Ethics Review Application Form
Common Application Format - FERCSL

For office use only

Application No:		Checked By:	
Date Received:	dd / mm / yyyy	ERC Meeting Date:	dd / mm / yyyy

Level of Risk: No Risk / Minimal Risk / Greater than Minimal Risk

Review Type: Exempted / Expedited Review / Full Board Review

Names of the Reviewers:

1)	2)
3)	4)

Date Informed:

Part-I: Basic Information

1.1. Title of Project

1.2. Details of Investigator(s)

Name	Qualifications	Affiliation of Investigators	Role	Signature
			PI, Co-PI, Co-Investigator, Supervisor,_____	
			PI, Co-PI, Co-Investigator, Supervisor,_____	
			PI, Co-PI, Co-Investigator, Supervisor,_____	
			PI, Co-PI, Co-Investigator, Supervisor,_____	
			PI, Co-PI, Co-Investigator, Supervisor,_____	
			PI, Co-PI, Co-Investigator, Supervisor,_____	
			PI, Co-PI, Co-Investigator, Supervisor,_____	

Attach separate sheet if needed

1.3. Contact Details of the Principal Investigator

Address for communication	
Telephone No(s)	
Fax No	
Email Address	

1.4. Is this a post graduate protocol

Yes		No	

If yes, give following details

Course/degree	
Institution	

1.5. Has this protocol been subjected to scientific review by any other institution/board/committee/BoS?

Yes		No	

If yes, give details

Name of the institution/board/committee/BoS

Outcome of the review and date

1.6. Funding

Is this project funded

Yes		No	

Name & Address of the Funding Source(s)†	Amount

† Please complete Annexure-1 for research funded

1.7. Proposed Starting & Ending Dates†,‡

Starting Date	*dd*	*mm*	*yyyy*	Ending Date	*dd*	*mm*	*yyyy*

† From initial recruitment of participants until completion of all data collection

*‡ Retrospective approval will **NOT** be given for the projects already started or completed*

1.8 Location/s where the study would be conducted

1.9. Has ethics approval for this protocol been requested from this ERC or another ERC

Yes		No	

If yes, give details (name of the committees and outcome)

1.10. Conflict of Interest

a. of Interest?

Yes		No	

If yes, please give details (investigator, co-investigator, collaborator)	
Commercially	
Financially	
Intellectually	
Other (explain)	

c.

If there is a duality of interest stated above describe how the conflict/s would be addressed.

Part-II: Project Overview

2.1. Study type (mark with "✓")

- [ ] Epidemiological study/ Non-interventional study
- [ ] Survey /Audit
- [ ] Clinical Trial *(Please complete Annexure-2)*
- [ ] Field Trial/ Community Trial
- [ ] Case study
- [ ] Qualitative study
- [ ] Health System Research
- [ ] Implementation Research
- [ ] Complementary and alternative medicine (CAM) research
- [ ] Experimental study
- [ ] Other (please specify) _____

2.2. Nature of the Protocol (mark all appropriate with a "✓")

- [ ] Research with Human Participants
- [ ] Research using stored human biological material
- [ ] Research involving medical devices
- [ ] Research using Medical Records, Registers or Databases
- [ ] Establishment and maintenance of research database *(Please complete Annexure 4)*

Part-III: Scientific Validity and Ethical Conduct

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

3.1. Justification		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 this is a replication study.			

3.2. Scientific validity		Applicable		Section in Protocol & page
		Yes	No	
1)	Justification for conducting the study in this population			
2)	Study design			
3)	Objectives: General and specific			
4)	The inclusion and exclusion criteria			
5)	How the sample size was calculated			
6)	Plan for selection of the sample			
7)	Details of data collection tools, methods, investigations, etc.			

† Please complete Annexure-3, if this is a community based study

3.3. Consent		Applicable		Section in Protocol & page
		Yes	No	
1)	The procedure for approaching the relevant community and initial contact of with the 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.			
6)	The procedure for consenting if vulnerable groups / children under 18 years of age are being recruited. (for children aged 12-18 years in addition to parental consent, children's assent must be sought)			
7)	The procedure for withdrawing consent and withdraw from the research			
8)	The procedure for re-consenting			

3.4. 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 be ensured			
6)	The procedure for data and sample storage			
7)	The procedure for data and sample disposal			

3.5. Vulnerability and Inducement		Applicable		Section in Protocol & page
		Yes	No	
1)	Justification for including vulnerable populations			
2)	Compensation provided to participants .			

3.6. 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)	Patient and public engagement and involvement (PPEI) in research			
4)	Benefit due to this collaboration to individual, institution, society, etc.			

3.7. 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			

3.7. Rights of the participants		Applicable		Section in Protocol & page
		Yes	No	
1)	Procedure for subjects to ask questions and register complaints			
2)	The contact person for research participants			
3)	Provisions for participants to be informed of results			

3.8. Assessment of Risks/Benefits		Applicable		Section in Protocol & page
		Yes	No	
1)	The risks to research participants (physical, psychological, etc.)			
2)	Benefits to research participants			
3)	Steps taken to minimize risks			
4)	Support provided to the research participants (medical, psychological and other)			
6)	Risk-benefit analysis/discussion			

3.9. Responsibilities of the researcher		Applicable		Section in Protocol & page
		Yes	No	
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			

Part-IV: Information Sheet (IFS)/Informed Consent Form (ICF) Check List

4.1. List the sections and page number in IFS/ICF where you have dealt with the following

		Section in IFS/ICF & page
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)	Collection and fate of biological samples	
7)	Reimbursements	
8)	Confidentiality	
9)	Termination of study participation	

Part-V: Document Check List & Declaration

I declare that I have attached the following documents (Please tick and confirm):

	Document		Version/ Date	Applicable		No. of Copies
				Yes	No	
1)	Covering Letter					
2)	Application Form (Part I, II, III, IV & V)					
3)	Annexure-1 (Research funded by foreign agencies/companies)					
4)	Annexure-2 (Clinical trials)					
5)	Annexure-3 (Community based research)					
6)	Annexure-4 (Establishment and maintenance of research database)					
7)	The complete research protocol including a section on ethics considerations					
8)	Information sheet for research participants (IFS)					
		English				
		Sinhalese				
		Tamil				
9)	Informed Consent Form (ICF)					
		English				
		Sinhalese				
		Tamil				
10)	Assent Form					
		English				
		Sinhalese				
		Tamil				
11)	Data collection booklets/forms/questionnaires					
		English				
		Sinhalese				
		Tamil				
12)	Summary of the protocol					
13)	Diagrammatic representative (flow chart) of the research procedures					
14)	Approval letter from BOS, institutions					
15)	Ethics approval letter (if any)					
16)	Indemnity/Insurance coverage (required for clinical trials)					
17)	Clinical Trials Contract (required for clinical trials)					
18)	Certificate of GAP training for relevant member of the research study					
19)	Materials Transfer Agreement (required for all research involving transfer of biological samples abroad)					
20)	Brief curriculum vitae of all investigators					
21)	A receipt of payment (if applicable)					
22)	Soft copies of the documents					

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 affirm that I will submit all relevant documents such as progress reports, final reports, Saes, etc. as required by the ERC
5) I declare that I am not seeking approval for a study that has already commenced or has already been completed.
6) I certify that the information given above is true and correct to the best of my knowledge. I understand that if this information is found to be incorrect the ERC approval if given will be withdrawn.

	Date:	*dd*	*mm*	*yyyy*

Signature of Principal Investigator

Full name of the Principal Investigator