Faculty of Medicine, General Sir John Kotelawala Defence University
Application for Ethics Review (Part I) – Basic Information

for official use

Application No:											Date Received:			/			/			
Reviewed By:											ERC Meeting Date:			/			/			
Decision:											Date Informed:			/			/			

1. Title of Project

2. Investigators

Applications from investigators based overseas will only be considered if the project is done in collaboration with investigators based in institutions in Sri Lanka who take equal responsibility for the conduct of the study and who will appear as co-authors in any publication arising out of the study.

Title, Name and Designation of Investigators	**Role**
	Principal Investigator

Please note that a short curriculum vitae of all investigators should be attached to the application.

3. Contact Details of the Principal Investigator

Address:	
Telephone numbers:	
Fax number:	
Email address:	

4. Funding

Name and Address of Funding Source(s)	Amount

5. Proposed starting and ending dates: *‡

Start Date ____ End Date ____

*From initial recruitment of participants until completion of all data collection.

‡Retrospective approval will not be given for projects already started or completed.

6. Has ethics approval for this study been requested earlier from KDU/ERC or another similar committee?

Yes ☐ No ☐

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

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

7. Scientific review

Has this research proposal been subjected to scientific review by any other committee?

Yes ☐ No ☐

If yes, give details (names of committees and outcome of review)
What is the name of the committee?

8. Clinical trials

8.1. What phase clinical trial is being conducted?

Phase I	☐
Phase II	☐
Phase III	☐
Phase IV (post marketing)	☐
Other	☐

If OTHER specify:

8.2. Is it a multicentre trial?

Yes ☐ No ☐

If yes, list the other trial sites

Please attach ethics approval from the sponsoring country or country of the overseas principal investigator (if any)

8.3. Is the clinical trial registered with a clinical trials registry?

Yes ☐ No ☐

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

8.4. Data Safety Monitoring Board (only if available)

Name and Designation of Members	Role

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

8.5. Details of Indemnity and Insurance coverage for participants, investigators and ethics committee

9. Conflict of Interest

9.1. Do you believe this project has a Conflict of Interest:

Commercially

Financially

Intellectually

Other (explain)**:**

9.2 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:

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

Faculty of Medicine, General Sir John Kotelawala Defence University

Ethics Review Application (Part II) - Protocol Checklist

for official use

Application No: ☐☐☐☐☐☐☐☐☐☐

1. Title of Protocol

2. Name of Principal Investigator

3. A List of Documents Submitted for Review

Title of Document	Version	Date

4. Protocol Checklist

Please indicate the following:

Collaborative partnership		**Applicable**		**Protocol Section Number**	**Reviewer checked**
		Yes	**No**		
1.	The collaborations you have established with institutions where the study is to be conducted	☐	☐		
2.	The collaborations you have established with the community where the study is to be conducted	☐	☐		
3.	The benefits to institutions, communities, and participants in your research	☐	☐		

Reviewers' comments:

Social Value		**Applicable**		**Protocol Section Number**	**Reviewer checked**
		Yes	**No**		
1.	The beneficiaries of your research and the benefit to them	☐	☐		
2.	The plan for dissemination of study findings	☐	☐		

Reviewers' comments:

Scientific Validity		**Applicable**		**Protocol Section Number**	**Reviewer checked**
		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	☐	☐		

Reviewers' comments:

Assessment of Risks/Benefits		**Applicable**		**Protocol Section Number**	**Reviewer checked**
		Yes	**No**		
1.	The risks to research subjects	☐	☐		
2.	Benefits to research subjects	☐	☐		
3.	Steps taken to minimize risks	☐	☐		
4.	Steps taken to enhance benefits	☐	☐		
5.	Justification of the potential benefits against the risks	☐	☐		
6.	Support provided to the research participants (medical, psychological and other)	☐	☐		

Reviewers' comments:

Consent		Applicable		Protocol Section Number	Reviewer checked
		Yes	No		
1.	The procedure for initial contact of participants	☐	☐		
2.	The procedure for obtaining informed consent	☐	☐		
3.	The information (written/oral) provided to participants	☐	☐		
4.	The procedure for ensuring that subjects have understood the information provided.	☐	☐		
3.	The procedure for obtaining proxy consent.	☐	☐		
4.	The procedure for withdrawing consent.	☐	☐		
5.	Incentives/rewards/compensation provided to participants.	☐	☐		
6.	The procedure for re-consenting if the research protocol changes during the course of research.	☐	☐		

