

ETHICS REVIEW COMMITTEE OF THE SRI LANKA COLLEGE OF PAEDIATRICIANS

STANDARD OPERATING PROCEDURE (SOP)

FUNCTION

1. The objectives of the Ethics Review Committee (ERC), Sri Lanka College of Paediatricians (SLCP) are:

- Consider research projects pertaining to child health/perinatology
- Deal with both clinical and biomedical research projects
- Grant or not grant ethical clearance to research projects

2. A submitted research project will be assessed on:

- Appropriateness of title
- Research methodology

Components that will be evaluated are:

- Informed consent
- Purpose of study or objectives
- If interventional (e.g. therapeutic trials), whether reasonable, ethical etc.
- Financial considerations, if any
- Confidentiality of information gathered

Decisions on the above aspects will be in accordance with basic ethical guidelines stipulated in the Forum of Ethics Review Committee, Sri Lanka (FERCSL) Guidelines.

MEMBERSHIP COMPOSITION

- The composition of the ERC shall be diverse in gender and shall include members and non-members of the SLCP including non-medical personnel.
- Where required, the ERC may seek advice and assistance from appropriate experts to assist with the review of a proposal. However, the ERC must be satisfied that such

experts have no conflicts of interest in relation to the project under consideration. Such person(s) shall be required to provide an undertaking of confidentiality.

- The number of members may vary from 7 to 15.

APPOINTMENT OF MEMBERS

- Members will be appointed by the Council of the SLCP for a period of 3 years.
- A chairperson and Secretary will be nominated by the ERC, from among its members.
- Vacancies in the ERC will be filled by the Council of the SLCP.
- Members shall not be remunerated.
- Membership will lapse if a member fails to attend three consecutive meetings of the ERC without reasonable excuse.
- A member may resign from the ERC at any time upon giving notice in writing. Steps shall be taken to fill the vacancy.

SUBMISSION PROCEDURE FOR NEW APPLICATIONS

- Only applications pertaining to paediatrics will be accepted.
- Applications for research using animals will not be accepted.
- The following documents have to be submitted to the ERC
 - Application Form. This can be obtained from the SLCP office at No. 6 Wijerama Mawatha, Colombo 7.
 - The complete research proposal including the justification, objectives, and methods in detail.
 - Information sheet/Consent form for research participants (Should be provided in all three languages – Sinhala, Tamil, and English).
 - Data collection booklets /forms /questionnaires (Should be provided in all three languages – Sinhala, Tamil, and English if self-administered by research participants).
- Applications should be submitted as hard copies with accompanying electronic copies.

CONDUCT OF MEETINGS

- The ERC shall meet on a regular basis, which will normally be at monthly intervals.
- A quorum comprising one third of total appointed members, including at least one non-member of the SLCP, must be present in order for the ERC to reach a final decision on any agenda item.
- In circumstances where members cannot be present, they may provide written comments which will be tabled at the meeting.

CONSIDERATION OF APPLICATIONS FOR ETHICS REVIEW

- All proposals shall be circulated to all members of the ERC for review prior to the meeting. Applications will be discussed at the meeting by all members present. Written submissions made by those not present will be considered.
- The ERC shall assess proposals submitted to it for review in accordance with the FERCSL guidelines. The ERC must ensure that it is sufficiently informed on all aspects of a research proposal, including its scientific validity, to make an assessment.
- The ERC may invite an investigator to the meeting to clarify issues in relation to the application. The applicant will be asked to leave the meeting prior to ERC deliberation and decision-making concerning the application.
- The ERC, after considering an application at a meeting, will make one of the following decisions:
 - Approve the proposal as being ethically acceptable, with or without conditions.
 - Defer making a decision until an issue is clarified or further information is provided or the proposal is modified.
 - Reject the proposal.

MINUTES OF MEETINGS

- The Secretary of the ERC will prepare and maintain minutes of all meetings.
- The minutes should include a record of decisions taken by the ERC.
- To encourage free and open discussion particular views shall not be attributed to particular individuals in the minutes.
- The minutes will be circulated to all members of the ERC.

NOTIFICATION OF DECISIONS OF ERC FOR NEW APPLICATIONS

- Decisions of the ERC with regard to all applications discussed shall be conveyed in writing, to the principal investigator as soon as possible.
- ERC decisions should be in the form: Approved, Pending subject to further information/clarification or Rejected.
- The approval letter shall be in writing and shall contain the following information:
 - The title of the proposal
 - The name of the principal investigator(s)
 - The date of the ERC approval
- In all instances, data collection shall not commence until written notification has been received by the applicant confirming approval.
- If the proposal is rejected on ethical or other grounds, the letter of rejection shall include the reasons on which the decision was made.

MONITORING OF APPROVED RESEARCH STUDIES

- The ERC may request, at any time, information on any relevant aspects of the study and discuss any issue of relevance with the researchers.
- It will require applicants to provide progress reports every six months and a final report at the conclusion of the study.