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Department of Health Services – NWP

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Application for Ethics Review

Part I – Basic Information

for office use																					
Application No:											Date Received:			–			–				
Decision :											ERC Meeting Date:			–			–				
Last decision by:	*Expedited*		*Full Board*								Date Informed:			–			–				

1. Title of Protocol

Click here to enter text.

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	Information		Signature
	Click here to enter text.	**Role**	Principal Investigator	
		Citizenship	text.	
		Employer*	text.	
	Click here to enter text.	**Role**	text.	
		Citizenship	text.	
		Employer*	text.	
	Click here to enter text.	**Role**	text.	
		Citizenship	text.	
		Employer*	text.	
	Click here to enter text.	**Role**	text.	
		Citizenship	text.	
		Employer*	text.	

* Employer or Academic Affiliation

If you need to add additional investigators above, please click the + sign *(✚)* at the end of the above row which will appear when you click inside any cell of that row

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

3. Contact Details of the Principal Investigator	
Address:	Click here to enter text.
Telephone numbers:	Click here to enter text.
Fax number:	Click here to enter text.
Email address:	Click here to enter text.

4. Funding		
#	**Name and Address of Funding Source(s)**	**Amount (Rs)**
	Click here to enter text.	Click here to enter text.
If you need to add additional funding source above, please click the + sign *(✚)* at the end of the above row which will appear when you click inside any cell of that row		

5. Proposed starting / ending dates*‡ and Study Setting:			
Start Date	Click here to enter a date.	End Date	Click here to enter a date.
Study Setting	Click here to enter text.		
*From initial recruitment of participants until completion of all data collection**.** ‡Retrospective approval will not be given for projects already started or completed**.**			

6. Ethical review **Has ethics approval for this study been requested earlier from this ERC or another similar committee?**	
○ **Yes** ○ **No**	
If yes, give details (names of committees and outcome of review)	
Name of committee	Outcome
Click here to enter text.	Click here to enter text.
If you need to add additional ethical review above, please click the + sign *(✚)* at the end of the above row which will appear when you click inside any cell of that row	

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)	
Name of committee	Outcome
Click here to enter text.	Click here to enter text.
If you need to add additional scientific review, please click the + sign *(✚)* at the end of the above row which will appear when you click inside any cell of that row	

8. Conflict of Interest

8.1 Do you believe this project has a Conflict of Interest? Please declare below :

Commercially

Click here to enter text.

Financially

Click here to enter text.

Intellectually

Click here to enter text.

Other (explain):

Click here to enter text.

8.2 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.

Click here to enter text.

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

Click here to enter text.

Part II – Protocol Checklist

V1.6

for office use										
Application No:										

1. Title of Project

Auto text.

2. Name of Principal Investigator

Auto text. Click here to enter text.

3. The List of Documents Submitted for Review

#	Title of Document	Version	Date
	Click here to enter text.	text.	date.
	Click here to enter text.	text.	date.
	Click here to enter text.	text.	date.
	Click here to enter text.	text.	date.
	Click here to enter text.	text.	date.

If you need to add additional document titles above, please click the + sign (✚) at the end of the above row which will appear when you click inside any cell of that row

4. Protocol Checklist
Please indicate the following:

	1. Collaborative partnership	Applicable (Yes/No)	Protocol Section & page Number
1.1	The collaborations you have established with institutions where the study is to be conducted	Choose	text.
1.2	The collaborations you have established with the community where the study is to be conducted	Choose	text.
1.3	The benefits to institutions, communities, and participants in your research	Choose	text.

	2. Social Value	Applicable (Yes/No)	Protocol Section & page Number
2.1	The beneficiaries of your research and the benefit to them	Choose	text.
2.2	The plan for dissemination of study findings	Choose	text.

	3. Scientific Validity	Applicable (Yes/No)	Protocol Section & page Number
3.1	The scientific importance of your study in relation to improving health care and/or knowledge on the subject.	Choose	text.
3.2	The justification for a replication study, if your study is a replication study.	Choose	text.
3.3	How the sample size was calculated	Choose	text.

	4. Assessment of Risks/Benefits	Applicable (Yes/No)	Protocol Section & page Number
4.1	The risks to research subjects	Choose	text.
4.2	Benefits to research subjects	Choose	text.
4.3	Steps taken to minimize risks	Choose	text.
4.4	Steps taken to enhance benefits	Choose	text.
4.5	Justification of the potential benefits against the risks	Choose	text.
4.6	Support provided to the research participants (medical, psychological and other)	Choose	text.

	5. Consent	Applicable (Yes/No)	Protocol Section & page Number
5.1	The procedure for approaching the relevant community	Choose	text.
5.2	The information (written/oral) provided to the community	Choose	text.
5.3	The procedure for initial contact of participants	Choose	text.
5.4	The information (written/oral) provided to participants	Choose	text.
5.5	The procedure for obtaining informed consent	Choose	text.
5.6	The procedure for ensuring that participants have understood the information provided	Choose	text.
5.7	The procedure for obtaining proxy consent	Choose	text.
5.8	The procedure for obtaining assent	Choose	text.
5.9	The procedure for consenting if the child reaches consenting age during the study	Choose	text.
5.10	The procedure for consenting if the participant acquires capacity to give consent during the study	Choose	text.
5.11	The procedure for re-consenting if data or specimens that have been collected are to be used for other research projects that may be in the same (Extended Consent) or a different (Unspecified Consent) field of study	Choose	text.
5.12	The procedure for withdrawing consent	Choose	text.
5.13	The justification for waiver of consent or waiver of written consent	Choose	text.
5.14	Incentives/rewards/compensation/reimbursement provided or not provided to participants and their accompanying persons	Choose	text.
5.15	The procedure for re-consenting if the research protocol changes during the course of research	Choose	text.