Reviewers' comments:

Confidentiality		Applicable		Protocol Section Number	Reviewer Checked
		Yes	No		
1.	How the data and samples will be obtained	☐	☐		
2.	How long data and samples will be kept	☐	☐		
3.	Justification for 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	☐	☐		

Reviewers' comments:

Rights of the participants		Applicable		Protocol Section Number	Reviewer Checked
		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.	Provisions for participants to be informed of results	☐	☐		
5.	Provision to make the study product available to the study participants after research	☐	☐		

Reviewers' comments:

Fair participant selection		Applicable		Protocol Section Number	Reviewer checked
		Yes	No		
1.	The justification for the selection of the study population	☐	☐		
2.	The inclusion and exclusion criteria	☐	☐		

Reviewers' comments:

Responsibilities of the researcher		Applicable		Protocol Section Number	Reviewer Checked
		Yes	No		
1.	The provision of medical services to research participants	☐	☐		
2.	The provisions 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.	☐	☐		

Reviewers' comments:

Vulnerable populations		Applicable		Protocol Section Number	Reviewer Checked
		Yes	No		
1.	Justification for conducting the study in this population	☐	☐		

Reviewers' comments:

Research funded by foreign agencies/companies		Applicable		Protocol Section Number	Reviewer Checked
		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 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	

Reviewers' comments:

Community based research		Applicable		Section in Protocol	Reviewer Checked
		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	☐	☐		

Reviewers' comments:

Clinical trials		Applicable		Section in Protocol	Reviewer Checked
		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 (e.g. 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.	Previsions for making the trial drug available to participants after the trial if found to be effective	☐	☐		

Reviewers' comments:

Information Sheet (IFS)/Informed Consent Form (ICF) Check List		Section IFS/ICF	Reviewer Checked
List the sections in IFS/ICF where you have dealt with the following:			
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		

Reviewers' comments:

Are the investigator's qualifications and experience appropriate to conduct the study? Yes ☐ No ☐

Recommendation:

Approve ☐

Conditional Approval (please state the conditions) ☐

Revisions (please state the contents to be revised) ☐

Reject ☐

……
……
……

Reviewers' comments:

Reviewer:…… Signature: …… Date:……./……./…….

Faculty of Medicine, General Sir John Kotelawala Defence University

Application for Ethics Review – Document Checklist

for official use

Application No: ☐☐☐☐☐☐☐☐☐☐

Application Checklist

I declare that I have attached the following documents (Please tick the check box and confirm). If any of the following sections are not relevant, please indicate N/A in the given space.

1. Application Form: Part I [2 copies] ☐ _____
2. Application Form: Part II [2copies] ☐ _____
3. The complete research protocol including a section on ethics considerations [3copies] ☐ _____
4. Information sheet for research participants (Should be provided in all three languages – Sinhala, Tamil, and English - if the participant is being interviewed or is filling up the form). [3 copies each] ☐ _____
5. Consent forms (Should be provided in all three languages: Sinhala, Tamil, and English). [3 copies each] ☐ _____
6. Data collection booklets/forms/questionnaires. (Should be provided in all three languages – Sinhala, Tamil, and English) [3 copies] ☐ _____
7. Clinical Trials Contract (required for clinical trials) ☐ ____
8. Materials Transfer Agreement (required for all research involving transfer of biological samples abroad) ☐ ____
9. Indemnity/Insurance coverage (required for clinical trials) ☐ ____
10. Ethics approval from sponsoring country or country of the overseas investigator (if any) ☐ _____
11. Brief curriculum vitae of all investigators [3 copies] ☐ _____
12. Curriculum vitae of all DSMB members [3 copies] ☐ _____
13. Soft copies of all documents (The documents should be in a compressed folder(zip/rar) have been submitted ☐ ____ via email to *ethicsreviewcommittee.fom@kdu.ac.lk*

**The above documents should be handed over to Secretary, Ethical Review Committee, Faculty of Medicine, KDU.*

Deadline for submission is first Thursday of each month for a new protocol and second Thursday for a re-submisision.

I understand that the application for ethics clearance will not be accepted unless all documents are submitted. 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 ethics clearance.

…… ……

Signature of Principal Investigator Date