there any risks to research team by conducting this study?

Yes ☐ No ☐

If Yes, identify the risks to the investigators and state the measures to be taken to prevent or minimize these risks.

16.4 What is the procedure for dealing with adverse events?

16.5 What are the provisions of safety monitoring and medical and psychological support to participants to ensure participant safety?

16.6 What is the procedure for reporting adverse events?

17. Sampling/ recruitment procedure

17.1 Does the study involve a vulnerable population?

Yes ☐ No ☐

If Yes, provide justification for including a vulnerable population for the study.

17.2 How do you plan to ensure fair participant selection?

17.3 What is the procedure for obtaining consent?

Enclose the Participant information sheet in English as well as Sinhala and Tamil if relevant, Informed consent form in English as well as Sinhala and Tamil if relevant.

14. Rights of the Participants

14.1 What is the procedure for the participants to leave the study?

Include details of the rights of the participants for voluntary participation and the right to refuse or withdraw without penalty (This statement must be included in the Participant information sheet and the Informed consent form.

14.2 What is the procedure for maintenance of data to ensure confidentiality?

(This statement must be included in the Participant information sheet and the informed consent form)

14.3 What is the fate of data to ensure confidentiality and ethical use of the data obtained? *(This statement must be included in the Participant information sheet and the informed consent form)*

15. Conflicts of Interest

15.1 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 ☐

15.2 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)

15.3 Are the participants paid?

Yes ☐ No ☐

If Yes, amount of money to be paid per participant?

15.4 Are the investigators paid?

Yes ☐ No ☐

If Yes, by whom and the amount to be paid?

15.5 Provide details of insurance coverage for participants (if any)

15.6 If Patient recruitment is not taking place in foreign collaborating institution explain why.

PART VI (Feasibility)

16. Experience of Investigators with this type of research

16.1 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. Include the CV of the investigators involved in the study with recent publications.

If there has not been previous experience, please describe how the principal investigator/research team will be trained.

17. 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 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/reports of adverse events and side effects as requested by the ERC FS/UoK.

…….. _ /____/_____

Signature of Principal Investigator Date

Full name of Principal Investigator:

…….. _ /____/_____

Name and Signature of Coinvestigator/collaborator Date

…….. _ /____/_____

Name and Signature of Coinvestigator/collaborator Date

…….. _ /____/_____

Name and Signature of Coinvestigator/collaborator Date

…….. _ /____/_____

Name and Signature of Coinvestigator/collaborator Date

…….. _ /____/_____

18. Acknowledgment

Name of Applicant: (Prof/Dr/Mr/Ms**)**
Title of study:

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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 three principal reviewers. The ERC may contact you in due course if any clarifications; additional documentation; or revisions are required.

Secretary
Ethics Review Committee FS/UoK

RISK MATRIX: VULNERABILITY AND RESEARCH RISK
Indicate the Risk Level for this project by checking the intersecting box

	Research Risk		
Group Vulnerability	**Low**	**Medium**	**High**
Low	1☐	1☐	2☐
Medium	1☐	2☐	3☐
High	2☐	3☐	3☐

Overall Risk Level :☐

Risk level= 1: Expedited Review; Risk level = 2 or 3: Full Board Review