

Application for Ethics Review – Part I

for official use

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

Type of Review Requested

Regular

Expedited *Please see ERC guidelines to determine whether this application qualifies for expedited review.*

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: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

Title: Mr. Ms. Dr. Prof.

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact Nos:

Email Address:

Principal Investigator Co-investigator Supervisor

Signature

3. 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.

4. Has ethics review for this study been requested earlier from this committee or another similar committee?

Yes* No

*Where?

*When?

*Result:

Application for Ethics Review – Part II

for official use

Application No:

1. Title of Project

2. Funding

Name and Address of Funding Source(s)	Amount
<input type="text"/>	<input type="text"/>

3. A brief summary of the research proposal in simple language (maximum 500 words)

4. Scientific importance and validity

4.1. What is the scientific importance of your study in relation to improving health care and/or knowledge on the subject?

4.2. Is your study an original one or a replication of a previous study?

Original Replication

If it is a replication study please justify.

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

Yes No

If YES, what is the name of the committee?

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

Yes No

4.5. Are the facilities at the site adequate to support the study?

Yes No

4.6. How will the results of the study be disseminated?

5. Assessment of Risks/Benefits

5.1. Is the involvement of human subjects necessary to obtain the necessary information?

Yes No

5.2. Are there any risks (physical, psychological, social, legal, economic) to the participants?

Yes No

If YES identify them and state how you plan to prevent or minimize these risks?

5.3. Are there any benefits to the participants?

Yes No

If YES identify them. If NO what are the benefits to the community or health care system?

5.4 Justify the potential benefits against the risks.

5.5. Is standard therapy going to be withheld from the participants?

Yes No Not Applicable

If YES, justify.

5.6. Is the standard of care the best available locally?

Yes No Not Applicable

If NO, explain.

5.7. Is the medical and psychological support for the participants adequate?

Yes No Not Applicable

If No, explain.

5.8. What is the procedure for dealing with adverse events?

5.9. What is the procedure for reporting adverse events?

5.10. Is there provision for compensation for participants who sustain injuries?

Yes No Not Applicable

If YES/NO explain.

5.11. What are the provisions for safety monitoring and termination of research?

5.12. What is the possibility of an effective intervention, if found, being available to the population?

6. Respect for the dignity of the research participants

Informed consent

6.1. Write briefly your procedure for obtaining informed consent.

6.2. Who will obtain consent?

6.3. Is it written or verbal consent?

Written Verbal Not Applicable

If written please include consent form with translations. If verbal, please state in simple words (in Sinhala / Tamil / English) in a separate sheet what information you would convey to the participants and state below how consent would be documented).

6.4. How will you ensure that the participant is adequately informed? Please include information sheets with translations.

6.5. How will you ensure your information is understood (comprehension) and queries answered?

6.6. Would the participants have difficulty understanding the information due to, for example, age (children under 16 or senility), illiteracy, impaired cognition due to illness/trauma?

Yes No

If YES justify the use of this group and detail the arrangement for obtaining proxy consent?

6.7. Are you offering any financial or other incentives/ rewards/ compensation to the research participants?

Yes No

If YES please list them and state why they do not constitute undue inducement to participate (All incentives to be provided to research participants must be approved by the ERC).

6.8. How will you ensure that consent is given voluntarily and not due to deception, intimidation or inducement?

6.9. Are the research participants under your care?

Yes No

If YES please state how you would ensure they would not feel obliged to participate in order to receive better medical care.

6.10. Will you obtain fresh informed consent if the procedures are changed during the research?

Yes No Not Applicable

Confidentiality

6.11. How will data/samples be obtained?

6.12. How long will data/samples be kept?

6.13. Are you collecting the minimum information/samples required to fulfill the study objectives?

Yes No

6.14. Who will have access to the personal data of the research participants?

6.15. How will you safeguard the privacy of the research participant?

6.16. What is the data/sample storage and disposal procedure in relation to ensuring confidentiality and security of personal information?

6.17. If you are planning to store data/samples for future study, will you obtain appropriate consent?

Yes No

Rights of the participants

6.18. How will you ensure the participants unconditional right to withdraw from the research at any time?

6.19. Outline the procedures you will provide for the research participants to ask questions and register complaints.

6.20. Who is the contact person for the research participants?

6.21. Is there provision for participants to receive information that is relevant to their participation? Explain.

Yes No Not Applicable

If Yes/NO Explain.

6.22. Is there provision for the subjects to be informed of results of clinical research? Explain.

Yes No Not Applicable

6.23. Is there provision to make the study product if any available to the study participants following the research?

Yes No Not Applicable

If Yes/NO Explain.

7. Fair participant selection

7.1. What is your study population?

7.2. Justify your choice of the study population.

7.3. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?

Yes No Not Applicable

If YES/NO Explain.

7.4. How is the initial contact and recruitment to be conducted?

7.5. Is the research conducted on a vulnerable group?

Yes No

If YES please fill up section 9.