	6. Confidentiality	Applicable (Yes/No)	Protocol Section & page Number
6.1	How the data and samples will be obtained	Choose	text.
6.2	How long data and samples will be kept	Choose	text.
6.3	Justification for collection of personal identification data	Choose	text.
6.4	Who will have access to the personal data of the research participants	Choose	text.
6.5	How the confidentiality of participants will be ensured	Choose	text.
6.6	The procedure for data and sample storage	Choose	text.
6.7	The procedure for data and sample disposal	Choose	text.

	7. Rights of the participants	Applicable (Yes/No)	Protocol Section & page Number
7.1	Procedure for subjects to withdraw from the research at any time	Choose	text.
7.2	Procedure for subjects to ask questions and register complaints	Choose	text.
7.3	The contact person for research subjects	Choose	text.
7.4	Provisions for participants to be informed of results	Choose	text.
7.5	Provision to make the study product available to the study participants after research	Choose	text.

	8. Fair participant selection	Applicable (Yes/No)	Protocol Section & page Number
8.1	The justification for the selection of the study population	Choose	text.
8.2	The inclusion and exclusion criteria	Choose	text.

	9. Responsibilities of the researcher	Applicable (Yes/No)	Protocol Section & page Number
9.1	The provision of medical services to research participants	Choose	text.
9.2	The provisions for continuation of care after the research is completed	Choose	text.
9.3	Declaration of conflicts of interests and how the investigators plan to manage the conflicts	Choose	text.
9.4	The ethical/legal/social and financial issues relevant to the study.	Choose	text.

	10. Vulnerable populations	Applicable (Yes/No)	Protocol Section & page Number
10.1	Justification for conducting the study in this population	Choose	text.

	11. Research funded by foreign agencies/ foreign companies	Applicable (Yes/No)	Protocol Section & page Number
11.1	Justification for conducting the study in Sri Lanka	Choose	text.
11.2	Relevance of the study to Sri Lanka	Choose	text.
11.3	Post research benefits to Sri Lanka	Choose	text.
11.4	The steps taken to take into account cultural and social customs, practices, and taboos in Sri Lanka	Choose	text.
11.5	The sharing of rights to intellectual property	Choose	text.
11.6	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	Choose	text.
11.7	How the results of research will be conveyed to relevant authorities in Sri Lanka	Choose	text.
11.8	The agreement between the sponsor/funding agency and the investigator	Choose	text.
11.9	The materials transfer agreement, if biological material is to be transferred abroad	Choose	text.

12. Community based research		Applicable (Yes/No)	Protocol Section & page Number
12.1	The impact and relevance of the research on the community in which it is to be carried out	Choose	text.
12.2	The steps taken to consult with the concerned community during the design of the research	Choose	text.
12.3	The procedure used to obtain community consent	Choose	text.
12.4	The contribution to capacity building of the community	Choose	text.
12.5	The procedure for making available results of research to the community	Choose	text.

13. Information Sheet (IFS)/Informed Consent Form (ICF)		IFS/ ICF	Section & page Number in IFS/ICF
13.1	Purpose of the study		text.
13.2	Voluntary participation		text.
13.3	Duration, procedures of the study and		text.
13.4	Potential benefits		text.
13.5	Risks, hazards and discomforts		text.
13.6	Reimbursements		text.
13.7	Confidentiality		text.
13.8	Termination of study participation		text.
13.9	Participant's responsibilities		text.

Part III – Document Checklist

for office use										
Application No:										

1. Title of Project
Auto text.

2. Application Check list			
Note: All documents shall be submitted in **3 hard copies & 1 soft copy**.			
I declare that I have attached the following documents (Please tick the check box and confirm):			
Documents			
2.1. Application Form: Part I , II & III			☐
		Version No	
2.2. The complete research protocol including a section on justification, objectives, methods and ethics considerations		text.	☐
2.3. Information sheet for research participants.	Sinhala	text.	☐
	Tamil	text.	☐
	English	text.	☐
2.4. Consent forms	Sinhala	text.	☐
	Tamil	text.	☐
	English	text.	☐
2.5. Assent forms	Sinhala	text.	☐
	Tamil	text.	☐
	English	text.	☐
2.6. Data collection booklets/ forms/ questionnaires	Sinhala	text.	☐
	Tamil	text.	☐
	English	text.	☐
2.7. Language Justification letter (applicable If any of above documents are not available three languages)			☐
2.8. ERC approval certificate from any other ERC (if applicable)			☐
2.9. Materials Transfer Agreement (required for all research involving transfer of biological samples abroad)			☐
2.10 Ethics approval from sponsoring country or country of the overseas investigator (if applicable)			☐
2.11 Brief curriculum vitae of all investigators & Supervisors			☐

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.

Click or tap here to enter text. Principal Investigator	 Signature	Click or tap to enter a date. Date