Education with Character
SAITM
Faculty of Medicine
South Asian Institute of Technology and Medicine Ltd.
ETHICAL REVIEW COMMITTEE

For official use						
App. Num.						

South Asian Institute of Technology & Medicine – Faculty of Medicine

Application for Ethical Review

For official use						
Application Num.						
Reviewed By						
Decision						

For official use			
Date Received	|	|	| | |
ERC Meeting Date	|	|	| | |
Date Informed	|	|	| | |

1. Purpose of the study : ☐ Undergraduate ☐ Postgraduate ☐ Other,: _____
2. Title of Project

3. Investigators

#	Name	Designation of investigator	Role
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			

Attach brief CV of all investigators separately

4. Contact Details of the Principal Investigator

Address :	Contact Number :
	E-mail address :

5. Institute where the work will be carried out

6. Financial source(s)

Name	Address	Amount

7. 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.

8. Has ethics approval for this study been requested earlier from SAITM ERC or another similar committee?

Yes ☐ No ☐

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

9. Has this research proposal been subjected to scientific review?

Yes ☐ No ☐

10. Conflict of Interest

10.1. Do you believe this project has a Conflict of Interest?

Yes ☐ No ☐

If yes, give details

10.2. 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:

11. If this study is a Clinical Trial

Yes ☐ No ☐ If yes, ∗

12. Detailed project proposal under the headings of; ∗

(1) Title of the project
(2) Background
(3) Justification and rationale
(4) Objectives
(5) Methodology (Refer Annex 1)
(6) Ethical issues
(7) Time frame

13. Summary of the project proposal (Maximum of 650 words) ∗

∗11, 12 & 13: attach as a separate documents

Protocol Checklist

Please indicate the following

A	Collaborative partnership	Applicable Yes / No	Protocol section number	Reviewer Checked
1	The collaborations you have established withinstitutions where the study is to be conducted			
2	The benefits to institutions, communities, and participants in your research			

Reviewers' comments:

B	Social Value	Applicable Yes / No	Protocol section number	Reviewer Checked
1	The plan for dissemination of study findings			

Reviewers' comments:

C	Scientific Validity	Applicable Yes / No	Protocol section number	Reviewer Checked
1	The scientific importance of your study in relation to improving health care and / or knowledge of 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:

D	Assessment of Risks / Benefits	Applicable Yes / No	Protocol section number	Reviewer Checked
1	The risks to research subjects and steps taken to minimize risks			
2	Benefits to research subjects			
3	Justification of the potential benefits against the Risks			
4	Support provided to the research participants (medical, psychological and other)			

Reviewers' comments:

E	Consent	Applicable Yes / No	Protocol section number	Reviewer Checked
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.			
5	The procedure for obtaining proxy consent.			

Reviewers' comments:

F	Confidentiality	Applicable Yes / No	Protocol section number	Reviewer Checked
1	How the data and samples will be obtained			
2	Justification for collection of personal identification data			
3	How the confidentiality of participants will be ensured			
4	The procedure for data and sample storage			
5	The procedure for data and sample disposal			

Reviewers' comments:

G	Rights of the participants	Applicable Yes / No	Protocol section number	Reviewer Checked
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			

Reviewers' comments:

H	Fair participant selection	Applicable Yes / No	Protocol section number	Reviewer Checked
1	The justification for the selection of the study population			
2	The inclusion and exclusion criteria			

Reviewers' comments:

I	Responsibilities of the researcher	Applicable Yes / No	Protocol section number	Reviewer Checked
1	Declaration of conflicts of interests and how the investigators plan to manage the conflicts.			
2	The ethical /legal /social and financial issues relevant to the study.			

Reviewers' comments:

J	Vulnerable populations	Applicable Yes / No	Protocol section number	Reviewer Checked
1	Justification for conducting the study in this population			

Reviewers' comments:

K	Clinical trials	Applicable Yes / No	Protocol section number	Reviewer Checked
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 for making the trial drug available to participants after the trial if found to be effective			

Reviewers' comments:

✳ *IFS - Information Sheet / ICF - Informed Consent Form Check list*

L	List the sections in IFS / ICF where you have dealt with the following:	✳ Section IFS / ICF	Reviewer Checked
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	Confidentiality		
7	Termination of study participation		

Reviewers' comments:

Official use only:

Are the investigator's qualifications and experience appropriate to conduct the study?

Yes ☐ No ☐

Recommendation:

Approve ☐ Reject ☐ Conditional Approval ☐

Please state the conditions

Reviewers' comments:

Reviewer:		
	Signature	Date

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Document checklist

I declare that I have attached the following documents

(Please tick the check box and confirm)

1. Application Form: [2 copies] ☐
2. The detailed project proposal including a section on ethical considerations [2 copies] ☐
3. Information sheet for research participants in English and Sinhala or Tamil languages [2 copies each] ☐
4. Consent forms: Should be provided in all three languages (Sinhala, Tamil and English depending on the study population). [2 copies each] ☐
5. Data collection Booklets / Forms / Questionnaires: Should be provided in all three languages (Sinhala, Tamil, and English depending on the study population) [2 copies] ☐
6. Soft copies of all documents e-mailed to: saitm.erc@hotmail.com ☐

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.

Principal Investigator :		
	Signature	Date

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SAITM
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Document Receipt Checklist

THIS WILL BE FILLED AND HANDED OVER TO THE APPLICANT BY THE ERC MEMBER ACCEPTING THE APPLICATION

The ERC confirms that the following documents were handed in by the applicant:

1. Application Form: [2 copies] ☐
2. The detailed project proposal including a section on ethical considerations [2 copies] ☐
3. Information sheet for research participants in English and Sinhala or Tamil languages [2 copies each] ☐
4. Consent forms: Should be provided in all three languages (Sinhala, Tamil and English depending on the study population). [2 copies each] ☐
5. Data collection Booklets / Forms / Questionnaires: Should be provided in all three languages (Sinhala, Tamil, and English depending on the study population) [2 copies] ☐
6. Soft copies of all documents received via e-mail ☐

The application number appearing on top of this page has been assigned to this application. Please quote the number in all correspondence with the committee.

Authorized person for ERC:		
	Signature	Date

Annexure 1

Research Protocol

1. Title of Project
2. Background and rationale
3. Justification
4. Objectives
5. Methodology
    - 5.1. Study design
    - 5.2. Study setting
    - 5.3. Study population
    - 5.4. Sample size
    - 5.5. Sampling method
    - 5.6. Study instrument/s
    - 5.7. Data collection
    - 5.8. Plan of analysis
6. Ethical considerations
7. Time frame