7.6. Is the research an externally sponsored research?

Yes No

If YES please fill up section 10.

7.7. Is your research a community research?

Yes No

If YES please fill up section 11.

7.8. Is your research a clinical trial?

Yes No

If YES please fill up section 12.

8. Responsibilities of the researcher

8.1. What are the responsibilities of the researcher for provision of medical services to research participants?

8.2. What are the provisions for continuation of care after the research is over?

8.3. Have you followed any applicable legal regulations or other guidelines?

Yes No Not Applicable

If No Explain.

8.4. Have you obtained permission from the relevant authorities?

Yes No Not Applicable

If YES name the authorities. If NO who are you planning to get permission from?

8.5. Please declare any conflicts of interest including payments received by you or co-researchers and other rewards (Please list them and state how you would prevent them from influencing the conduct of the study).

8.6. Do you see any other ethical / legal/ social /financial issues in your study? (Please list them and state how you would prevent them from influencing conduct of the study)

8.7. I do not wish the following reviewers / ERC members to review my application.

8.8. I am willing to provide 6 monthly reports of my research to the Ethics Committee.

Yes No Not Applicable

9. Vulnerable groups (those socially disadvantaged on account of illiteracy, economic status, social status etc. and those with limited autonomy such as prisoners, service personnel etc.)

9.1. What is the justification for using the vulnerable group instead of the general population?

9.2. What is the procedure for obtaining (proxy) consent?

9.3. What is the procedure for withdrawal from research due to refusal(dissent) of research participant?

9.4. Are you providing adequate medical and psychological support? Explain.

Yes No Not Applicable

9.5. Will the benefits of research be made reasonably available to this population? Explain.

Yes No Not Applicable

10. Externally sponsored research

10.1. Has the research project been approved by an ERC/ IRB in the sponsoring country?

Yes No

If YES, please attach documentary evidence. If NO, why?

10.2. Why is the research carried out in Sri Lanka and not in the sponsoring country?

10.3. What is the relevance of this study to Sri Lanka?

10.4. What are the post-research benefits to Sri Lanka such as availability of product, capacity building?

10.5. Are you adhering to any specific laws/ regulations/ guidelines of Sri Lanka and the sponsoring country/countries applicable to the study?

Yes Not applicable

If YES, list them.

10.6. How have you taken into account cultural and social customs, practices, and taboos in Sri Lanka when designing your study? Explain.

Yes No Not Applicable

10.7. Are participants receiving the best current treatment as part of the protocol?

Yes No

If NOT, explain why?

10.8. What is the ancillary care provided (treatment that is not part of the protocol)?

10.9. What are the provisions for continuity of care?

10.10. How will the rights to intellectual property be shared?

10.11. Are any of the data or biological samples to be transferred overseas?

Yes No

If YES, describe the fate of the data or biological samples at the conclusion of the study.

10.12. How will the results of research be conveyed to relevant authorities in Sri Lanka?

11. Community based research

11.1. State the impact and relevance of the research on the community in which it is to be carried out.

11.2. State the steps taken to consult with the concerned community during the design of the research.

11.3. What procedures will be used to obtain community consent?

11.4. What procedures will be used to obtain individual consent?

11.5. How will you safeguard the privacy of the participants?

11.6. If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study? If not, explain why.

Yes No

11.7. Will the intervention or product developed or knowledge generated be made reasonably available and affordable for the benefit of the population?

Yes No

11.8. How does the research contribute to capacity building of the community?

11.9. How will the results of the research be made available to the concerned community?

12. Clinical trials

12.1. What phase clinical trial is being conducted?

Phase I

Phase II

Phase III

Phase IV (post marketing)

Other

If OTHER specify.

12.2. Is it a multicentre trial?

Yes No

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

Yes No

If YES name it.

12.4. Have adequate animal toxicity and teratogenicity trials been carried out?

Yes No

12.5. What is the justification for using a control arm?

12.6. Does the control group receive the standard therapy?

Yes No Not Applicable

12.7. Are all participants treated equally?

Yes No Not Applicable

If NOT explain.

12.8. What is the procedure for dealing with adverse events?

12.9. What is the procedure for reporting adverse events?

12.10. Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?

Yes No

12.11. What are the criteria for termination of the trial?

12.12. Is there provision for insurance of the trial participants? Explain.

Yes No

Application for Ethics Review – Part III

for official use

Application No:

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Application Checklist

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

1. Application Form: Part I

[2 copies]

2. Application Form: Part II

[2 copies]

3. The complete research proposal including the justification, objectives, and methods in detail.

[2 copies]

4. Information sheet for research participants (Should be provided in all three languages – Sinhala, Tamil, and English).

[2 copies each]

5. Consent forms (Should be provided in all three languages – Sinhala, Tamil, and English).

[2 copies each]

6. Data collection booklets/forms/questionnaires. (Should be provided in all three languages – Sinhala, Tamil, and English if self administered by research participants)

[2 copies]

7. A receipt for the appropriate payment to the accounts department.

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/Supervisor

.....
Date