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| **Institutional Ethical Review Committee**  **Teaching Hospital - Kurunegala** | | | | | | | | | | | | | | | | | | | |
| **Application for Ethics Review – Part I** | | | | | | | | | | | | | | | | | | | |
| *For ERC official use only:* | | | | | | | | | | | | | | |  |  | | | |
| Application No: | *ERC* | */* | *2* | *0* |  |  | */* |  |  |  | Date Received: |  |  | */* |  |  | */* |  |  |
|  |  | | | | | | | | | |  |  | | | | | | | |
| ERC ID: |  | | | | | | | | | | Date Informed: |  |  | */* |  |  | */* |  |  |
|  |  | | | | | | | | | |  |  | | | | | | | |
| **Type of Review**  Regular **⬜**  Expedited **⬜** | | | | | | | | | | | | | | | | | | | |
| **Decision**  Accepted **⬜** Review with Major Modifications **⬜**  Review with Minor Modifications **⬜** Rejected **⬜**  Exempted ⬜ | | | | | | | | | | | | | | | | | | | |

**Please type inside the provided cages. (The cages will expand as needed.)**

**1. Title of Project**

|  |
| --- |
|  |

**2. Investigators & Supervisors:**

*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.*

*2.1. Principle Investigator*

|  |  |
| --- | --- |
|  |  |
| Title: | Mr.  Ms.  Dr.  Prof. |

|  |  |
| --- | --- |
| Name: | - |

|  |  |
| --- | --- |
| Qualifications: | - |

|  |  |
| --- | --- |
| Designation: | - |

|  |  |
| --- | --- |
| Place of Work: | - |

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| Address: | - |

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| --- | --- |
| Contact Nos: | - |

|  |  |
| --- | --- |
| Email Address: | - |
| Nationality | - |

|  |  |
| --- | --- |
| Signature |  |

*2.2. Supervisors & other Investigators*

|  |  |
| --- | --- |
|  |  |
| Title: | Mr.  Ms.  Dr.  Prof. |

|  |  |
| --- | --- |
| Name: | - |

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| Qualifications: | - |

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|  | Co-investigator |  |  | Supervisor |  |  |  |  |

|  |  |
| --- | --- |
| Signature |  |
|  |  |
| Title: | Mr.  Ms.  Dr.  Prof. |

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| Name: | - |

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| Qualifications: | - |

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|  |  |  |  | Co-investigator |  |  | Supervisor |  |  |  |  |

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| Signature |  |
|  |  |
| Title: | Mr.  Ms.  Dr.  Prof. |

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| Name: | - |

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|  |  |  |  | Co-investigator |  |  | Supervisor |  |  |  |  |

|  |  |
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| Signature |  |

|  |  |
| --- | --- |
| Title: | Mr.  Ms.  Dr.  Prof. |

|  |  |
| --- | --- |
| Name: | - |

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| Qualifications: | - |

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|  |  |  |  | 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 |  |

|  |  |
| --- | --- |
| **If yes …** | |
| \*Where? | - |

|  |  |
| --- | --- |
| \*When? | - |

|  |  |
| --- | --- |
| \*Result: | - |

|  |
| --- |
| **Institutional Ethical Review Committee**  **Teaching Hospital - Kurunegala** |
| **Application for Ethics Review – Part II** |

**1. Title of Project**

|  |
| --- |
| - |

**2. Funding**

|  |  |
| --- | --- |
| Name and Address of Funding Source(s) | Amount |
| - |  |
| - |  |
| - |  |

**3. A brief summary of the research proposal in simple language (maximum 250 words)**

|  |
| --- |
| - |

**4. Scientific importance and validity**

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

|  |  |  |  |
| --- | --- | --- | --- |
| Original |  | Replication |  |

If it is a replication study please justify.

|  |
| --- |
| - |

4.2. Are the investigator’s qualifications and experience appropriate to conduct the study?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

**5. Assessment of Risks/Benefits**

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

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

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

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

If YES have you identified those and state how you plan to prevent or minimize in your proposal ?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

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, justification shall be included in the proposal.

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

|  |
| --- |
| - |

5.7. What is the procedure for reporting adverse events?

|  |
| --- |
| - |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Yes |  | No |  | Not Applicable |  |

**6. Respect for the dignity of the research participants**

***Informed consent***

6.1. Who will obtain the consent?

|  |
| --- |
| - |

6.2. Is it written or verbal consent?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Written |  | Verbal |  | Not Applicable |  |

If written please attache 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).

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

6.4. 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 have you arranged for obtaining proxy consent?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

6.5. 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).

|  |
| --- |
| - |

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

|  |
| --- |
| - |

***Confidentiality***

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

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

***Rights of the participants***

6.18. Have you ensured the participants unconditional right to withdraw from the research at any time?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

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 |  |

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 |  |

**7. Fair participant selection**

7.1. What is your study population?

|  |
| --- |
| - |

7.2 Justify your choice of the study population.

|  |
| --- |
| - |

7.3. Is the research conducted on a vulnerable group?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

If YES please fill up section 9.

**8. Responsibilities of the researcher**

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Yes |  | No |  | Not Applicable |  |

If No Explain.

|  |
| --- |
| - |

8.2. 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).

|  |
| --- |
| - |

8.3. 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)

|  |
| --- |
| - |

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

|  |
| --- |
| - |

8.5. 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?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Yes |  | No |  | Not Applicable |  |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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**

Please note that community based research is not under the purview of this institutional ERC.

**12. Clinical trials**

Please note that clinical trials research is not under the purview of this institutional ERC.

|  |  |  |  |
| --- | --- | --- | --- |
| **Institutional Ethical Review Committee**  **Teaching Hospital - Kurunegala** | | | |
| **Application for Ethics Review – Part III** | | | |
|  |  |  |  | |

**Application Checklist**

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

1. Application Form: Part I

[4 copies]

1. Application Form: Part II

[4 copies]

1. Application Form: Part III

[1 copy]

1. The complete research proposal including (not limited to) the justification, objectives, methodology & ethical concerns in detail (each subtopic under a separate heading).

[4 copies]

1. Information sheet for research participants (Should be provided in all three languages – Sinhala, Tamil, and English. If a language is not required, please submit a justification letter on that.)

[4 copies] )

1. Consent forms (Should be provided in all three languages – Sinhala, Tamil, and English. If a language is not required, please submit a justification letter on that.)

[4 copies]

1. Data collection tools. (Should be provided in all three languages – Sinhala, Tamil, and English. If a language is not required, please submit a justification letter on that. )

[4 copies]

1. Brief CV of Principle Investigator/ Supervisor

[4 copies]

1. A soft copy of all above documents in email to [ercofficethk@gmail.com](file:///C:\Users\Dell\OneDrive\THK\THK\ERC\Web%20site\Application_for_Ethical_Review_-_IERC_-_TH_Kurunegala_V3_3\ercofficethk@gmail.com).

[1 copy]

**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, up to two months are required for ethics review process.**

*………………………………………………………… ……………………………*

*Signature of Principal Investigator Date*