Application form for Ethics Review

1. **Title of Project:**
2. **Investigators:**

Title: Mr. ☐ Ms. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact No:

Email Address:

Signature:

Principal Investigator ☐ Co-investigator ☐ Supervisor ☐

Title: Mr. ☐ Ms. ☐ Dr. ☐ Prof. ☐

Name:

Qualifications:

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Name:

Qualifications:

Designation:

Place of Work:

Address:

Contact No:

Email Address:

Signature:

Principal Investigator ☐ Co-investigator ☐ Supervisor ☐

3. **Proposed starting and ending dates:** From initial recruitment of participants until completion of all data collection.

Start Date: End Date:

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

   Yes ☐ No ☐

   If yes: Where?
   When?
   Result?

5. **Funding**

   Name and Address of Funding Source(s)

   Amount

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

7. **Scientific importance and validity**

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

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

Original ☐ Replication ☐

If it is a replication study please justify

- Are the facilities at the site adequate to support the study?

Yes ☐ No ☐

- How will the results of the study be disseminated?

8. **Assessment of Risks/Benefits**

- Is the involvement of children necessary to obtain the required information?

Yes ☐ No ☐

- Are there any risks (physical, psychological) to the children?

Yes ☐ No ☐

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

- Are there any benefits to the children?

Yes ☐ No ☐

If yes, identify them. If no, what are the benefits to the community or health care system?

- Justify the potential benefits against the risks.

Yes ☐ No ☐

- Is standard therapy going to be withheld from the children?

Yes ☐ No ☐

If yes, justify.

- Is the standard of care the best available locally?

Yes ☐ No ☐

If no, explain.

- Is the medical and psychological support for the children adequate?

  Yes ☐ No ☐

  If no, explain.

- What is the procedure for dealing with adverse events?
- What is the procedure for reporting adverse events?
- What are the provisions for safety monitoring and termination of research?
- What is the possibility of an effective intervention, if found, being available to the population?

9. **Informed consent**

- Include consent form and information sheets with Sinhala and Tamil translations.
- How will you ensure your information is understood and queries answered?
- List any incentives to the parents/guardians of research participants and state why they do not constitute undue inducement.
- How will you ensure that consent is given voluntarily and not due to deception, intimidation or inducement?
- How will you ensure that parents/ guardians would not feel obliged to get their children to participate in order to receive better medical care?
- Will you obtain fresh informed consent if the procedures are changed during the research?

  Yes ☐ No ☐

10. **Confidentiality**

- How will data/samples be obtained?
- How long will data/samples be kept?
- Are you collecting the minimum information/samples required to fulfill the study objectives?

  Yes ☐ No ☐

- Who will have access to the personal data of the research participants?
- How will you safeguard the privacy of the research participant?
- What is the data/sample storage and disposal procedure to ensure confidentiality and security of personal information?

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

  Yes ☐ No ☐

11. **Rights of the participants**

- How will you ensure parents/guardians of participants, unconditional right to withdraw from the research at any time?

- Outline the procedures you will provide for the parents/ guardians of research participants to ask questions and register complaints.

- Is there provision for parents/ guardians of participants to receive information that is relevant to the participation of their children? Explain.

- Is there provision for the parents/ guardians of participants to be informed of results of clinical research?

  Yes ☐ No ☐

- Is there provision to make the study product if any available to the parents/ guardians of study participants following the research?

  Yes ☐ No ☐

12. **Fair participant selection**

- What is your study population?

- Justify your choice of the study population.

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

  Yes ☐ No ☐

- How is the initial contact and recruitment to be conducted?

13. **Responsibilities of the researcher**

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

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

- Have you obtained permission from the relevant authorities?

  Yes ☐ No ☐

  If yes, name the authorities.

- Declare any conflicts of interest including payments received by you or co-researchers and other rewards and state how you would prevent them from influencing the conduct of the study.

- List any other ethical issues in your study and state how you would prevent them from influencing the conduct of the study

- I am willing to provide 6 monthly reports of my research to the ERC.

  Yes ☐ No ☐

14. **Externally sponsored research**

- Attach documentary evidence that the research project has been approved by an ERC in the sponsoring country.

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

- What is the relevance of this study to Sri Lanka?

- What are the post-research benefits to Sri Lanka?

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

  Yes ☐ No ☐

  If no, explain why?

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

- What are the provisions for continuity of care?

- If any of the data/biological samples are to be transferred overseas, describe the fate of the data/ biological samples at the conclusion of the study.

15. **Community based research**

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

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

- What procedures will be used to obtain community consent and individual consent?

- How will you safeguard the privacy of the participants?

- If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study?

  Yes ☐ No ☐

- How does the research contribute to capacity building of the community?
- How will the results of the research be made available to the concerned community?

16. **Clinical trials**

- Is it a multicentre trial?

  Yes ☐ No ☐

- Is the trial registered with the Sri Lanka Clinical Trials Registry?

  Yes ☐ No ☐

- What is the justification for using a control arm?
- Does the control group receive the standard therapy?

  Yes ☐ No ☐

- Are all participants treated equally?

  Yes ☐ No ☐

  If no, explain.

- What is the procedure for reporting adverse events?
- What is the procedure for dealing with adverse events?
- Will the sponsoring agency provide the drug / device to the patient till it is marketed in the country?

  Yes ☐ No ☐

- What are the criteria for termination of the trial?