Application for Ethical Review

For office use only

Application No:	KIU/ERC/2020	Date received	D	M	Y

	Initial submission		**Amendments**
	Resubmission		**Progress report**
	Continuing review		**Terminal/ Final report**

Names of the Reviewers:

Reviewer 1	
Reviewer 2	

Part I

1. **Title of the Project**

2. **Investigators**

2.1. Principal investigator

Name	
Qualifications	
Designation	
Official Address	
Telephone	
E-mail address	
Signature	

2.2. Other investigators

Name	
Qualifications	
Designation	
Official Address	
Telephone	
E-mail address	
Signature	

2.3. Other investigators

Name	
Qualifications	
Designation	
Official Address	
Telephone	
E-mail address	
Signature	

2.4. Other investigators

Name	
Qualifications	
Designation	
Official Address	
Telephone	
E-mail address	
Signature	

(If there are any more investigators please add their details)

2.5. Is the principal investigator affiliated to KIU? ☐ YES ☐ NO

2.6. Is/are any of the investigator/s affiliated to KIU? ☐ YES ☐ NO

If the answer to 2.6 is **NO**, please justify submitting your proposal to the Ethics review committee, KIU Battaramulla

3. **Nature of the research project**

3.1. Is this for a postgraduate degree? (Specify) ☐ YES ☐ NO

3.2. Is this an undergraduate research? (Specify) ☐ YES ☐ NO

3.3. Other (Specify)

3.4. Is this a clinical trial? ☐ YES ☐ NO

3.5. If clinical trial – Is it industry sponsored? ☐ YES ☐ NO

4. **Planned date of commencement and completion**

[From initial recruitment of participants until completion of all data collection]

Date of commencement:

Date of completion:

5. **Has ethical review for this study been requested earlier from this Ethics Review Committee?**

☐ YES ☐ NO

If yes,

Reference number	
Decision*	
Date	

6. **Has ethical review for this study been requested from any other Ethics Review Committee?**

☐ YES ☐ NO

If yes,

Reference number	
Decision *	
Date	

* Attach documentary evidence

7. **Funding**

7.1. Is the funding agency within Sri Lanka? ☐ YES ☐ NO

Name and address of funding agency		
Amount		

7.2. Do the study subjects have to incur any expenses by being participants in the study?

☐ YES (Specify) ☐ NO

8. **Collaborative research**

8.1. List the collaborating institutes and its role

	Institution	Recruitment	Lab facility	Logistics	Intellectual	Any other
1.						
2.						
3.						

* Attach documentary evidence

8.2. Has this study been submitted to an ERC / similar body in the country/ countries of foreign collaborator/s? ☐ YES ☐ NO

If yes,

a)

Name and address of the committee	
Decision *	
Date	

b)

Name and address of the committee	
Decision *	
Date	

c)

Name and address of the committee	
Decision *	
Date	

If no, give reason/s

* Attach documentary evidence

8.3. What is the relevance of this study to Sri Lanka?

8.4. Are biological samples to be transferred abroad?

☐ YES ☐ NO

If yes,

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

9. **Intervention study/ to be filled if conducting a clinical trial**

9.1. What phase clinical trial/intervention study is being conducted?

Phase II ☐

Phase I ☐

Phase III ☐

Phase IV ☐

Others (Specify) ☐

9.2. Is the clinical trial registered with a clinical trial registry (CTR)?

In which CTR this will be registered?

Name of the registry	

Submit documentary evidence of approval from CTR when you receive registration.

9.3. Is it a multicenter trial? ☐ YES ☐ NO

If yes, list the other centers.

Country	Center	ERC	Date

***Has ethical approval obtained from relevant bodies?**

9.4. What is the procedure for dealing with adverse events?

9.5. What is the procedure for reporting adverse events?

* Attach documentary evidence

9.6. What is / are the criteria for termination of the trial?

9.7. Are the participants paid? ☐ YES ☐ NO

If yes, amount of money per participant?

9.8. Are the investigators paid? ☐ YES ☐ NO

If yes, by whom and the amount?

10. **Details of insurance coverage for participants**

11. **. If Participant recruitment is not taking place in foreign collaborating institution explain why.**

12. **Potential conflict of interest (if any)**

Part II – Protocol Checklist

Title of the Project: -

		Page No.	**Checked**
1	Title		
2	Summary of the project		
3	Introduction/ background		
4	Objectives of the study		
5	Justification		
6	Review of literature		
	Methodology		
7	Study design		
8	Place of study		
9	Duration of the study		
10	Study population		
11	Sample size and calculation of sample size		
12	Inclusion criteria		
13	Exclusion criteria		
14	Study instrument/s		
15	Pilot study		
16	Sampling/ recruitment procedure		
17	Description of procedure		
18	Data collection		
19	Data analysis		
20	Maintenance and fate of data		
21	Dissemination of results		
	Ethical issues		
22	Assessment of risks/ benefits		
23	Procedure for obtaining consent		
24	Informed consent form		
25	Participants Information sheet		
26	Justification for including vulnerable population		
27	Fair participant selection		
28	Procedures to protect the rights of participants		
29	Confidentiality/Privacy		
30	Voluntary participation right to refuse or withdraw without penalty		
31	Safety monitoring		
32	Responsibilities of the researchers		
33	Provision of medical and psychological support to participants		

	Biological Samples		
34	Justification for using biological sample/s		
35	Procedures for collection, storage and disposal of biological		
36	Consent for collecting biological sample/s		
37	Protection of the rights of local collaborator		
38	Justification for transfer of data and /or biological/ genetic		
39	Fate of transferred data and biological/ genetic material		
	Clinical trial		
40	Criteria for termination of participants from the trial		
41	Criteria for termination of the trial		
42	Adverse event monitoring, management and reporting		

I understand that the application for ethics clearance will not be accepted unless all necessary documents are submitted. I declare that I am not seeking approval for a study that has already commenced or has already been completed.

Date:

Signature of the Principal Investigator:

Application submitting investigator: