ETHICS REVIEW COMMITTEE

Sri Lanka Medical Association
No 6, Wijerama Mawatha, Colombo 7

Office use only

Application No ……/…….. **Date received** ____/____/_____
Version : ……..

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

APPLICATION FORM – HUMAN RESEARCH

This form should be filled **online** and **signed** by the principal investigator who requests ethical approval for a research project involving **human subjects**. All entries should be typed. **Hand written forms will not be accepted.** No cages should be left blank.

The spaces in this form are expandable as you type.

Please read the **instructions carefully when completing the application** and ensure all relevant documents as per the document checklist are submitted.

PART 1 (Administrative details)

1. **Title of Research Project:**

2. Details of Principal Investigator

Title(Prof./Dr./Mr/Ms):	Name:
Current designation **AND** name and address of institution where the applicant is attached:	
Highest educational qualification of applicant:	
Mailing address:	
Phone no for contact:	e-mail:

3. Is this study a requirement for a postgraduate degree/ requirement by PGIM for Board Certification? Yes ☐ No ☐

3.1 Have you already registered for this degree? Yes ☐ No ☐

Type of degree (MSc/PhD/MD/MS/other):		
Awarding University:		
Date of registration :	Date of protocol approval by board of study :	Letter annexed ☐

Please append letter of approval from Board of Study of University/PGIM.

4. Are there supervisors for this project? Yes ☐ No☐

4.1 Details of Supervisors:

Title:	Name:
Institutional affiliations:	
Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Title:	Name:
Institutional affiliations:	
Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Please append additional pages with Supervisors names if necessary

5. Are there Co-investigators for this project? Yes ☐ No☐

5.1 Details of co-investigators:

Title:	Name:
Institutional Affiliations:	
Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Title:	Name:
Institutional affiliations:	
Highest educational qualification :	
Mailing address:	
Phone:	e-mail:

Please append additional pages with co-investigators names if necessary

6. Location(s) where the research will be conducted:

6.1 Is this a multi-site study ? Yes ☐ No ☐

6.2 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 researcher to obtain approval prior to starting the project.

Type of site (hospital/clinic/school/community etc.)	Details

7. Other Research Ethics Committee approval(s)

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

If Yes, please attach 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 ☐ If unfunded, please explain why no funding is needed:	

9. For Clinical Trials only

9.1 What is the phase of the clinical trial that is being conducted?

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

If OTHER specify:

9.2 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)

9.3 Is the clinical trial registered with a clinical trials registry?

Yes ☐ No ☐ Pending ☐

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

If No, give reasons

9.4 *Has this study been approved by the SCOCT (Subcommittee on Clinical Trials) at the Ministry of Health*

Yes ☐ No ☐ Pending ☐

If yes, give details of Approval Number

If No, give reasons

9.5 Data Safety Monitoring Board (only if available)

Name and Designation of Members*	Role

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

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

PART 11 (Research Proposal)

10. 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:

11. Please include the following information as given in your project proposal indicating the page number(s) relevant to each section in the box.

11. 1 Collaborative partnership		**Applicable**		**Section in Protocol & page**
		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	☐	☐	

11.2 Social Value		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The beneficiaries of your research and the benefit to them	☐	☐	
2.	The plan for dissemination of study findings	☐	☐	

11.3. Scientific Validity		Applicable		Section in Protocol & page
		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	☐	☐	

11.4 Confidentiality		Applicable		Section in Protocol & page
		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	☐	☐	

11.5 Rights of the participants		Applicable		Section in Protocol & page
		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	☐	☐	

11.6 Fair participant selection		Applicable		Section in Protocol & page
		Yes	No	
1.	The justification for the selection of the study population	☐	☐	
2.	The inclusion and exclusion criteria	☐	☐	

11.7 Responsibilities of the researcher		Applicable		Section in Protocol & page
		Yes	No	
1.	The provision of medical services to research participants with special reference to research/trial related injuries	☐	☐	
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	☐	☐	

11.8 Vulnerable populations		Applicable		Section in Protocol & page
		Yes	No	
1.	Justification for conducting the study in this population	☐	☐	

11.9 Research funded by foreign agencies/companies		Applicable		Section in Protocol & page
		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

11.10 Community based research		Applicable		Section in Protocol & page
		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	☐	☐	

11.11 Clinical trials		Applicable		Section in Protocol & page
		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.	Measures in place for management of trial related injuries			
7.	Provisions for safety monitoring	☐	☐	
8.	Provisions/criteria for termination of the trial	☐	☐	
9.	Provisions for making the trial drug available to participants after the trial if found to be effective	☐	☐	

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

11.13 Consent		**Applicable**		**Section in Protocol & page**
		Yes	**No**	
1.	The procedure for initial contact of participants*	☐	☐	
2.	The procedure for obtaining informed consent			
	Verbal	☐	☐	
	Written	☐	☐	
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.	☐	☐	
7.	The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited.	☐	☐	
8	The procedure for consenting if children aged 12 - 18 years of age are being recruited. (for children aged 12-18 years in addition to parental consent, children's assent must be sought)**	☐	☐	

* **Attach a copy of all posters, advertisements, flyers, letters, to be used for recruitment.**
** **Please attach an assent form for children aged 12-18 years**

13. Data Collection

13.1 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).

Page Number/s	
Section/s	

14. Experience of Investigators with this type of research

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

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 If Yes to any of the above, please describe.

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 inappropriate.

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. Do you have any any conflict of interests with regards to this project?

Yes ☐ No ☐

If yes, please state below.

19.1 Commercially

19.2 Financially

19.3 Intellectually

19.4 Other (Explain)

20. 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:

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

22. Declaration of applicant

1. 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.
2. I understand that if there is any deviation from the project as originally approved I must submit an amendment to the ERC for approval prior to its implementation.
3. I have submitted all significant previous decisions by this or any other ERC and/or regulatory authorities relevant for the proposed study.
4. I declare that I am not seeking approval for a study that has already commenced or has already been completed.
5. I understand that at least two months are required for ethics review and granting of ethics clearance.
6. I will submit progress reports/reports of adverse events and side effects as requested by the ERC SLMA.

……..

Signature of Principal Investigator Date :___ /____/_____

Full name of Principal Investigator :

23. Consent from all Investigators

We, the undersigned hereby confirm that we have consented to be co investigators of the project titled:

Name	Qualifications	Institutional Affiliations	Signature

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24. Acknowledgment (*Office use only)*

Name of Applicant: (Prof/Dr/Mr/Ms) ……

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 /ERC, SLMA