

**APPLICATION FORM**

**ETHICS REVIEW COMMITTEE**

SRI LANKA COLLEGE OF PAEDIATRICIANS

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

Title : Choose an item.

Name :

Qualifications :

Designation :

Place of Work :

Address :

Contact No :

E-mail :

Signature : 

Choose an item.

Title : Choose an item.

Name :

Qualifications :

Designation :

Place of Work :

Address :

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Name :

Qualifications :

Designation :

Place of Work :

Address :

Contact No :

E-mail :

Signature : 

Choose an item.

1. **Proposed starting and ending dates**

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

Start Date : Click or tap to enter a date. End Date : Click or tap to enter a date.

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

Choose an item.

If yes: Where?

When?

Result?

1. **Funding**

|  |  |  |
| --- | --- | --- |
| Name | Address | Amount |
|  |  |  |

1. **A brief summary of the research proposal in simple language (maximum 500 words)**
2. **Scientific importance and validity**
3. What is the scientific importance of your study in relation to improving health care and/or knowledge on the subject?
4. Is your study an original one or a replication of a previous study?

Choose an item.

If it is a replication study please justify

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

Choose an item.

1. How will the results of the study be disseminated?
2. **Assessment of Risks/Benefits**
3. Is the involvement of children necessary to obtain the required information?

Choose an item.

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

Choose an item.

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

1. Are there any benefits to the children?

Choose an item.

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

1. Justify the potential benefits against the risks.

Choose an item.

1. Is standard therapy going to be withheld from the children?

Choose an item.

If yes, justify.

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

Choose an item.

If no, explain.

1. Is the medical and psychological support for the children adequate?

Choose an item.

If no, explain.

1. What is the procedure for dealing with adverse events?
2. What is the procedure for reporting adverse events?
3. What are the provisions for safety monitoring and termination of research?
4. What is the possibility of an effective intervention, if found, being available to the population?
5. **Informed consent**
6. Include consent form and information sheets with Sinhala and Tamil translations.
7. How will you ensure your information is understood and queries answered?
8. List any incentives to the parents/guardians of research participants and state why they do not constitute undue inducement.
9. How will you ensure that consent is given voluntarily and not due to deception, intimidation or inducement?
10. How will you ensure that parents/ guardians would not feel obliged to get their children to participate in order to receive better medical care?
11. Will you obtain fresh informed consent if the procedures are changed during the research?

Choose an item.

1. **Confidentiality**
2. How will data/samples be obtained?
3. How long will data/samples be kept?
4. Are you collecting the minimum information/samples required to fulfill the study objectives?

Choose an item.

1. Who will have access to the personal data of the research participants?
2. How will you safeguard the privacy of the research participant?
3. What is the data/sample storage and disposal procedure to ensure confidentiality and security of personal information?
4. If you are planning to store data/samples for future study, will you obtain appropriate consent?

Choose an item.

1. **Rights of the participants**
2. How will you ensure parents/guardians of participants, unconditional right to withdraw from the research at any time?
3. Outline the procedures you will provide for the parents/ guardians of research participants to ask questions and register complaints.
4. Is there provision for parents/ guardians of participants to receive information that is relevant to the participation of their children? Explain.
5. Is there provision for the parents/ guardians of participants to be informed of results of clinical research?

Choose an item.

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

Choose an item.

1. **Fair participant selection**
2. What is your study population?
3. Justify your choice of the study population.
4. 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?

Choose an item.

1. How is the initial contact and recruitment to be conducted?
2. **Responsibilities of the researcher**
3. What are the responsibilities of the researcher for provision of medical services to research participants?
4. What are the provisions for continuation of care after the research is over?
5. Have you obtained permission from the relevant authorities?

Choose an item.

If yes, name the authorities.

1. 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.
2. List any other ethical issues in your study and state how you would prevent them from influencing the conduct of the study
3. I am willing to provide 6 monthly reports of my research to the ERC.

Choose an item.

1. **Externally sponsored research**
2. Attach documentary evidence that the research project has been approved by an ERC in the sponsoring country.
3. Why is the research carried out in Sri Lanka and not in the sponsoring country?
4. What is the relevance of this study to Sri Lanka?
5. What are the post-research benefits to Sri Lanka?
6. Are participants receiving the best current treatment as part of the protocol?

Choose an item.

If no, explain why?

1. What is the ancillary care (treatment that is not part of the protocol) provided?
2. What are the provisions for continuity of care?
3. 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.
4. **Community based research**
5. State the impact and relevance of the research on the community in which it is to be carried out.
6. State the steps taken to consult with the concerned community during the design of the research.
7. What procedures will be used to obtain community consent and individual consent?
8. How will you safeguard the privacy of the participants?
9. If the intervention is shown to be beneficial will the sponsor continue to provide it to participants after conclusion of the study?

Choose an item.

1. How does the research contribute to capacity building of the community?
2. How will the results of the research be made available to the concerned community?
3. **Clinical trials**
4. Is it a multicentre trial?

Choose an item.

1. Is the trial registered with the Sri Lanka Clinical Trials Registry?

Choose an item.

1. What is the justification for using a control arm?
2. Does the control group receive the standard therapy?

Choose an item.

1. Are all participants treated equally?

Choose an item.

If no, explain.

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

Choose an item.

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

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